ELEVATE
EXCHANGE PLANS
Denver Health Medical Plan Inc.™

Prior Authorization Approval Criteria

Effective Date: 04/01/2025

Standard Commercial
Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

1. **Formulary Agents**
   Drug products that are listed in the Formulary as Prior Authorization (PA) require evaluation, per MedImpact Pharmacy and Therapeutics Committee guidelines, when the member presents a prescription to a network pharmacy. Each request will be reviewed on individual patient need. If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
2. **Non-Formulary Agents**
   Any product not found in the Formulary listing, or any Formulary updates published by MedImpact**,** shall be considered a Non-Formulary drug. Coverage for non-formulary agents may be applied for in advance. When a member gives a prescription order for a non-formulary drug to a pharmacist, the pharmacist will evaluate the patient's drug history and contact the physician to determine if there is a legitimate medical need for a non-formulary drug. Each request will be reviewed on individual patient need. The following basic criteria are used:
   a. The use of Formulary Drug Products is contraindicated in the patient.
   b. The patient has failed an appropriate trial of Formulary or related agents.
   c. The choices available in the Drug Formulary are not suited for the present patient care need, and the drug selected is required for patient safety.
   d. The use of a Formulary drug may provoke an underlying condition, which would be detrimental to patient care.

   If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
3. **Obtaining Coverage**
   Coverage may be obtained by:
   a. Faxing a completed **Prior Authorization Request** to DHMP at (303) 602-2081.
   b. Contacting DHMP Pharmacy Department at (303) 602-2070 and providing all necessary information requested.

   Non-approved requests may be appealed. The prescriber must provide information to support the appeal on the basis of medical necessity.

ABALOPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABALOPARATIDE	TYMLOS	44231		GPI-10 (3004400500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and meet **ONE** of the following criteria?
   - The patient has a high risk for fractures defined as ONE of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as Synarel [nafarelin])
     - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

     If yes, continue to #3.
     If no, continue to #2.

2. Is the request to increase bone density in a male patient with osteoporosis who meets **ONE** of the following criteria?
   - The patient is at high risk for fracture defined as ONE of the following:
     - History of osteoporotic fracture (e.g., fragility, low trauma)
     - Multiple risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, use of GnRH analogs such as Synarel [nafarelin])
   - The patient has failed or is intolerant to other available osteoporosis therapy (e.g., Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

     If yes, continue to #3.
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

3. Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Tymlos [abaloparatide], Forteo [teriparatide])?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve up to 24 months cumulative lifetime treatment duration by HICL or GPI-10 with a quantity limit of #1.56mL per 30 days.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Postmenopausal osteoporosis (a type of bone condition)
   2. Increase bone density in a male patient with osteoporosis (a type of bone condition)

B. **If the request is for postmenopausal osteoporosis, approval also requires:**
   1. You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
   2. You meet ONE of the following (a, b, or c):
      a. You have high risk for fractures defined as ONE of the following:
         i. History of osteoporotic fracture(s) (broken bones) due to trauma (injury) or fragility (weakness)
         ii. Two or more risk factors for fracture such as history of multiple recent low trauma fractures, bone mineral density T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, or use of GnRH (gonadotropin-releasing hormone) analogs such as Synarel (nafarelin)
         iii. No prior treatment for osteoporosis AND FRAX (Fracture Risk Assessment Tool) score greater than or equal to 20 percent for any major fracture OR greater than or equal to 3 percent for hip fracture
      b. You are unable to use oral therapy due to upper gastrointestinal (stomach and intestine) problems, you cannot tolerate oral medication, you have lower gastrointestinal problems (unable to absorb oral medications), you have trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate]) with other oral medications in your daily routine
      c. You had a trial of, intolerance (side effect) to, or a contraindication (harmful for) to a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase bone density in a male patient with osteoporosis, approval also requires:**
   1. You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
   2. You meet ONE of the following (a or b):
      a. You have high risk for fractures defined as ONE of the following:
         i. History of osteoporotic fracture (such as fragility [weakness] fracture, low trauma [injury] fracture)
         ii. Multiple risk factors for fracture (such as history of multiple recent low trauma fractures, bone mineral density T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, use of GnRH [gonadotropin-releasing hormone] analogs such as Synarel [nafarelin])
      b. You have failed or are intolerant (side effect) to other available osteoporosis therapy (such as Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tymlos.

REFERENCES

- Tymlos [Prescribing Information]. Boston, MA: Radius Health, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 04/17
Client Approval: 03/23
P&T Approval: 01/23

ABATACEPT - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT/ MALTOSE	ORENCIA		26306	GPI-14 (66400010002120)	

NOTE: For requests for the SQ dosage form of Orencia, please see the ABATACEPT - SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #8 per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #4 per 28 days (start date is 3 days before the end date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #8 per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #4 per 28 days (start date is 3 days before the end date of the first approval).

   If no, continue to #4.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #8 per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #4 per 28 days (start date is 3 days before the end date of the first approval).

   If no, continue to #5.

5. Is the request for prophylaxis of acute graft versus host disease (aGVHD) and the patient meets **ALL** of the following?
   The patient is 2 years of age or older
   The patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or one allele-mismatched unrelated-donor
   Orencia will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate
   Orencia will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of aGVHD prophylaxis

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #16.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Prophylaxis (prevention) of acute graft versus host disease (aGVHD: a short-term type of immune disorder)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

If the request is for prophylaxis of acute graft versus host disease, approval also requires:

You are 2 years of age or older

You are undergoing hematopoietic stem cell transplantation (HSCT: a type of cell transplantation) from a matched or one allele (version of a gene)-mismatched unrelated-donor

Orencia will be used in combination with a calcineurin inhibitor (such as cyclosporine or tacrolimus) and methotrexate

You will NOT use Orencia concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of acute graft versus host disease prophylaxis

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABATACEPT - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of acute graft versus host disease (aGVHD), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia IV.

REFERENCES

Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.

Created: 05/05
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ABATACEPT - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT	ORENCIA, ORENCIA CLICKJECT		30289 41656 43389 43397	GPI-14 (6640001000D520, 6640001000E510, 6640001000E515, 6640001000E520)	

NOTE: For requests for the IV dosage form of Orencia, please see the ABATACEPT - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 125mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 as follows:**
   50mg/0.4mL: #1.6mL per 28 days.
   87.5mg/0.7mL: #2.8mL per 28 days.
   125mg/mL: #4mL per 28 days.

   If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   The patient is 2 to 5 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Taltz (ixekizumab), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 as follows:**
   50mg/0.4mL: #1.6mL per 28 days.
   87.5mg/0.7mL: #2.8mL per 28 days.
   125mg/mL: #4mL per 28 days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   (Initial denial text continued on next page)

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ABATACEPT – SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

(Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:

- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You meet ONE of the following:
  - You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
  - You are 6 to 17 years of age AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Taltz (ixekizumab), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABATACEPT - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 125mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14 as follows:**
   50mg/0.4mL: #1.6mL per 28 days.
   87.5mg/0.7mL: #2.8mL per 28 days.
   125mg/mL: #4mL per 28 days.

   If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   The patient is 2 to 5 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Taltz (ixekizumab), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14 as follows:**
   50mg/0.4mL: #1.6mL per 28 days.
   87.5mg/0.7mL: #2.8mL per 28 days.
   125mg/mL: #4mL per 28 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   (Renewal denial text continued on next page)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You meet ONE of the following:
  - You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
  - You are 6 to 17 years of age AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Taltz (ixekizumab), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia SQ.

REFERENCES

Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.

Created: 11/11
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ABEMACICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABEMACICLIB	VERZENIO	44537		GPI-10 (2153101000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive
   Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [e.g., anastrozole, letrozole, exemestane]) for adjuvant treatment
   The patient is at high risk of recurrence

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Groups C50, C79.81) **AND** meet the following criterion?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will Verzenio be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) **AND** the patient meets the following criterion?
   Verzenio will be used as initial endocrine-based therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Will Verzenio be used in combination with fulvestrant (Faslodex) **AND** the patient meets the following criterion?
   The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #5.

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ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

5. Will Verzenio be used as monotherapy **AND** the patient meets the following criterion?
   The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen) and prior chemotherapy in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABEMACICLIB (Verzenio)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Early breast cancer (initial stage of breast cancer)
   - Advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body)

   If you have early breast cancer, approval also requires:
   - Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, node-positive (cancer that has spread to the lymph nodes)
   - Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [such as letrozole, anastrozole, exemestane]) for adjuvant (add-on) treatment
   - You are at high risk of recurrence (disease returning)

   If you have advanced or metastatic breast cancer, approval also requires:
   - Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   - You meet ONE of the following:
     - Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, exemestane) as initial endocrine (hormone)-based therapy
     - Verzenio will be used in combination with fulvestrant (Faslodex), and you have had disease progression following endocrine therapy (a type of hormone-based treatment such as letrozole, anastrozole, tamoxifen)
     - Verzenio will be used as monotherapy (one drug), and you have had disease progression following endocrine therapy (a type of hormone-based treatment such as letrozole, anastrozole, tamoxifen) and prior chemotherapy (drugs used to treat cancer) in the metastatic setting (cancer that has spread to other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABEMACICLIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verzenio.

REFERENCES

Verzenio [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/17
Effective: 01/01/25 Client Approval: 08/24 P&T Approval: 04/23

ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACETATE	ZYTIGA, ABIRATERONE ACETATE	37571		GPI-10 (2140601020)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   Metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61)
   Metastatic high-risk castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will the requested medication be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient had a bilateral orchiectomy
   The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   250mg: #8 per day.
   500mg: #4 per day.

   If no, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   250mg: #4 per day.
   500mg: #2 per day.

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ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE (Zytiga)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
- Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)

The requested medication will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
You meet ONE of the following:
- You had a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
- The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zytiga.

REFERENCES
Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Created: 06/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

ABIRATERONE SUBMICRONIZED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946		GPI-10 (2140601025)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   Yonsa will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)
   The patient had a trial of or contraindication to Zytiga (abiraterone acetate)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a bilateral orchiectomy
   The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   Yonsa will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**

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ABIRATERONE SUBMICRONIZED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE SUBMICRONIZED (Yonsa)** requires the following rule(s) be met for approval:

You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

Yonsa will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)

You have tried or have a contraindication to (harmful for you to use) Zytiga (abiraterone acetate)

You meet ONE of the following:

- You had a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
- Yonsa will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yonsa.

REFERENCES

Yonsa [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 03/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

ABROCITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABROCITINIB	CIBINQO	47767		GPI-10 (9027200500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of refractory, moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   The patient had a trial of or contraindication to THREE preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   Cibinqo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABROCITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for approval:
You have refractory, moderate to severe atopic dermatitis (AD: a type of skin condition)
You are 12 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
You have tried or have a contraindication to (harmful for you to use) THREE preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABROCITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of refractory, moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient has shown improvement while on Cibinqo
   The patient had a trial of or contraindication to THREE preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   Cibinqo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for renewal:
   You have refractory, moderate to severe atopic dermatitis (AD: a type of skin condition)
   You have shown improvement while on Cibinqo
   You have tried or have a contraindication to (harmful for you to use) THREE preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABROCITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cibinqo.

REFERENCES

Cibinqo [Prescribing Information]. New York, NY: Pfizer Inc.; December 2023.

Created: 02/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

ACALABRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		GPI-10 (2153210300)	
ACALABRUTINIB MALEATE	CALQUENCE	48182		GPI-10 (2153210350)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient previously untreated and meets **ALL** of the following criteria?
   Calquence is being used in combination with bendamustine and rituximab
   The patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Has the patient received at least one prior therapy (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone [R-CHOP])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ACALABRUTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:
You have ONE of the following:
- Mantle cell lymphoma (MCL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Small lymphocytic lymphoma (SLL: a type of blood cancer)

If you have untreated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- Calquence will be used in combination with bendamustine and rituximab
- You are NOT eligible for autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

If you have previously treated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received at least one prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
- You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Calquence.

REFERENCES
Calquence [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; January 2025.

Created: 02/18
Effective: 02/17/25 Client Approval: 01/25 P&T Approval: 04/25

ACETAMINOPHEN DAILY LIMIT OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the patient taking a dose of the requested drug in an amount exceeding 4000mg of acetaminophen per day?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the requested medication being taken together with other acetaminophen containing product(s) and the combination will exceed 4000mg of acetaminophen per day?

   If yes, continue to #3.
   If no, **approve for ONE FILL count by GPID or GPI-14 for the requested medication and set override type MAXINGREDIENTDOSE to a value of "Y".**

3. Will the patient discontinue the concurrent acetaminophen containing drug(s) that place the patient over 4000mg of acetaminophen per day?

   If yes, **approve for ONE FILL count by GPID or GPI-14 for the requested medication and set override type MAXINGREDIENTDOSE to a value of "Y".**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ACETAMINOPHEN DAILY LIMIT OVERRIDE** will cause a denied claim for acetaminophen when the total daily dose acetaminophen exceeds 4000mg. The claim will also deny if the requested drug is being used at the same time with other acetaminophen containing product(s) and the combination exceeds 4000mg of acetaminophen per day limit.
   Approval requires the following rule be met:
   A. You will discontinue the other acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ACETAMINOPHEN DAILY LIMIT OVERRIDE

RATIONALE

To ensure appropriate use of acetaminophen products and address overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. The maximum daily dose for an adult is 4000 mg. However, in some people, taking the maximum daily dose or more for an extended period of time can lead to serious liver damage.
A claim may reject at POS due to exceeding the acetaminophen daily limit as a result of concurrent use with other acetaminophen products. An approval is granted if the the concurrent acetaminophen containing product will be discontinued. In some cases, the member's history claim may have an incorrect day supply due to a pharmacy error. This will cause the new claim to reject at POS for exceeding the acetaminophen daily limit. This is addressed in question #2.

REFERENCES

- "FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure". January 13, 2011. Available at https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm [Accessed 12/3/18].
- "Medicare Part D Overutilization Monitoring System – Updates". October 25, 2013. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoMedicare-Part-D-OMS-Updates-10-25-13.pdf [Accessed 12/3/18].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 12/18
Client Approval: 04/20
P&T Approval: 01/19

ACNE AGE RESTRICTION OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAPALENE	DIFFERIN		28403	GPI-14 (90050003004110)	BRAND = DIFFERIN
TAZAROTENE	TAZAROTENE, TAZORAC		29221 29222 85362	GPI-14 (90250070004020, 90250070004030, 90250070003720)	
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP, TRETINOIN MICROSPHERES	32888		GPI-10 (9005003020)	
TRIFAROTENE	AKLIEF	46048		GPI-10 (9005003500)	

GUIDELINES FOR USE

1. Is the claim denying for an age limit, as noted in the POS reject message?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for a cosmetic indication (e.g., melasma, photoaging, or wrinkles)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Has the patient had a trial of **TWO** low cost generic agents (e.g., Adapalene lotion, cream or gel, Tretinoin cream or gel, Adapalene/Benzoyl Peroxide gel)?

   If yes, **approve the requested agent for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

ACNE AGE RESTRICTION OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACNE AGE RESTRICTION OVERRIDE** requires the following rule(s) be met for approval:
The request is for a non-cosmetic (not for appearance) diagnosis (such as melasma, photoaging, wrinkles)
You had a trial of TWO low cost generic medications (such as Adapalene lotion, cream or gel, Tretinoin cream or gel, Adapalene/Benzoyl Peroxide gel)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for agents in this guideline

REFERENCES

Differin [Prescribing Information]. Dallas, TX: Galderma laboratories, L.P; April 2023.
Retin-A [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals International, Inc.; June 2018.
Aklief [Prescribing Information]. Dallas, TX: Galderma laboratories, L.P; January 2022.
Differin [Prescribing Information]. Dallas, TX: Galderma laboratories, L.P; April 2023.
Tazorac [Prescribing Information]. Medison, NJ: Allergan, Inc.; April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 08/11
Client Approval: 11/23
P&T Approval: 07/23

ACORAMIDIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACORAMIDIS HCL	ATTRUBY	50022		GPI-10 (4055001030)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1 Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or variant transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
- The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
- Attruby will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., tafamidis [Vyndaqel, Vyndamax])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2 Is the patient's diagnosis confirmed by **ONE** of the following?
- A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP *(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
- A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ACORAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
D. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
E. You will NOT use Attruby concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as tafamidis [Vyndaqel, Vyndamax])
F. Your diagnosis is confirmed by ONE of the following:
    1. A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
    2. A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ACORAMIDIS

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or variant transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
   - Attruby will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., tafamidis [Vyndaqel, Vyndamax])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for renewal:
   A. You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
   B. You will NOT use Attruby concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as tafamidis [Vyndaqel, Vyndamax])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Attruby.

REFERENCES

- Attruby [Prescribing Information]. Palo Alto, CA: BridgeBio Pharma Inc.; November 2024.

Created: 12/24
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ADAGRASIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAGRASIB	KRAZATI	48522		GPI-10 (2153241000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
   The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced or metastatic colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
   Krazati will be used in combination with Erbitux (cetuximab)
   The patient has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ADAGRASIB (Krazati)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   - Locally advanced or metastatic colorectal cancer (CRC: a type of digestive tract cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)

   If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
   - You are 18 years of age or older
   - Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
   - You have received at least one prior systemic therapy

   (Denial text continued on next page)

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ADAGRASIB

GUIDELINES FOR USE (CONTINUED)

If you have locally advanced or metastatic colorectal cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
- Krazati will be used in combination with Erbitux (cetuximab)
- You have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Krazati.

REFERENCES
Krazati [Prescribing Information]. San Diego, CA: Mirati Therapeutics, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 01/23
Client Approval: 07/24
P&T Approval: 07/24

ADALIMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB	HUMIRA	24800		GPI-10 (6627001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #2.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of all of the following strengths:**
   10mg/0.1mL.
   20mg/0.4mL.
   20mg/0.2mL.
   40mg/0.8mL.
   40mg/0.4mL.

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #4.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, continue to #6.
   If no, continue to #8.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Humira
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the requested medication for 1 month as follows:
   40mg/0.8mL PSOR-UVEITS-ADOL HS Starter Package: #4 pens.
   80mg-40mg PSOR-UV-ADOL HS Starter Package: #3 pens.
   SECOND APPROVAL: Approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 5 months with a quantity limit of #2 per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the requested medication for 1 month as follows:
   40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.
   80mg/0.8mL CROHN'S-UC-HS Starter Package: #3 pens.
   80mg/0.8mL Pediatric Crohn's Starter Package: #3 syringes.
   80mg-40mg Pediatric Crohn's Starter Package: #2 syringes.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
   20mg/0.4mL: #2 per 28 days.
   20mg/0.2mL: #2 per 28 days.
   40mg/0.8mL: #2 per 28 days.
   40mg/0.4mL: #2 per 28 days.

   If no, continue to #9.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 5 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the requested medication for 1 month as follows:
   40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.
   80mg/0.8mL CROHN'S-UC-HS Starter Package: #3 pens.
   80mg/0.8mL Pediatric UC Starter Package: #4 pens.
   40mg/0.8mL or 40mg/0.4mL: #8 pens/syringes.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
   20mg/0.4mL: #4 per 28 days.
   20mg/0.2mL: #4 per 28 days.
   40mg/0.8mL: #4 per 28 days.
   40mg/0.4mL: #4 per 28 days.
   80mg/0.8mL: #2 per 28 days.

   If no, continue to #10.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient is 12 years of age or older
    Therapy is prescribed by or in consultation with a dermatologist
    Humira will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
    The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

    If yes, **approve for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
    FIRST APPROVAL: Approve the requested medication for 1 month as follows:
    40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.
    80mg/0.8mL CROHN'S-UC-HS Starter Package: #3 pens.
    80mg-40mg PSOR-UV-ADOL HS Starter Package: #3 pens.
    40mg/0.8mL PSOR-UVEITS-ADOL HS Starter Package: #4 pens.
    SECOND APPROVAL: Approve all formulations of the requested strength for 3 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
    40mg/0.8mL: #4 per 28 days.
    40mg/0.4mL: #4 per 28 days.
    80mg/0.8mL: #2 per 28 days.

    If no, continue to #11.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
    The patient is 2 years of age or older
    Therapy is prescribed by or in consultation with an ophthalmologist
    The patient does NOT have isolated anterior uveitis
    Humira will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
    The patient is switching from a Humira biosimilar (e.g., Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR had a trial of or contraindication to adalimumab-adaz or Simlandi

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    For age 2 to 17 years, approve with a quantity limit of #2 per 28 days for all formulations of all of the following:
    10mg/0.1mL.
    20mg/0.4mL.
    20mg/0.2mL.
    40mg/0.8mL.
    40mg/0.4mL.
    For age 18 years and above, please enter two authorizations as follows:
    FIRST APPROVAL: Approve the requested medication for 1 month as follows:
    40mg/0.8mL PSOR-UVEITS-ADOL HS Starter Package: #4 pens.
    80mg-40mg PSOR-UV-ADOL HS Starter Package: #3 pens.
    SECOND APPROVAL: Approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 5 months with a quantity limit of #2 per 28 days.

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate posterior and panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to adalimumab-adaz or Simlandi

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to adalimumab-adaz or Simlandi

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Humira
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

If you have non-infectious intermediate, posterior and panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use Humira concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis
- You are switching from a Humira biosimilar (such as Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm]) OR you have tried or have a contraindication to (harmful for you to use) adalimumab-adaz or Simlandi

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) **AND** meet the following criterion?
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for **Humira 40mg dosed every other week AND** the patient meets the following criterion?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #3.

3. Is the request for **Humira 40mg dosed every week OR Humira 80mg dosed every other week** and the patient meets **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient had a trial of at least a 3-month regimen of Humira 40mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the requested strength as follows:**
   40mg/0.8mL: #4 per 28 days.
   40mg/0.4mL: #4 per 28 days.
   80mg/0.8mL: #2 per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization(s) for 12 months by GPID or GPI-14 for all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength with a quantity limit of #2 per 28 days.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Humira will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of the requested strength as follows:**
   10mg/0.1mL.
   20mg/0.4mL.
   20mg/0.2mL.
   40mg/0.8mL.
   40mg/0.4mL.

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #6.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 40mg/0.4mL OR 40mg/0.8mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of the requested strength as follows:**
   20mg/0.4mL.
   20mg/0.2mL.
   40mg/0.8mL.
   40mg/0.4mL.

   If no, continue to #9.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Humira will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the requested strength as follows:**
   20mg/0.4mL: #4 per 28 days.
   20mg/0.2mL: #4 per 28 days.
   40mg/0.8mL: #4 per 28 days.
   40mg/0.4mL: #4 per 28 days.
   80mg/0.8mL: #2 per 28 days.

   If no, continue to #10.

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient has experienced improvement in HS symptoms
    Humira will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the requested strength as follows:**
    40mg/0.8mL: #4 per 28 days.
    40mg/0.4mL: #4 per 28 days.
    80mg/0.8mL: #2 per 28 days.

    If no, continue to #11.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
    Humira will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
    The patient has NOT experienced treatment failure, defined as ONE of the following criteria:
    Development of new inflammatory chorioretinal or retinal vascular lesions
    A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
    A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of the requested strength as follows:**
    10mg/0.1mL.
    20mg/0.4mL.
    20mg/0.2mL.
    40mg/0.8mL.
    40mg/0.4mL.

    If no, do not approve.

    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal:
    You have ONE of the following:
    Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
    Psoriatic arthritis (PsA: a type of skin and joint condition)
    Ankylosing spondylitis (AS: a type of joint condition)
    Moderate to severe plaque psoriasis (PsO: a type of skin condition)
    Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
    Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
    Non-infectious intermediate posterior and panuveitis (a type of eye condition)
    (Renewal denial text continued on next page)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing, at least a 3-month trial of Humira 40mg every other week dosing is required

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:
- You will NOT use Humira concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis
- You have NOT experienced treatment failure, defined as ONE of the following:
  - You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
  - You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
  - Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Humira.

REFERENCES

Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; November 2023.

Created: 05/03
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ADALIMUMAB-ADAZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ	45444		GPI-10 (6627001504)	GENERIC ONLY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve all formulations of all strengths for 6 months by GPID or GPI-14 as follows:**
   40mg/0.4mL: #0.8mL per 28 days.
   20mg/0.2mL: #0.4mL per 28 days.

   If no, continue to #3.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #6.
   If no, continue to #8.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to the requested medication
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve all formulations of the 40mg/0.4mL strength for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1.6mL.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #0.8mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   80mg/0.8mL: #2.4mL.
   40mg/0.4mL: #2.4mL.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
   40mg/0.4mL: #0.8mL per 28 days.
   20mg/0.2mL: #0.4mL per 28 days.

   If no, continue to #9.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 5 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   80mg/0.8mL: #3.2mL.
   40mg/0.4mL: #3.2mL.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
   80mg/0.8mL: #1.6mL per 28 days.
   40mg/0.4mL: #1.6mL per 28 days.
   20mg/0.2mL: #0.8mL per 28 days.

   If no, continue to #10.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient is 12 years of age or older
    Therapy is prescribed by or in consultation with a dermatologist
    The requested medication will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

    If yes, **approve for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
    FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
    80mg/0.8mL: #2.4mL.
    40mg/0.4mL: #2.4mL.
    SECOND APPROVAL: Approve all formulations of the requested strength for 3 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
    80mg/0.8mL: #1.6mL per 28 days.
    40mg/0.4mL: #1.6mL per 28 days.

    If no, continue to #11.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
    The patient is 2 years of age or older
    Therapy is prescribed by or in consultation with an ophthalmologist
    The patient does NOT have isolated anterior uveitis
    The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    For age 2 to 17 years, approve all formulations of all strengths as follows:
    40mg/0.4mL: #0.8mL per 28 days.
    20mg/0.2mL: #0.4mL per 28 days.
    For age 18 years and above, please enter two authorizations as follows:
    FIRST APPROVAL: Approve all formulations of the 40mg/0.4mL strength for 1 month with a quantity limit of #1.6mL.
    SECOND APPROVAL: Approve all formulations of the 40mg/0.4mL strength for 5 months with a quantity limit of #0.8mL per 28 days (enter a start date of 1 week AFTER the END date of the first approval).

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB-ADAZ** requires the following rule(s) be met for approval:
    You have ONE of the following:
    Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
    Psoriatic arthritis (PsA: a type of skin and joint condition)
    Ankylosing spondylitis (AS: a type of joint condition)
    Moderate to severe plaque psoriasis (PsO: a type of skin condition)
    Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
    Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
    Non-infectious intermediate posterior and panuveitis (a type of eye condition)
    (Initial denial text continued on next page)

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to the requested medication
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior and panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) **AND** meet the following criterion?
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for **adalimumab-adaz 40mg dosed every other week AND** the patient meets the following criterion?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #3.

3. Is the request for **adalimumab-adaz 40mg dosed every week OR adalimumab-adaz 80mg dosed every other week** and the patient meets **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient had a trial of at least a 3-month regimen of adalimumab-adaz 40mg dosed every other week

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   80mg/0.8mL: #1.6mL per 28 days.
   40mg/0.4mL: #1.6mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization(s) for 12 months by GPID or GPI-14 for all formulations of the 40mg/0.4mL strength with a quantity limit of #0.8mL per 28 days.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   40mg/0.4mL: #0.8mL per 28 days.
   20mg/0.2mL: #0.4mL per 28 days.

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #7.

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RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.8mL per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   40mg/0.4mL: #0.8mL per 28 days.
   20mg/0.2mL: #0.4mL per 28 days.

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   80mg/0.8mL: #1.6mL per 28 days.
   40mg/0.4mL: #1.6mL per 28 days.
   20mg/0.2mL: #0.8mL per 28 days.

   If no, continue to #10.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient has shown improvement in HS symptoms
    The requested medication will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

    If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
    80mg/0.8mL: #1.6mL per 28 days.
    40mg/0.4mL: #1.6mL per 28 days.

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
    The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
    The patient has NOT experienced treatment failure, defined as ONE of the following criteria:
    Development of new inflammatory chorioretinal or retinal vascular lesions
    A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
    A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
    40mg/0.4mL: #0.8mL per 28 days.
    20mg/0.2mL: #0.4mL per 28 days.

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADAZ** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate posterior and panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- If you are requesting adalimumab-adaz 40mg weekly dosing OR adalimumab-adaz 80mg every other week dosing, at least a 3-month trial of adalimumab-adaz 40mg every other week dosing is required

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis
- You have NOT experienced treatment failure, defined as ONE of the following:
  - You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
  - You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
  - Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyrimoz and Humira.

REFERENCES

Hyrimoz [Prescribing Information]. Princeton, NJ: Sandoz Inc.; June 2024.
Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; November 2023.

Created: 11/23
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ADALIMUMAB-RYVK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-RYVK	SIMLANDI	49415		GPI-10 (6627001540)	BRAND ONLY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of all of the following strengths:**
   20mg/0.2mL.
   40mg/0.4mL.

   If no, continue to #3.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #6.
   If no, continue to #8.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Simlandi
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve all formulations of the 40mg/0.4mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**
   (PAC NOTE: Please also enter #1 fill of 80mg/0.8mL strength.)

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   80mg/0.8mL: #3.
   40mg/0.4mL: #6.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
   20mg/0.2mL: #2 per 28 days.
   40mg/0.4mL: #2 per 28 days.

   If no, continue to #9.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 5 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   80mg/0.8mL: #4.
   40mg/0.4mL: #8.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
   20mg/0.2mL: #4 per 28 days.
   40mg/0.4mL: #4 per 28 days.
   80mg/0.8mL: #2 per 28 days.

   If no, continue to #10.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient is 12 years of age or older
    Therapy is prescribed by or in consultation with a dermatologist
    Simlandi will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

    If yes, **approve for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
    FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
    80mg/0.8mL: #3.
    40mg/0.4mL: #6.
    SECOND APPROVAL: Approve all formulations of the requested strength for 3 months as follows (enter a start date of 3 days BEFORE the END date of the first approval):
    40mg/0.4mL: #4 per 28 days.
    80mg/0.8mL: #2 per 28 days.

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior, and panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
    The patient is 2 years of age or older
    Therapy is prescribed by or in consultation with an ophthalmologist
    The patient does NOT have isolated anterior uveitis
    Simlandi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

    If yes, **approve all formulations of the following strengths for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days:**
    20mg/0.2mL.
    40mg/0.4mL.
    (PAC NOTE: Please also enter #1 fill of 80mg/0.8mL strength.)

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-RYVK (Simlandi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, and panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Simlandi
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

(Initial denial text continued on next page)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, and panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) **AND** meet the following criterion?
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for **Simlandi 40mg dosed every other week AND** the patient meets the following criterion?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #3.

3. Is the request for **Simlandi dosed at 40mg every week OR 80mg dosed every other week** and the patient meets **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient had a trial of at least a 3-month regimen of Simlandi 40mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the requested strength as follows:**
   40mg/0.4mL: #4 per 28 days.
   80mg/0.8mL: #2 per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization(s) for 12 months by GPID or GPI-14 for all formulations of the 40mg/0.4mL strength with a quantity limit of #2 per 28 days.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of the requested strength as follows:**
   20mg/0.2mL.
   40mg/0.4mL.

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #7.

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RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 40mg/0.4mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of the requested strength as follows:**
   20mg/0.2mL.
   40mg/0.4mL.

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Simlandi will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the requested strength as follows:**
   20mg/0.2mL: #4 per 28 days.
   40mg/0.4mL: #4 per 28 days.
   80mg/0.8mL: #2 per 28 days.

   If no, continue to #10.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient has shown improvement in HS symptoms
    Simlandi will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the requested strength as follows:**
    40mg/0.4mL: #4 per 28 days.
    80mg/0.8mL: #2 per 28 days.

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior, and panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
    Simlandi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
    The patient has NOT experienced treatment failure, defined as ONE of the following criteria:
    Development of new inflammatory chorioretinal or retinal vascular lesions
    A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
    A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all formulations of the requested strength as follows:**
    20mg/0.2mL.
    40mg/0.4mL.

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-RYVK (Simlandi)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, and panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:

- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- If you are requesting Simlandi 40mg weekly dosing OR Simlandi 80mg every other week dosing, at least a 3-month trial of Simlandi 40mg every other week dosing is required

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa

If you have non-infectious intermediate, posterior, and panuveitis, renewal also requires:
- You will NOT use Simlandi concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis
- You have NOT experienced treatment failure, defined as ONE of the following:
  - You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
  - You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
  - Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simlandi and Humira.

REFERENCES

Simlandi [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; August 2024.
Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; November 2023.

Created: 08/24
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ADAPALENE-BENZOYL-CLINDAMYCIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAPALENE/BENZOYL/ CLINDAMYCIN	CABTREO	46076		GPI-10 (9005990302)	BRAND = CABTREO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a cosmetic indication (e.g., melasma, photoaging, or wrinkles)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of acne vulgaris and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Cabtreo will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Winlevi)
   The patient had a trial of or contraindication to **ONE** agent in each of the following categories:
   Benzoyl peroxide product
   Topical retinoid (e.g., adapalene, tretinoin)
   Topical antibiotic (e.g., clindamycin, erythromycin)

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for approval:
   The request is NOT for a cosmetic (for appearance) diagnosis (such as melasma [freckle-like spots on your skin], photoaging [skin damage from the sun], wrinkles)
   You have acne vulgaris (a type of skin condition usually called pimples)
   You are 12 years of age or older
   Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)
   (Denial text continued on the next page)

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ADAPALENE-BENZOYL-CLINDAMYCIN

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) ONE medication in each of the following categories:
Benzoyl peroxide product
Topical retinoid (such as adapalene, tretinoin)
Topical antibiotic (such as clindamycin, erythromycin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADAPALENE-BENZOYL-CLINDAMYCIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acne vulgaris and meet **ALL** of the following criteria?
   Cabtreo will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Winlevi)
   The patient has shown improvement in acne symptoms

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for renewal:
   You have acne vulgaris (a type of skin condition usually called pimples)
   Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)
   You have shown improvement in acne symptoms (the treatment is working)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cabtreo.

REFERENCES

Cabtreo [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/23
Client Approval: 11/23
P&T Approval: 10/23

AFATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFATINIB DIMALEATE	GILOTRIF	40478		GPI-10 (2136000610)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - The patient has disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test
   - Gilotrif will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [Osimertinib], Iressa [gefitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic squamous non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
      2. Metastatic non-small cell lung cancer (a different type of lung cancer that has spread to other parts of the body)
   B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
      1. Your disease has worsened after using platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   C. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. Your tumors have non-resistant epidermal growth factor receptor (EGFR: type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test
      2. You will NOT be using Gilotrif concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [Osimertinib], Iressa [gefitinib])

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AFATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilotrif.

REFERENCES

- Gilotrif (afatinib) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.; Ridgefield, CT. April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 10/13
Client Approval: 05/22
P&T Approval: 04/22

ALECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALECTINIB HCL	ALECENSA	42895		GPI-10 (2153050710)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) and meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer is node positive or the tumors are at least 4cm
   The patient's cancer is anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test
   Alecensa will be used as adjuvant treatment following tumor resection

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240 per 30 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:
   You have ONE of the following:
   - Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   - Non-small cell lung cancer (NSCLC: a type of lung cancer)

   If you have metastatic non-small cell lung cancer, approval also requires:
   - You are 18 years of age or older
   - Your tumor is anaplastic lymphoma kinase (ALK)-positive (a type of abnormal gene change), as detected by a Food and Drug Administration (FDA)-approved test

   (Denial text continued on the next page)

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ALECTINIB

GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:

You are 18 years of age or older
Your cancer is node positive (cancer that has spread to the lymph nodes), or you have tumors that are at least 4cm
Your tumor is anaplastic lymphoma kinase (ALK)-positive (a type of abnormal gene change), as detected by a Food and Drug Administration (FDA)-approved test
Alecensa will be used as adjuvant (additional) treatment following tumor resection (surgical removal of a tumor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alcensa.

REFERENCES

Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/17/24
Created: 12/15
Client Approval: 05/24
P&T Approval: 07/24

ALGLUCOSIDASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALGLUCOSIDASE ALFA	LUMIZYME	33588		GPI-10 (3090771500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02)?

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALGLUCOSIDASE ALFA (Lumizyme)** requires the following rule(s) be met for approval:
   You have Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumizyme.

REFERENCES

Lumizyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; December 2024.

Created: 08/14
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 01/24

ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITE,D.FARINAE-D.PTERONYSSINUS	ODACTRA		42527	GPI-14 (20109902220740)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis (ICD-10 J30.89) and meet **ALL** of the following criteria?
   - The patient is 5 to 65 years of age
   - The patient's diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
   - Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
   - The patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for an auto-injectable epinephrine within the past 365 days

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-HOUSE DUST MITE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites
B. You are 5 to 65 years of age
C. Your diagnosis is confirmed by in vitro testing (testing outside of the body in a tube) for IgE (immunoglobulin E) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
D. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, impairment of school or work)
G. You have a current claim or prescription for an auto-injectable epinephrine within the past 365 days

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

ALLERGEN EXTRACT-HOUSE DUST MITE

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) is met for renewal:
   A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odactra.

REFERENCES

- Odactra [Prescribing Information]. Hørsholm, Denmark: ALK-Abelló A/S; February 2025.

Created: 02/18
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR	39918		GPI-10 (2010990520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis that is confirmed by a positive skin prick test and/or a positive titer to specific IgE antibodies for any of the five grass (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens) species included in Oralair?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Was Oralair prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include of one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

5. Is the patient between the ages of 5 and 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #3 tablets of 100 IR for the first 2 days of therapy initiation and #1 tablet of 300 IR per day thereafter.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, continue to #6.

6. Is the patient between 18 and 65 years of age?

   If yes, **approve for 12 months by GPID or GPI-10 for a quantity limit of #1 tablet (300 IR) per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
   B. Your diagnosis is confirmed by a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
   C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
   D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   E. You have a current claim or prescription for auto-injectable epinephrine
   F. You are between 5 and 65 years of age
   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by HICL or GPI-14 for a quantity limit of #1 tablet per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:
   A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oralair.

REFERENCES

- Oralair [Prescribing Information]. Lenoir, NC: GREER Laboratories, Inc., December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 05/14
Client Approval: 04/20
P&T Approval: 01/19

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK		36402	GPI-14 (20100060200720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short ragweed pollen-induced allergic rhinitis and meet **ALL** of the following criteria?
   - The patient is between 5 and 65 years of age
   - Diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
   - Therapy was prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. You are between 5 and 65 years of age
C. Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
D. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
F. You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:
A. You have experienced an improvement in signs and symptoms of allergic rhinitis from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ragwitek.

REFERENCES

- Ragwitek [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21
Created: 05/14
Client Approval: 05/21
P&T Approval: 07/21

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GRASS POLLEN-TIMOTHY, STD	GRASTEK	22138		GPI-10 (2010004800)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis and meet **ALL** of the following criteria?
   - The patient is between 5 and 65 years of age
   - Diagnosis is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens
   - Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:
   A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
   B. You are between 5 and 65 years of age
   C. Your diagnosis is confirmed a positive skin prick test and/or a positive titre (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
   D. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases

   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

E. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
F. You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #1 per day.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule be met for renewal:
A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Grastek.

REFERENCES

- Grastek [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2020.

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 05/14
Client Approval: 12/21
P&T Approval: 01/18

ALPELISIB-PIQRAY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	PIQRAY	45761		GPI-10 (2153801000)	BRAND ≠ VIJOICE

GUIDELINES FOR USE

1 Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
- Piqray will be used in combination with Faslodex (fulvestrant)
- The patient's breast cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
- The patient's tumor is PIK3CA-mutated as detected by an FDA-approved test
- The patient has disease progression on or after an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

If yes, **approve for 12 months by GPID or GPI -14 for all strengths as follows:**
- **300mg daily dose: #56 per 28 days.**
- **250mg daily dose: #56 per 28 days.**
- **200mg daily dose: #28 per 28 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPELISIB-PIQRAY** requires the following rule(s) be met for approval:
A. You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. Piqray will be used in combination with Faslodex (fulvestrant)
C. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
D. Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
E. You have disease progression (condition has worsened) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALPELISIB-PIQRAY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES

- Piqray [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 08/19
Client Approval: 01/24
P&T Approval: 04/24

ALPELISIB - VIJOICE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	VIJOICE	45761		GPI-10 (9948601000)	BRAND ≠ PIQRAY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of PIK3CA-related overgrowth spectrum (PROS) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has severe manifestations of PROS that require systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **50 mg daily dose: #28 per 28 days.**
   - **125 mg daily dose: #28 per 28 days.**
   - **250 mg daily dose: #56 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALPELISIB - VIJOICE** requires the following rule(s) be met for approval:
   A. You have PIK3CA-related overgrowth spectrum (PROS: group of disorders that cause overgrowth of parts of the body due to mutations in a type of gene)
   B. You are 2 years of age or older
   C. You have severe manifestations of PROS that require systemic therapy (treatment that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vijoice.

REFERENCES

- Vijoice [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

AMANTADINE EXTENDED RELEASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMANTADINE EXTENDED RELEASE	GOCOVRI		43787 43788	GPI-14 (73200010107020) (73200010107040)	
AMANTADINE HCL	OSMOLEX ER		44471 44472 44473 48017	GPI-14 (73200010107520) (73200010107530) (73200010107540) (7320001010C320)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

GOCOVRI

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient has dyskinesia
   - The patient is receiving levodopa-based therapy
   - The patient had a trial of generic amantadine capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **Gocovri 68.5mg: #1 per day.**
   - **Gocovri 137mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is experiencing 'off' episodes
   - Therapy is given as an adjunctive treatment to levodopa/carbidopa therapy
   - The patient had a trial of generic amantadine capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **Gocovri 68.5mg: #1 per day.**
   - **Gocovri 137mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE - GOCOVRI (CONTINUED)

GOCOVRI DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (nervous system disorder that affects movement)
B. **If you have dyskinesia (abnormal involuntary movements), approval also requires:**
1. You are receiving levodopa-based therapy
2. You have previously tried generic amantadine capsules, tablets, or solution

C. **If you are experiencing 'off' episodes (when the medication stops working), approval also requires:**
1. You are also receiving levodopa-carbidopa therapy
2. You have previously tried generic amantadine capsules, tablets, or solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

OSMOLEX ER

1. Does the patient have a diagnosis of Parkinson's disease?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request for the treatment of drug-induced extrapyramidal symptoms (EPS) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE - OSMOLEX ER (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a psychiatrist, neurologist, or geriatrician
   - The patient has had a trial of generic amantadine IR capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit of #1 per day.**
   If no, do not approve.

   OSMOLEX ER DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (nervous system disorder that affects movement) OR you are being treated for drug-induced extrapyramidal symptoms (group of movement disorders)
   B. Therapy is prescribed by or given in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who treats elderly people)
   C. You have previously tried generic amantadine immediate-release capsules, tablets or solution
   D. **If you are being treated for drug-induced extrapyramidal symptoms, approval also requires:**
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gocovri and Osmolex ER.

REFERENCES

- Gocovri [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.
- Osmolex ER [Prescribing Information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC. October 2019.

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AMANTADINE EXTENDED RELEASE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 09/17
Client Approval: 05/21
P&T Approval: 04/21

AMBRISENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMBRISENTAN	LETAIRIS, AMBRISENTAN	34849		GPI-10 (4016000700)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does NOT have idiopathic pulmonary fibrosis (IPF)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
   (Initial denial text continued on next page)

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AMBRISENTAN

INITIAL CRITERIA (CONTINUED)

D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMBRISENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Letairis.

REFERENCES

- Letairis [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/22
Client Approval: 06/24
P&T Approval: 01/24

AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		GPI-10 (7600001210)	
AMIFAMPRIDINE	RUZURGI	34158		GPI-10 (7600001200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10 G70.80) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
   The patient's diagnosis is confirmed by ALL of the following:
   Electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing
   Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for **Firdapse** and the patient meets the following criterion?
   The patient is 6 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, continue to #3.

3. Is the request for **Ruzurgi**?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:
You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or hematologist-oncologist (a type of blood-cancer doctor)
Your diagnosis is confirmed by ALL of the following:
- Electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing
- Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes

If you are requesting Firdapse, approval also requires:
- You are 6 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMIFAMPRIDINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10 G70.80) **AND** meet the following criterion?
   The patient has experienced improvement or stabilization in muscle weakness compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:
   You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
   You have experienced improvement or stabilization in muscle weakness compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc; May 2024.
Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/19
Client Approval: 06/24
P&T Approval: 10/22

AMIKACIN LIPOSOMAL INHALATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE	45298		GPI-10 (0700001012)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) with limited or no alternative treatment options and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has NOT achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
   - Arikayce will be used as part of a combination antibacterial drug regimen
   - Arikayce is being prescribed by or in consultation with a pulmonologist or infectious disease specialist physician

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:
   A. You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease with limited or no alternative treatment options
   B. You are 18 years of age or older
   C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
   D. Arikayce will be used as part of a combination antibacterial drug regimen
   E. Arikayce is being prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or infectious disease specialist physician

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMIKACIN LIPOSOMAL INHALATION

RENEWAL CRITERIA

1. Is the request for the first renewal of Arikayce for the treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and the patient meets **ALL** of the following criteria?
   - The patient has at least ONE negative sputum culture for MAC by 6 months of Arikayce treatment
   - The patient has NOT had a positive MAC sputum culture after consecutive negative cultures
   - The patient has had an improvement in symptoms

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL per day.**
   If no, continue to #2.

2. Is the request for the second or subsequent renewal of Arikayce for the treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and the patient meets **ALL** of the following criteria?
   - The patient has at least THREE negative sputum cultures for MAC by 12 months of Arikayce treatment
   - The patient has NOT had a positive MAC sputum culture after consecutive negative cultures
   - The patient has had an improvement in symptoms

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:
   A. You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
   B. You have NOT had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
   C. You have experienced an improvement in symptoms
   D. You meet ONE of the following:
      1. For first renewal requests, approval also requires you have at least ONE negative sputum culture (mucus test) for *Mycobacterium avium complex* by 6 months of Arikayce treatment
      2. For second or later renewal requests, approval also requires you have at least THREE negative sputum cultures (mucus test) for *Mycobacterium avium complex* by 12 months of Arikayce treatment

   (Renewal denial text continued on next page)

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AMIKACIN LIPOSOMAL INHALATION

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES

- Arikayce [Prescribing information]. Bridgewater, NJ: Insmed Incorporated; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 11/18
Client Approval: 06/24
P&T Approval: 10/18

AMLODIPINE SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMLODIPINE BENZOATE	KATERZIA	45864		GPI-10 (3400000308)	

GUIDELINES FOR USE

1. Is the patient unable to swallow oral amlodipine tablets at prescribed dose?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMLODIPINE SUSPENSION (Katerzia)** requires the following rule(s) be met for approval:
   A. You are unable to swallow oral amlodipine tablets at prescribed dose

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Katerzia.

REFERENCES

- Katerzia [Prescribing Information]. Greenwood Village, CO: Silvergate Pharmaceuticals, Inc., July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
Client Approval: 02/20
P&T Approval: 01/20

AMPHETAMINE SULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMPHETAMINE SULFATE	EVEKEO		19821 19822	GPI-14 (61100010100320, 61100010100310)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit disorder with hyperactivity and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient had a previous trial of at least **ONE** of the following stimulant medications: mixed amphetamine salts (Adderall IR), methylphenidate (Ritalin IR), or dextroamphetamine (Dexedrine)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Is the requested medication being used for weight loss or exogenous obesity?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #5.
   If no, guideline does not apply for plans that exclude treatment of obesity.

5. Is this an initial request (per MRF and claims history)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMPHETAMINE SULFATE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a previous trial of other weight loss medications (e.g., Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion)

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

   Our guideline named **AMPHETAMINE SULFATE (Evekeo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (condition where you suddenly fall asleep)
      2. Attention deficit disorder with hyperactivity (difficulty paying attention)
      3. Use for weight loss or exogenous obesity (overweight due to overeating)
   B. **If you have narcolepsy, approval also requires:**
      1. You are 6 years of age or older
   C. **If you have attention deficit disorder with hyperactivity, approval also requires:**
      1. You are 3 years of age or older
      2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)
   D. **If the request is for weight loss or exogenous obesity, approval also requires:**
      1. You are 12 years of age or older
      2. You had a previous trial of other weight loss medications such as Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion

      Note: The approval of Evekeo for use as a short-term adjunct (add-on) in a regimen of weight reduction is for a maximum duration of 12 weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMPHETAMINE SULFATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo.

REFERENCES

- Evekeo [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 07/19

AMPHETAMINE SULFATE ODT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMPHETAMINE SULFATE	EVEKEO ODT		45976 45977 45978 45979	GPI-14 (61100010107210, 61100010107220, 61100010107230, 61100010107240)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of attention deficit disorder with hyperactivity (ADHD) and meet **ALL** of the following criteria?
   - The patient is 6 to 17 years of age
   - The patient is unable to swallow amphetamine sulfate tablets
   - The patient had a trial of **TWO** of the following immediate-release stimulant medications: methylphenidate, dexmethylphenidate, amphetamine, dextroamphetamine, dextroamphetamine-amphetamine

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **5 mg: #8 per day.**
   - **10 mg: #4 per day.**
   - **15 mg and 20 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMPHETAMINE SULFATE ODT (Evekeo ODT)** requires the following rule(s) be met for approval:
   A. You have attention deficit disorder with hyperactivity (ADHD: difficulty paying attention)
   B. You are 6 to 17 years of age
   C. You are unable to swallow amphetamine sulfate tablets
   D. You had a trial of TWO of the following immediate-release stimulant medications: methylphenidate, dexmethylphenidate, amphetamine, dextroamphetamine, dextroamphetamine-amphetamine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMPHETAMINE SULFATE ODT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo ODT.

REFERENCES

- Evekeo ODT [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 11/22
Client Approval: 02/23
P&T Approval: 10/22

ANABOLIC STEROIDS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OXYMETHOLONE	ANADROL-50	01409		GPI-10 (2320005000)	
OXANDROLONE	OXANDRIN	01412		GPI-10 (2320004000)	FDB: ROUTE ≠ MISCELL.

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

1. Does the patient have a diagnosis of anemia and meet **ALL** of the following criteria?
   - The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's anemia
   - The patient does **not** have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

CONTINUED ON NEXT PAGE

ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

2. Does the patient have a diagnosis of cachexia associated with AIDS and meet the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months
   - Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional Support Specialist (SBS) or Infectious Disease specialist
   - The patient meets **ONE** of the following criteria:
     - The patient has 10% unintentional weight loss over 12 months
     - The patient has 7.5% unintentional weight loss over 6 months
     - The patient has 5% body cell mass (BCM) loss within 6 months
     - The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
     - The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
     - The patient has a BMI of less than 18.5 kg per meter squared
   - The patient does **not** have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

   A. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

   (Initial denial text continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have anemia, approval also requires:**
   1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in recommendation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS), or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANABOLIC STEROIDS

INITIAL CRITERIA (CONTINUED)

OXANDRIN

1. Is the request for adjunctive therapy to promote weight gain and the patient meet **ALL** of the following criteria?
   - The patient's weight loss is due to one of the following conditions: extensive surgery, chronic infections, or severe trauma
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request for adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids and the patient meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for the relief of the bone pain accompanying osteoporosis and the patient meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

4. Does the patient have a diagnosis of cachexia associated with AIDS and meet **ALL** of the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months
   - Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional support specialist (SBS) or Infectious disease specialist
   - The patient meets ONE of the following criteria:
     - The patient has 10% unintentional weight loss over 12 months,
     - The patient has 7.5% unintentional weight loss over 6 months
     - The patient has 5% body cell mass (BCM) loss within 6 months
     - The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
     - The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
     - The patient has a BMI of less than 18.5 kg per meter squared
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Turner's Syndrome and meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***See Oxandrin initial denial text on the next page.***

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANABOLIC STEROIDS (Oxandrin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Weight loss
   2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
   3. Bone pain accompanying osteoporosis (weak and brittle bones)
   4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   5. Turner's Syndrome (disorder where female has one X chromosome

B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have weight loss, approval also requires:**
   1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
   2. Medication is being used as add-on therapy to help weight gain

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS) or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

(Initial denial text continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

(**NOTE:** For the diagnosis of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's Syndrome, please refer to the Initial Criteria section)

OXANDRIN and ANADROL-50

1. Is the request for cachexia associated with AIDS and the patient meet **ALL** of the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient's viral load is less than 200 copies per mL within the past 3 months
   - The patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
   - The patient has not received more than 24 weeks of therapy in a calendar year

   If yes, **approve for 12 weeks by HICL or GPI-10.** (**Note**: therapy is limited to 24 weeks per calendar year.)
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ANABOLIC STEROIDS (Oxandrin and Anadrol-50)** requires the following rule(s) be met for renewal:

A. You have cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
C. Your viral load (amount of virus in your blood) is less than 200 copies per mL within the past 3 months
D. You have a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
E. You have not received more than 24 weeks of therapy in a calendar year

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ANABOLIC STEROIDS

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anadrol-50 and Oxandrin.

REFERENCES

- Anadrol-50 [Prescribing Information]. Marietta, GA: Alaven Pharmaceutical LLC; October 2012
- Oxandrin [Prescribing Information]. East Brunswick, NJ: Savient Pharmaceuticals; April 2007.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 05/15

ANAKINRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANAKINRA	KINERET	22953		GPI-10 (6626001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, **do not approve**. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Kineret will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.67 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID) (ICD-10 M04.2) and meet **ALL** of the following criteria?
   The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein [SAA] or S100 proteins)
   The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   Kineret will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS, including NOMID

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) (ICD-10 M04.8) and meet **ALL** of the following criteria?
   The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   Kineret will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DIRA

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Cryopyrin-associated periodic syndromes (CAPS: a type of immune disorder) including neonatal-onset multisystem inflammatory disease (NOMID: a types of immune system disorder)
- Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

If you have cryopyrin-associated periodic syndromes, including neonatal-onset multisystem inflammatory disease, approval also requires:
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes, including Neonatal-Onset Multisystem Inflammatory Disease

If you have deficiency of interleukin-1 receptor antagonist, approval also requires:
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body])
- You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: nail shedding)
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist

NOTE: Kineret will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANAKINRA

RENEWAL CRITERIA

NOTE: For the diagnoses of cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Kineret will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.67 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ANAKINRA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:
You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
- You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANAKINRA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kineret.

REFERENCES

Kineret [Prescribing Information]. Stockholm, Sweden: Swedish Orphan Biovitrum; September 2024.

Created: 02/03
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

APALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APALUTAMIDE	ERLEADA	44773		GPI-10 (2140241000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **60mg: #3 per day.**
   - **240mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APALUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that does not respond to hormone reduction therapy and has not spread to other parts of the body)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have a non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] levels)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-sensitive prostate cancer (mCSPC)
   - Non-metastatic castration-resistant prostate cancer (nmCRPC)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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APALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **60mg: #3 per day.**
   - **240mg: #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that does not respond to hormone reduction therapy but has not spread)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread and responds to hormone therapy)
   B. You meet ONE of the following:
      1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APALUTAMIDE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Erleada.

REFERENCES

- Erleada [Prescribing Information]. Horsham, PA: Janssen; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/18
Client Approval: 05/23
P&T Approval: 04/23

APOMORPHINE - APOKYN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	APOKYN, APOMORPHINE HCL		42078	GPI-14 (7320301010E220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist
   - The requested medication will be used for the acute, intermittent treatment of hypomobility, 'OFF' episodes associated with advanced Parkinson's disease

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the physician optimized the patient's medication therapy as evidenced by **BOTH** of the following?
   - The patient had a change in levodopa/carbidopa dosing strategy or formulation
   - The patient had a trial of or contraindication to TWO Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #60mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - APOKYN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for approval:

A. You have a diagnosis of advanced Parkinson's disease (PD: a type of movement disorder)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
C. The requested medication will be used for acute, intermittent treatment of hypomobility, 'OFF' episodes (short and sudden episodes where there is decreased ability to move) associated with advanced Parkinson's disease
D. Your doctor has optimized your medication therapy as shown by BOTH of the following:
   1. You had a change in levodopa/carbidopa dosing strategy or formulation
   2. You have tried or have a contraindication to (harmful for you to use) TWO Parkinson disease medications from two different classes: dopamine agonist (ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (entacapone, tolcapone)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - APOKYN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?
   - The patient has experienced improvement with motor fluctuations during 'OFF' episodes while on the requested medication (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #60mL per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for renewal:
   A. You have a diagnosis of advanced Parkinson's disease (PD: a type of movement disorder)
   B. You have experienced improvement with motor fluctuations (changes in the ability to move) during 'OFF' episodes with the use of the requested medication (such as improvement in speech, facial expression, tremor [shaking] at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Apokyn.

REFERENCES

- Apokyn [Prescribing Information]. Rockville, MD: MDD US Operations, LLC, January 2025.

Created: 11/04
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/19

APOMORPHINE - SL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE	KYNMOBI	01934		GPI-10 (7320301010)	BRAND = KYNMOBI

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)
   - Kynmobi is being used for the acute, intermittent treatment of 'OFF' episodes

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 as follows:**
   - **Kynmobi Titration Kit: no quantity limit.**
   - **Kynmobi 10mg, 15mg, 20mg, 25mg and 30mg: #5 per day.**

   APPROVAL TEXT: Renewal requires the patient had improvement with motor fluctuations during OFF episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a neurologist
   (Initial denial text continued on next page)

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APOMORPHINE - SL

INITIAL CRITERIA (CONTINUED)

D. The physician has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to at least two Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-o-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

E. The requested medication is being used for acute, intermittent treatment (sudden and periodic treatment) of 'OFF' episodes (when symptoms return due to your medication for Parkinson's disease wearing off)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during 'OFF' episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **Kynmobi 10mg, 15mg, 20mg, 25mg and 30mg: #5 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for renewal:
   A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   (Renewal denial text continued on next page)

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APOMORPHINE - SL

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynmobi.

REFERENCES

- Kynmobi [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 08/20
Client Approval: 08/20
P&T Approval: 07/20

APOMORPHINE - ONAPGO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	ONAPGO	01934		GPI-10 (7320301010)	BRAND = ONAPGO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
   Onapgo will be used for the treatment of motor fluctuations associated with Parkinson's disease
   Therapy is prescribed by or in consultation with a neurologist
   The patient's disease is responsive to treatment with levodopa
   The patient's current medication regimen, including levodopa, has been at a stable dose for at least 28 days
   The patient has motor symptoms that are currently uncontrolled (defined as an average 'off' time of at least 3 hours per day, with a minimum of 2 hours each day)
   The patient does not have any of the following: orthostatic hypotension, history of prolonged QTc (greater than 450 msec for male or greater than 470 msec for female), active or uncontrolled psychosis, active or uncontrolled depression

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - ONAPGO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
Onapgo will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
Your disease is responsive to treatment with levodopa
Your current medication regimen (treatment plan), including levodopa, has been at a stable dose for at least 28 days
Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 3 hours per day, with a minimum of 2 hours each day)
You do not have any of the following: orthostatic hypotension (a type of low blood pressure), history of prolonged QTc (a type of irregular heart rhythm) (greater than 450 msec for male or greater than 470 msec for female), active or uncontrolled psychosis (a type of mental health disorder), active or uncontrolled depression (a type of mental health disorder)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - ONAPGO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?
   The patient has experienced improvement in motor symptoms while on Onapgo

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for renewal:
   You have advanced Parkinson's disease (PD: a type of movement disorder)
   You have experienced improvement in motor symptoms while on Onapgo

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onapgo.

REFERENCES

Onapgo [Prescribing Information]. Rockville, MD: Supernus Pharmaceuticals, Inc.; February 2025.

Created: 02/25
Effective: 03/10/25 Client Approval: 03/25 P&T Approval: 04/25

APREMILAST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APREMILAST	OTEZLA	40967		GPI-10 (6670001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Otezla will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PsA

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   If the starter pack is requested for dosage titration, approve for #1 fill for either #1 Otezla 10-20-30mg Two Week Starter Pack (#27 tablets) OR for #1 Otezla 10-20-30mg 28-day Starter Pack (#55 tablets), AND
   Approve the 30mg strength for 6 months with a quantity limit of #2 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of plaque psoriasis (PsO) (ICD-10 L40.0)?

   If yes, continue to #3.
   If no, continue to #8.

3. Is the patient's disease mild and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to one conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) OR one conventional topical agent (e.g., topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate])
   Otezla will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of mild PsO

   If yes, continue to #4.
   If no, continue to #5.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Otezla
   The patient has a static Physician Global Assessment (sPGA) score of 2
   The patient has a Psoriasis Area and Severity Index (PASI) score of 2 to 9

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   If the starter pack is requested for dosage titration, approve for #1 fill for either #1 Otezla 10-20-30mg Two Week Starter Pack (#27 tablets) OR for #1 Otezla 10-20-30mg 28-day Starter Pack (#55 tablets), AND
   Approve the 30mg strength for 6 months with a quantity limit of #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the patient's disease moderate to severe and the patient meets **ALL** of the following criteria?
   The patient is 6 to 17 years of age and weighs at least 20 kg (44 lbs), OR 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Otezla will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of moderate to severe PsO

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor, or JAK inhibitor for the same indication

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Otezla
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   If the starter pack is requested for dosage titration, approve for #1 fill for the requested starter pack as follows:
   10-20-30mg Two Week Starter Pack: #27 tablets per 14 days.
   10-20-30mg 28-day Starter Pack: #55 tablets per 28 days.
   10-20mg 28-day Starter Pack: #55 tablets per 28 days.
   Approve the requested strength for 6 months as follows:
   30mg: #2 per day.
   20mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have a diagnosis of Behcet's disease (ICD-10 M35.2) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient had a trial of or contraindication to ONE or more conservative treatments (e.g., colchicine, topical corticosteroid [e.g., triamcinolone], oral corticosteroid [e.g., prednisolone])
   Otezla will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Behcet's disease

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   If the starter pack is requested for dosage titration, approve for #1 fill for either #1 Otezla 10-20-30mg Two Week Starter Pack (#27 tablets) OR for #1 Otezla 10-20-30mg 28-day Starter Pack (#55 tablets), AND
   Approve the 30mg strength for 6 months with a quantity limit of #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Plaque psoriasis (PsO: a type of skin condition)
- Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of psoriatic arthritis

If you have mild plaque psoriasis, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) one conventional (standard) systemic (treatment that targets the entire body) medication (such as methotrexate, acitretin, cyclosporine) OR one conventional topical medication (such as topical corticosteroids [such as betamethasone dipropionate, clobetasol propionate])
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)] for the treatment of mild plaque psoriasis
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Otezla
  - You have a static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) score of 2
  - You have a Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) score of 2 to 9

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APREMILAST

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 to 17 years of age and weigh at least 20 kilograms (44 pounds), OR you are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of moderate to severe plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor, or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Otezla
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) ONE or more conservative treatments (such as colchicine, topical corticosteroid [such as triamcinolone], oral corticosteroid [such as prednisolone])
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Otezla will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PsA

   If yes, **approve the 30mg strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of plaque psoriasis (PsO) (ICD-10 L40.0)?

   If yes, continue to #3.
   If no, continue to #5.

3. Is the patient's disease mild and the patient meets **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more OR a decrease in sPGA (static Physician Global Assessment) by at least a 2-point reduction from baseline
   Otezla will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of mild PsO

   If yes, **approve the 30mg strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, continue to #4.

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

4. Is the patient's disease moderate to severe and the patient meets **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Otezla will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of moderate to severe PsO

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   30mg: #2 per day.
   20mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
5. Does the patient have a diagnosis of Behcet's disease (ICD-10 M35.2) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
   The patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers)
   Otezla will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Behcet's disease

   If yes, **approve the 30mg strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Plaque psoriasis (PsO: a type of skin condition)
   Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
   (Renewal denial text continued on next page)

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of psoriatic arthritis

If you have mild plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more OR a decrease in static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) by at least a 2-point reduction from baseline
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)] for the treatment of mild plaque psoriasis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast) for the treatment of moderate to severe plaque psoriasis

If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:
- You have achieved or maintained clinical benefit compared to baseline (such as an improvement in pain scores, number of ulcers)
- You will NOT use Otezla concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Otezla.

REFERENCES
Otezla [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2024.

Created: 04/14
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

APROCITENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APROCITENTAN	TRYVIO	49465		GPI-10 (3618001000)	

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist
   The patient's blood pressure is NOT controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine], a diuretic [e.g., hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
   The patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except sleep apnea)
   Tryvio will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
   The patient had a trial of or contraindication to a potent diuretic (i.e., chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (i.e., spironolactone or eplerenone)

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for approval:
   You have hypertension (high blood pressure)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
   (Initial denial text continued on next page)

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APROCITENTAN

INITIAL CRITERIA (CONTINUED)

Your blood pressure is NOT controlled on at least three anti-hypertensive medications (drugs used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine], a diuretic [such as hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (high blood pressure that is caused by another medical condition) (except sleep apnea [a type of sleep condition with difficulty breathing])
You will use Tryvio concurrently (at the same time) with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
You have tried or have a contraindication to (harmful for you to use) a potent diuretic (chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APROCITENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   The patient continues to benefit from the medication
   Tryvio will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for renewal:
   You have hypertension (high blood pressure)
   You continue to benefit from Tryvio
   You will use Tryvio concurrently (at the same time) with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryvio.

REFERENCES

Tryvio [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/23/24
Created: 05/24
Client Approval: 09/24
P&T Approval: 10/23

ARIMOCLOMOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ARIMOCLOMOL CITRATE	MIPLYFFA	49879		GPI-10 (6200000320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a neurologist or geneticist
   Miplyffa will be used in combination with miglustat (Zavesca)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for approval:
   You have Niemann-Pick disease type C (NPC: a type of genetic condition)
   You are 2 years of age or older
   Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)
   Miplyffa will used in combination with miglustat (Zavesca)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ARIMOCLOMOL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
   The patient has experienced improvement or a slowing of disease progression

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for renewal:
   You have Niemann-Pick disease type C (NPC: a type of genetic condition)
   You have shown improvement or a slowing of disease progression

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Miplyffa.

REFERENCES

Miplyffa [Prescribing Information]. Celebration, FL: Zevra Therapeutics, Inc.; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 10/24
Client Approval: 10/24
P&T Approval: 07/24

ARIPIPRAZOLE SENSOR TABS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ARIPIPRAZOLE TABLETS WITH SENSOR	ABILIFY MYCITE	24551		GPI-10 (5925001502, 5925001503)	BRAND = ABILIFY MYCITE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of schizophrenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient has a medical necessity for tracking medication ingestion

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #1 kit per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - Abilify MyCite will be used as an adjunctive treatment
   - The patient has a medical necessity for tracking medication ingestion

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #1 kit per 30 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of bipolar I disorder and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient has a medical necessity for tracking medication ingestion

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ARIPIPRAZOLE SENSOR TABS

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The request is for acute treatment of manic and mixed episodes as monotherapy, OR as an adjunct to lithium or valproate
   - The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #1 kit per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ARIPIPRAZOLE SENSOR TABS (Abilify MyCite)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Schizophrenia (a type of mental health disorder)
      2. Bipolar I disorder (a type of mood disorder)
      3. Major depressive disorder (MDD: a type of mental health disorder)
   B. **If you have schizophrenia, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
      3. You have a medical necessity for medication ingestion tracking
   C. **If you have major depressive disorder, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
      3. Abilify MyCite will be used as an adjunctive (add-on) treatment
      4. You have a medical necessity for medication ingestion tracking
   D. **If you have bipolar I disorder, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
      3. You have a medical necessity for medication ingestion tracking
      4. You meet ONE of the following:
         i. The request is for acute (short-term) treatment of manic and mixed episodes as monotherapy (used alone), OR as an adjunct (add-on) to lithium or valproate
         ii. The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

   (Denial text continued on the next page)

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ARIPIPRAZOLE SENSOR TABS

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Abilify MyCite.

REFERENCES

- Abilify MyCite [Prescribing Information]. Redwood City, CA: Proteus Digital Health, Inc.: February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 02/19
Client Approval: 10/22
P&T Approval: 01/19

ASCIMINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASCIMINIB HYDROCHLORIDE	SCEMBLIX	47647		GPI-10 (2153180610)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) (ICD-10 Group C92.1) **AND** meets the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer newly diagnosed?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   20mg: #2 per day.
   40mg: #2 per day.

   If no, continue to #3.

3. Does the patient's cancer have the T315I mutation **AND** meets the following criterion?
   The patient had a mutational analysis prior to initiation of therapy AND Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   40mg: #8 per day.
   100mg: #4 per day.

   If no, continue to #4.

CONTINUED ON NEXT PAGE

ASCIMINIB

GUIDELINES FOR USE (CONTINUED)

4. Has the patient been previously treated **AND** meets the following criterion?
   The patient had a mutational analysis prior to initiation of therapy AND Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   20mg: #2 per day.
   40mg: #2 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASCIMINIB (Scemblix)** requires the following rule(s) be met for approval:
   You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase (CP)
   You are 18 years of age or older
   You meet ONE of the following:
   - Your cancer is newly diagnosed
   - Your cancer has the T315I mutation (abnormal change in a type of gene) AND you had a mutational analysis (a type of lab test) prior to the start of therapy and Scemblix is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on the profile for the breakpoint cluster region-Abelson murine leukemia 1 (BCR-ABL1: a type of gene) mutation
   - You have been previously treated AND you had a mutational analysis prior to the start of therapy and Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on the profile for the BCR-ABL1 mutation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASCIMINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Scemblix.

REFERENCES

Scemblix [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Co.; October 2024.

Created: 02/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/22

ASPARAGINASE ERWINIA-RYWN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPARAGINASE ERWINIA-RYWN	RYLAZE	47474		GPI-10 (2125001060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The patient has developed hypersensitivity to E. coli-derived asparaginase
   - Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASPARAGINASE ERWINIA-RYWN (Rylaze)** requires the following rule(s) be met for approval:
   A. You have acute lymphoblastic leukemia (ALL: type of blood cancer) or lymphoblastic lymphoma (LBL: type of cancer affecting the immune system)
   B. You are 1 month of age or older
   C. You have developed hypersensitivity to E.coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)
   D. Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rylaze.

REFERENCES

- Rylaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 10/21
Client Approval: 11/21
P&T Approval: 10/21

ASFOTASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		GPI-10 (3090561000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is this a request for treatment of perinatal/infantile-onset hypophosphatasia (HPP)?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient was 6 months of age or younger at hypophosphatasia (HPP) onset
   - The patient is NOT currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meets at least TWO of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of two or more of the following:
       - Rachitic chest deformity
       - Craniosynostosis (premature closure of skull bones)
       - Delay in skeletal growth resulting in delay of motor development
       - History of vitamin B_6 dependent seizures
       - Nephrocalcinosis or history of elevated serum calcium
       - History or presence of non-traumatic postnatal fracture and delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is this a request for treatment of juvenile-onset hypophosphatasia (HPP)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a documented diagnosis of juvenile-onset hypophosphatasia (HPP) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient was 18 years of age or younger at hypophosphatasia (HPP) onset
   - The patient is NOT currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meets at least TWO of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of two or more of the following:
       - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
       - Premature loss of primary teeth prior to 5 years of age
       - Delay in skeletal growth resulting in delay of motor development
       - History or presence of non-traumatic fractures or delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ANY** of the following criteria?
   - The patient's serum calcium or phosphate level is below the normal range
   - The patient has a treatable form of rickets

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

   If no, **approve for 6 months by HICL or GPI-10.**

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP: a type of genetic condition) or juvenile-onset hypophosphatasia (HPP).
B. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
C. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
D. **If you have perinatal/infantile-onset hypophosphatasia, approval also requires:**
    1. You were 6 months of age or younger at hypophosphatasia onset
    2. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing OR you meet at least TWO of the following criteria:
        a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
        b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
        c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
        d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
        e. Presence of two or more of the following:
            i. Rachitic chest deformity (chest bones are not normal)
            ii. Craniosynostosis (premature closure of skull bones)
            iii. Delay in skeletal growth resulting in delay of motor development
            iv. History of vitamin B6 dependent seizures
            v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
            vi. History or presence of fracture after birth not due to injury or delayed fracture healing

(Initial denial text continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

E. **If you have juvenile-onset hypophosphatasia, approval also requires:**
   1. You were 18 years of age or younger at hypophosphatasia onset
   2. You are positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meet at least TWO of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)]
      e. Presence of two or more of the following:
         i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
         ii. Premature loss of primary teeth prior to 5 years of age
         iii. Delay in skeletal growth leading to motor development delay
         iv. History or presence of fracture after birth not due to injury or delayed fracture healing

Strensiq will not be approved if you meet any of the following:
1. Your serum calcium or phosphate level is below the normal range
2. You have a treatable form of rickets (softening and weakening of bones in children, usually due to low vitamin D)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the last 6 months of treatment, has the patient experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or by GPI-10.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule(s) be met for renewal:
   A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.
   B. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Strensiq.

REFERENCES

- Strensiq [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/15
Client Approval: 05/22
P&T Approval: 04/22

ASPIRIN ER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPIRIN ER	DURLAZA		17988	GPI-10 (8515001000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic coronary artery disease, (e.g., a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet the following criteria?
   - Patient has previously tried aspirin over-the-counter (OTC)
   - Durlaza is NOT being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

   If yes, **approve for 12 months by GPID or GPI-10 for a quantity limit of #30 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ASPIRIN ER (Durlaza)** requires the following rules be met for approval:
   1. You have ONE of the following:
      a. Diagnosis of chronic coronary artery disease [damage or disease in the heart's major blood vessels; may include a history of myocardial infarction (heart attack) or unstable angina (chest pain when your heart doesn't get enough oxygen)] OR
      b. History of an ischemic stroke or transient ischemic attack (arteries to your brain become narrowed or blocked, causing blood flow loss).
   2. You have previously tried aspirin over-the-counter (OTC)
   3. Durlaza is NOT being used for acute treatment (short term treatment) of myocardial infarction (heart attack) or before percutaneous coronary intervention (non-surgical procedure used to treat narrowing of the coronary arteries of the heart)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor.

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ASPIRIN ER

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Durlaza.

REFERENCES

- Durlaza [Prescribing Information] North Haven, CT. New haven Pharmaceuticals, Inc., September 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/15
Client Approval: 04/20
P&T Approval: 11/15

ASPIRIN-OMEPRAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPIRIN-OMEPRAZOLE	YOSPRALA, ASPIRIN-OMEPRAZOLE	43771		GPI-10 (8515990204)	

GUIDELINES FOR USE

1. Does the patient require aspirin for secondary prevention of cardiovascular or cerebrovascular events and have **ONE** of the following diagnoses?
   - Ischemic stroke
   - Transient ischemia of the brain due to fibrin platelet emboli
   - Previous myocardial infarction
   - Unstable angina pectoris
   - Chronic stable angina pectoris
   - Previously undergone revascularization procedures (i.e., coronary artery bypass graft, percutaneous transluminal coronary angioplasty)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a risk of developing aspirin associated gastrointestinal (GI) ulcers and meet **ALL** of the following criteria?
   - The patient is 55 years of age or older
   - Documented history of gastrointestinal (GI) ulcers

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried **ALL** of the following medications?
   - Aspirin over-the-counter (OTC)
   - Generic proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, or rabeprazole)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ASPIRIN-OMEPRAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASPIRIN-OMEPRAZOLE (Yosprala)** requires the following rule(s) be met for approval:

A. The request is for secondary prevention of cardiovascular (related to heart and blood vessels) or cerebrovascular (related brain and blood vessels) events
B. You have ONE of the following:
    1. Ischemic stroke (arteries to your brain become narrowed or blocked, causing less blood flow)
    2. Transient ischemia of the brain due to fibrin platelet emboli (blood flow to your brain gets cut off for a short time due to temporary blockage)
    3. Previous myocardial infarction (heart attack)
    4. Unstable angina pectoris (chest pain when your heart doesn't get enough oxygen)
    5. Chronic stable angina pectoris (chest pain when your heart doesn't get enough oxygen)
    6. History of undergoing revascularization procedures (procedures that restore blood flow to heart such as coronary artery bypass graft, percutaneous transluminal coronary angioplasty)
C. You have a risk of developing aspirin associated gastrointestinal (GI) ulcers due to age (55 years or older) **AND** have a documented history of gastrointestinal (GI) ulcers
D. You have tried both aspirin over-the-counter (OTC) **AND** generic proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole, rabeprazole)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yosprala.

REFERENCES

- Yosprala [Prescribing Information]. Princeton, NJ: Aralez Pharmaceuticals US Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
Client Approval: 04/20
P&T Approval: 11/16

ATOGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATOGEPANT	QULIPTA	47599		GPI-10 (6770101000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Qulipta is prescribed for the preventive treatment of migraines
   Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Qulipta is prescribed for the preventive treatment of migraines
   Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine, Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ATOGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
You have migraines (a type of headache)
If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines
- You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines
- You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine, Botox [Note: For Botox, previous trial of only **National Drug Code** (**NDC**) 00023-1145-01 or NDC 00023-3921-02 are allowable]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Qulipta therapy
   The patient has experienced a reduction in migraine severity with Qulipta therapy
   The patient has experienced a reduction in migraine duration with Qulipta therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
   Qulipta is prescribed for the preventive treatment of migraines
   You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   You meet ONE of the following:
      You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Qulipta therapy
      You have experienced a reduction in migraine severity with Qulipta therapy
      You have experienced a reduction in migraine duration with Qulipta therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qulipta.

REFERENCES

Qulipta [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/23

ATORVASTATIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATORVASTATIN CALCIUM	ATORVALIQ		53672	GPI-14 (39400010101810)	

GUIDELINES FOR USE

1. Is the patient 18 years of age or older and the request is to reduce the risk of **ONE** of the following?
   Myocardial infarction (MI), stroke, revascularization procedures, or angina and the patient has multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
   MI or stroke and the patient has type 2 diabetes mellitus and multiple risk factors for CHD but without clinically evident CHD
   Non-fatal MI, fatal or non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, or angina and the patient has clinically evident CHD

   If yes, continue to #6.
   If no, continue to #2.

2. Does the patient have a diagnosis of primary hyperlipidemia and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Atorvaliq will be used in addition to diet

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and meet **ALL** of the following criteria?
   The patient is 10 years of age or older
   Atorvaliq will be used in addition to diet

   If yes, continue to #6.
   If no, continue to #4.

4. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) and meet ALL of the following criteria?
   The patient is 10 years of age or older
   Atorvaliq will be used in addition to other LDL-C lowering therapies (e.g., ezetimibe, fenofibrate) OR will be used alone if other LDL-C lowering therapies are unavailable

   If yes, continue to #6.
   If no, continue to #5.

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of primary dysbetalipoproteinemia or hypertriglyceridemia and meet **ALL** of the following?
   The patient is 18 years of age or older
   Atorvaliq will be used in addition to diet

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   The patient had a trial of or contraindication to generic atorvastatin tablets
   The patient cannot swallow atorvastatin tablets AND had a trial of rosuvastatin (Ezallor) sprinkle capsule

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the patient also requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #8.
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20 mL per day.**

8. Does the patient meet **ALL** of the following criteria?
   The patient is between 40 to 75 years old
   The requested quantity is within the low to moderate intensity daily dosage of 10 to 20 mg
   The patient is not concurrently taking any of the below secondary prevention medications for cardiovascular disease:
   Aspirin/dipyridamole (Aggrenox)
   Clopidogrel (Plavix)
   Dipyridamole
   Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
   Prasugrel (Effient)
   Ticagrelor (Brilinta)
   Ticlopidine
   Vorapaxar (Zontivity)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per day at zero copay.**
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20 mL per day.**

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATORVASTATIN (Atorvaliq)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- To reduce the risk of one of the following and you are 18 years of age or older:
  - Myocardial infarction (MI: heart attack), stroke, revascularization procedures (restoring blood flow to heart and other areas), or angina (chest pain) and you have multiple risk factors for coronary heart disease (CHD: heart arteries get blocked with fats and plaques) but without clinically evident CHD
  - MI or stroke and you have type 2 diabetes mellitus (a disorder with high blood sugar) and multiple risk factors for CHD but without clinically evident CHD
  - Non-fatal (not deadly) MI, fatal (deadly) or non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (a type of heart failure), or angina and you have clinically evident CHD
- Primary hyperlipidemia (high level of fat in the blood due to genetic causes)
- Heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol)
- Homozygous familial hypercholesterolemia (HoFH: a type of inherited high cholesterol)
- Primary dysbetalipoproteinemia (a condition leading to increased total cholesterol and triglyceride levels in the blood)
- Hypertriglyceridemia (high level of fat in the blood)

You had a trial of or contraindication (harmful for) to generic atorvastatin tablets
You cannot swallow atorvastatin tablets AND had a trial of rosuvastatin (Ezallor) sprinkle capsule
If you have primary hyperlipidemia, approval also requires:
- You are 18 years of age or older
- Atorvaliq will be used in addition to diet

If you have heterozygous familial hypercholesterolemia, approval also requires:
- You are 10 years of age or older
- Atorvaliq will be used in addition to diet

If you have homozygous familial hypercholesterolemia, approval also requires:
- You are 10 years of age or older
- Atorvaliq will be used in addition to other LDL-C lowering therapies (such as ezetimibe, fenofibrate) OR will be used alone if other LDL-C lowering therapies are unavailable

If you have dysbetalipoproteinemia or hypertriglyceridemia, approval also requires:
- You are 18 years of age or older
- Atorvaliq will be used in addition to diet

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

Requests for zero dollar cost share also requires the following:
- You are between 40 to 75 years old
- The requested quantity is within the low to moderate intensity daily dosage of 10 to 20mg
- You are not concurrently (at the same time) taking any of the below secondary prevention medications for cardiovascular disease (heart disease):
  - Aspirin/dipyridamole (Aggrenox)
  - Clopidogrel (Plavix)
  - Dipyridamole
  - Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
  - Prasugrel (Effient)
  - Ticagrelor (Brilinta)
  - Ticlopidine
  - Vorapaxar (Zontivity)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Atorvaliq.

This guideline also applies to plans where the pharmacy benefit allows for coverage Atorvaliq at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to Atorvaliq, which is included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

Atorvaliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; February 2023.
U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2023.
U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2023.

Created: 05/23
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 04/23

AVACOPAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVACOPAN	TAVNEOS	47626		GPI-10 (8580551000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
   - The patient is ANCA seropositive (anti-PR3 or anti-MPO)
   - Tavneos will be used as adjunctive therapy in combination with standard therapy including glucocorticoids (e.g., methylprednisolone, prednisone)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for approval:
   A. You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA: condition that affects the blood vessels] or microscopic polyangiitis [MPA: condition that affects the blood vessels])
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
   D. You are ANCA seropositive for anti-PR3 or anti-MPO (a type of lab test)
   E. Tavneos will be used as adjunctive (add-on) therapy in combination with standard therapy including glucocorticoids (such as methylprednisolone, prednisone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVACOPAN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) AND meet the following criterion?
   - The patient continues to benefit from therapy (e.g., improvement of clinical manifestations, if renal vasculitis - improvement in eGFR and proteinuria values, reduction of corticosteroid dose without disease flares)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for renewal:
   A. You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA: condition that affects the blood vessels] or microscopic polyangiitis [MPA: condition that affects the blood vessels])
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavneos.

REFERENCES
- Tavneos [Prescribing Information]. Cincinnati, OH: ChemoCentryx Inc.; October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 02/22
Client Approval: 10/22
P&T Approval: 01/22

AVAPRITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVAPRITINIB	AYVAKIT	46291		GPI-10 (2149000900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL), **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of indolent systemic mastocytosis (ISM) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day**.
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that cannot be removed through surgery or has spread to other parts of the body)
      2. Advanced systemic mastocytosis (AdvSM: a type of blood disorder), including aggressive systemic mastocytosis (ASM: a type of blood disorder), systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood disorder), or mast cell leukemia (MCL: a type of blood cancer)
      3. Indolent systemic mastocytosis (ISM: a type of blood disorder)

   (Denial text continued on next page)

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AVAPRITINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have unresectable or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You have a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations (a type of gene mutation)

C. **If you have advanced systemic mastocytosis, approval also requires:**
   1. You are 18 years of age or older

D. **If you have indolent systemic mastocytosis, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ayvakit.

REFERENCES

- Ayvakit [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation, May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 05/20
Client Approval: 06/23
P&T Approval: 07/23

AVATROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVATROMBOPAG MALEATE	DOPTELET	44942		GPI-10 (8240501020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of thrombocytopenia in chronic liver disease and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy
   The patient has a platelet count of less than 50 x 10^9/L
   Doptelet will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag])

   If yes, **approve by HICL or GPI-10 for 1 fill with a quantity limit of #15.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy
   Doptelet will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AVATROMBOPAG

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The patient has a platelet count of less than 30 x 10^9/L
   The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

   Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Thrombocytopenia (a type of blood disorder) in chronic (long-term) liver disease
   Chronic immune thrombocytopenia (cITP: a type of blood disorder)
   If you have thrombocytopenia in chronic liver disease, approval also requires:
   You are 18 years of age or older
   You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   You have a platelet (a type of blood cell) count of less than 50 x 10^9/L
   You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag])
   (Initial denial text continued on next page)

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AVATROMBOPAG

INITIAL CRITERIA (CONTINUED)

If you have chronic immune thrombocytopenia, approval also requires:

- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
- You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])
- You meet ONE of the following:
  - You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
  - You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVATROMBOPAG

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia in chronic liver disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   Doptelet will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for renewal:
   You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
   You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Doptelet) OR a decrease in bleeding events
   You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVATROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Doptelet.

REFERENCES

Doptelet [prescribing information]. Morrisville, NC: Sobi, Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 08/18
Client Approval: 08/24
P&T Approval: 04/24

AXATILIMAB-CSFR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXATILIMAB-CSFR	NIKTIMVO	49817		GPI-10 (9939261010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   The patient weighs at least 40kg (88 lbs)
   The patient has failed at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil)
   Niktimvo will NOT be used concurrently with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AXATILIMAB-CSFR (Niktimvo)** requires the following rule(s) be met for approval:
   You have chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)
   You weigh at least 40 kilograms (88 pounds)
   You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   You will NOT use Niktimvo concurrently (at the same time) with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Niktimvo.

REFERENCES
Niktimvo [Prescribing Information]. Wilmington, DE: Incyte Corporation; January 2025.

Created: 02/25
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

AXITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXITINIB	INLYTA	38446		GPI-10 (2133501300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - The patient has tried at least **ONE** systemic therapy for the treatment of RCC [e.g., Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon]
   - Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
   - Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Inlyta 1mg: #6 per day.**
   - **Inlyta 5mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
   A. You have advanced renal cell carcinoma (RCC; type of kidney cancer)
   B. You also meet ONE of the following:
      1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
      2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
      3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AXITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inlyta.

REFERENCES

- Inlyta [Prescribing Information]. New York, NY: Pfizer; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 02/12
Client Approval: 03/21
P&T Approval: 07/20

AZACITIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZACITIDINE	ONUREG		48545 48540	GPI-14 (21300003000330) (21300003000320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
   - The patient is not able to complete intensive curative therapy

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:
   A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
   B. You are 18 years of age or older
   C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
   D. You are not able to complete intensive curative therapy (treatment to cure the disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Onureg.

REFERENCES

- Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 10/20
Client Approval: 11/20
P&T Approval: 10/20

AZTREONAM INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZTREONAM LYSINE	CAYSTON		28039	GPI-10 (1614001040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - The patient has a lung infection with a Gram negative species (such as *Pseudomonas aeruginosa*; not *Staphylococcus aureus* because it is not a Gram negative species)

   If yes, **approve for 12 months by GPI-10 for 6 fills of #84 vials per 56 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AZTREONAM INHALED** requires the following rule(s) be met for approval:
   A. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
   B. You are 7 years of age or older
   C. You have a lung infection with a Gram negative species such as *Pseudomonas aeruginosa*

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cayston.

REFERENCES

- Cayston [Prescribing Information]. Foster City, CA. Gilead Sciences, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/12
Client Approval: 04/20
P&T Approval: 05/12

BACLOFEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BACLOFEN	OZOBAX, OZOBAX DS, BACLOFEN		64209 54913	GPI-14 (75100010002070, 75100010002075)	
BACLOFEN	FLEQSUVY, BACLOFEN		51885	GPI-14 (75100010001825)	
BACLOFEN	LYVISPAH		51638 51639 51652	GPI-14 (75100010003010, 75100010003020, 75100010003030)	

GUIDELINES FOR USE

1. Is the request for Ozobax (baclofen) or Ozobax DS (baclofen) and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic baclofen tablets
   - The patient is unable to swallow generic baclofen tablets

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **5mg/5mL: #80mL per day.**
   - **10mg/5mL: #40mL per day.**

   If no, continue to #2.

2. Is the request for Fleqsuvy (baclofen) and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic baclofen tablets
   - The patient is unable to swallow generic baclofen tablets

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #3.

3. Is the request for Lyvispah and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic baclofen tablets
   - The patient is unable to swallow generic baclofen tablets

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **5mg: #9 per day.**
   - **10mg: #3 per day.**
   - **20mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BACLOFEN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BACLOFEN (Ozobax, Ozobax DS, Fleqsuvy, Lyvispah)** requires the following rule(s) be met for approval:
A. You have tried or have a contraindication (harmful for you to use) to generic baclofen tablets
B. You are unable to swallow generic baclofen tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozobax, Ozobax DS, Fleqsuvy, and Lyvispah.

REFERENCES

- Ozobax [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
- Ozobax DS [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; October 2023.
- Fleqsuvy [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; February 2023.
- Lyvispah [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23
Created: 11/19
Client Approval: 11/23
P&T Approval: 07/22

BARICITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BARICITINIB	OLUMIANT	44296		GPI-10 (6660301000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, **do not approve**. [**NOTE:** This indication is for hospital use only.]
   DENIAL TEXT: See initial denial text at the end of the guideline.

   If no, continue to #3.

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of severe alopecia areata (ICD-10 L63.9) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has had at least 50 percent scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months
   Olumiant will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Severe alopecia areata (a type of hair loss)
   If you have moderate to severe rheumatoid arthritis, approval also requires:
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
   (Initial denial text continued on next page)

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

If you have severe alopecia areata, approval also requires:

You are 18 years of age or older

Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)

You have had at least 50 percent scalp hair loss as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool) for more than 6 months

You will NOT use Olumiant concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

NOTE: Olumiant will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BARICITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe alopecia areata (ICD-10 L63.9) and meet **ALL** of the following criteria?
   The patient has had improvement while on therapy (e.g., scalp hair coverage)
   Olumiant will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BARICITINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Severe alopecia areata (a type of hair loss)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq [upadacitinib]), PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)

If you have severe alopecia areata, renewal also requires:
- You have experienced improvement while on therapy (such as scalp hair coverage)
- You will NOT use Olumiant concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BARICITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Olumiant.

REFERENCES

Olumiant [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; June 2022.

Created: 06/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

BEDAQUILINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO	39895		GPI-10 (0900001510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) and meet **ALL** of the following criteria?
   - The patient meets ONE of the following:
     - The patient is 5 to less than 18 years of age **AND** weighs at least 15kg
     - The patient is 18 years of age or older
   - Sirturo will be used in combination with at least 3 other antibiotics

   If yes, **approve for a total of 24 weeks by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks for the requested strength as follows:**
     - **Sirturo 20mg: #340 per 28 days.**
     - **Sirturo 100mg: #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 20 weeks (total fill count 5) for the requested strength as follows:**
     - **Sirturo 20mg: #120 per 28 days.**
     - **Sirturo 100mg: #24 per 28 days.**

     Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

   If no, continue to #2.

2. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) **OR** pulmonary extensively drug resistant tuberculosis (XDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sirturo will be used in combination with pretomanid and linezolid

   If yes, **approve for a total of 26 weeks for Sirturo 100mg by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks with a quantity limit of #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. Please enter a start date of 3 WEEKS AFTER the START date of the first approval.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BEDAQUILINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
   2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. **If you have pulmonary multi-drug resistant tuberculosis, approval also requires ONE of the following:**
   1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
   2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
   3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. **If you have pulmonary extensively drug resistant tuberculosis, approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Sirturo in combination with pretomanid and linezolid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo.

REFERENCES

- Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/21
Created: 05/13
Client Approval: 11/21
P&T Approval: 07/20

BELIMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELIMUMAB	BENLYSTA	37462		GPI-10 (9942201500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
   The patient is 5 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives
   Benlysta will NOT be used concurrently with another systemic biologic (e.g., Saphnelo [anifrolumab-fnia]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 as follows:**
   200mg/mL (all formulations): #4mL per 28 days.
   120mg, 400mg: no quantity limit.

   If no, continue to #2.

2. Does the patient have a diagnosis of lupus nephritis (ICD-10 M32.14) and meet **ALL** of the following criteria?
   The patient is 5 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
   The patient is receiving standard therapy (e.g., steroids, antimalarials, NSAIDs, immunosuppressives)
   Benlysta will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of lupus nephritis

   If yes, **approve the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
   120mg, 400mg: Approve for 6 months by GPID or GPI-14 with no quantity limit.
   200mg/mL (all formulations):
   <u>FIRST APPROVAL</u>: Approve for 1 month with a quantity limit of #8mL per 28 days.
   <u>SECOND APPROVAL</u>: Approve for 5 months with a quantity limit of #4mL per 28 days (Please enter a start date 3 weeks after the start date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BELIMUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Systemic lupus erythematosus (SLE: a type of immune condition)
- Lupus nephritis (LN: a type of immune condition that affects the kidneys)

If you have systemic lupus erythematosus, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (standard therapy for the treatment of systemic lupus erythematosus [SLE])
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic (such as Sahnelo [anifrolumab-fnia]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of SLE

If you have lupus nephritis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
- You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs [NSAIDs], or immunosuppressives
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of lupus nephritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BELIMUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
   The patient has shown clinical improvement while on Benlysta
   Benlysta will NOT be used concurrently with another systemic biologic (e.g., Saphnelo [anifrolumab-fnia]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   200mg/mL (all formulations): #4mL per 28 days.
   120mg, 400mg: no quantity limit.

   If no, continue to #2.

2. Does the patient have a diagnosis of lupus nephritis (ICD-10 M32.14) and meet **ALL** of the following criteria?
   The patient has shown clinical improvement in renal response as compared to baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)
   Benlysta will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of lupus nephritis

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   200mg/mL (all formulations): #4mL per 28 days.
   120mg, 400mg: no quantity limit.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BELIMUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Systemic lupus erythematosus (SLE: a type of immune condition)
- Lupus nephritis (LN: a type of immune condition that affects the kidneys)

If you have systemic lupus erythematosus, renewal also requires:
- You have shown clinical improvement while on Benlysta
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic (such as Sahnelo [anifrolumab-fnia]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

If you have lupus nephritis, renewal also requires:
- You have shown clinical improvement in renal (kidney) response as compared to baseline (before starting Benlysta) laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in the urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of lupus nephritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Benlysta.

REFERENCES

Benlysta [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; May 2024.

Created: 08/17
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/24

BELUMOSUDIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELUMOSUDIL MESYLATE	REZUROCK	47503		GPI-10 (9939851050)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic graft-versus-host-disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has failed at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to Jakafi (ruxolitinib)
   - Rezurock will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELUMOSUDIL (Rezurock)** requires the following rule(s) be met for approval:
   A. You have chronic graft-versus-host-disease (cGVHD: a type of long-term immune disorder)
   B. You are 12 years of age or older
   C. You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
   D. You will NOT use Rezurock concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezurock.

REFERENCES
- Rezurock [Prescribing Information]. Bridgewater, NJ: Kadmon Pharmaceuticals, LLC; December 2024.

Created: 08/21
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

BELZUTIFAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELZUTIFAN	WELIREG	47546		GPI-10 (2142102000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of von Hippel-Lindau (VHL) disease and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient requires therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
   The patient does NOT require immediate surgery

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

2. Does the patient have advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient was previously treated with a programmed death receptor-1 (PD-1) inhibitor (e.g., Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (e.g., Bavencio [avelumab])
   The patient was previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI; e.g., Nexavar [sorafenib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Von Hippel-Lindau (VHL) disease (genetic disorder that causes tumors to grow in the body)
   Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   If you have von Hippel-Lindau disease, approval also requires:
   You are 18 years of age or older
   You require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
   You do NOT require immediate surgery
   (Denial text continued on next page)

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BELZUTIFAN

GUIDELINES FOR USE (CONTINUED)

If you have advanced renal cell carcinoma, approval also requires:

- You are 18 years of age or older
- You were previously treated with a programmed death receptor-1 (PD-1) inhibitor (such as Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (such as Bavencio [avelumab])
- You were previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI: a type of treatment such as Nexavar [sorafenib])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Welireg.

REFERENCES

Welireg [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 10/21
Client Approval: 12/23
P&T Approval: 01/24

BENRALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BENRALIZUMAB	FASENRA	44635		GPI-10 (4460402000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   Fasenra will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve all strengths and formulations for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 2 months with the following quantity limits:
   10mg/0.5mL: #0.5mL per 28 days.
   30mg/mL: #1mL per 28 days.
   SECOND APPROVAL: Approve for 2 months with the following quantity limits (please enter a start date of 1 week before the end date of the first approval):
   10mg/0.5mL: #0.5mL per 56 days.
   30mg/mL: #1mL per 56 days.

   If no, continue to #3.

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   Daytime asthma symptoms more than twice per week
   Any night waking due to asthma
   Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   Any activity limitation due to asthma

   If yes, **approve all strengths and formulations for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 2 months with the following quantity limits:
   10mg/0.5mL: #0.5mL per 28 days.
   30mg/mL: #1mL per 28 days.
   SECOND APPROVAL: Approve for 2 months with the following quantity limits (please enter a start date of 1 week before the end date of the first approval):
   10mg/0.5mL: #0.5mL per 56 days.
   30mg/mL: #1mL per 56 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve all formulations of the 30mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
- Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

If you have severe asthma with an eosinophilic phenotype, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
- You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
- Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as formoterol, salmeterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline, or an oral corticosteroid [such as prednisone])
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
- You meet ONE of the following:
  - You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
  - You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
  - You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
    - Daytime asthma symptoms more than twice per week
    - Any night waking due to asthma
    - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
    - Any activity limitation due to asthma

(Initial denial text continued on next page)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have eosinophilic granulomatosis with polyangiitis, approval also requires:
You are 18 years of age or older
You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BENRALIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   Fasenra will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   Reduction in asthma exacerbations from baseline
   Decreased utilization of rescue medications (e.g., albuterol)
   Increase in percent predicted FEV1 from pre-treatment baseline
   Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
   10mg/0.5mL: #0.5mL per 56 days.
   30mg/mL: #1mL per 56 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   The patient has a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid (e.g., prednisone) use
   Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve all formulations of the 30mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   - Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

   If you have severe asthma with an eosinophilic phenotype, renewal also requires:
   - You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   - You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   (Renewal denial text continued on next page)

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

You have shown a clinical response as evidenced by ONE of the following:
- You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Fasenra)
- You have decreased your use of rescue medications (such as albuterol)
- Your percent predicted FEV1 (a type of lung test) has increased from pre-treatment baseline (before starting Fasenra)
- You have experienced a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:
- You have a reduction in eosinophilic granulomatosis with polyangiitis (EGPA) symptoms compared to baseline (before starting Fasenra), OR you have been able to decrease or eliminate (stop) corticosteroid (such as prednisone) use
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of EGPA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fasenra.

REFERENCES

Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 11/04/24
Created: 02/18
Client Approval: 10/24
P&T Approval: 10/24

BEROTRALSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO	47016		GPI-10 (8584001020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Orladeyo will be used for prophylaxis against HAE attacks
   - The patient's diagnosis of HAE is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
   - Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 12 years of age or older
   C. Orladeyo will be used for the prevention of hereditary angioedema attacks
   D. Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of lab test)
   E. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   F. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEROTRALSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline
   - Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
   C. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orladeyo.

REFERENCES

- Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; October 2024.

Created: 12/20
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 07/24

BETAINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BETAINE	CYSTADANE, BETAINE ANHYDROUS	12233		GPI-10 (3090452000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homocystinuria (including cystathionine beta-synthase (CBS) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency, and cobalamin cofactor metabolism (cbl) defect)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #20 grams per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BETAINE (Cystadane)** requires the following rule(s) be met for approval:
   A. You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, and cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystadane.

REFERENCES

- Cystadane [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 05/22
Client Approval: 02/23
P&T Approval: 04/22

BEXAROTENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEXAROTENE SOFTGEL	TARGRETIN, BEXAROTENE	20832		GPI-10 (2170822000)	
BEXAROTENE 1% TOPICAL GEL	TARGRETIN, BEXAROTENE			GPI-10 (9037622000)	

GUIDELINES FOR USE

TARGRETIN (BEXAROTENE) CAPSULE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) **AND** meet the following criterion?
   The patient is refractory to at least one prior systemic therapy (e.g., gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEXAROTENE (Targretin capsule)** requires the following rule(s) be met for approval:
   A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer)
   B. You are refractory (resistant) to at least one prior systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or bortezomib

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

TARGRETIN (BEXAROTENE) GEL

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (stage IA or IB) and meet **ONE** of the following criteria?
   - The patient has refractory or persistent disease after other therapies
   - The patient has not tolerated other therapies

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BEXAROTENE

GUIDELINES FOR USE - TARGRETIN (BEXAROTENE) GEL (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEXAROTENE (Targretin gel)** requires the following rule(s) to be met for approval:

A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer) (stage IA or IB)
B. You meet ONE of the following:
   1. You have refractory (resistant) or persistent disease after other therapies
   2. You have not tolerated other therapies

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Targretin.

REFERENCES

- Targretin Capsule [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
- Targretin Gel [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 05/12
Client Approval: 05/22
P&T Approval: 04/20

BIMEKIZUMAB-BKZX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BIMEKIZUMAB-BKZX	BIMZELX	47629		GPI-10 (9025051800)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient is a candidate for systemic therapy or phototherapy
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to ONE of the following preferred agents: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient have **ONE** of the following objective signs of inflammation?
   C-reactive protein (CRP) levels above the upper limit of normal
   Sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**
   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
   The patient had a trial of or contraindication to ONE topical therapy (e.g., clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (e.g., tetracycline, dapsone)
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), adalimumab-adaz, Simlandi
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You are a candidate for systemic therapy (treatment that targets the entire body) or phototherapy (light therapy)
- You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You have tried or have a contraindication to ONE of the following preferred medications: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
- You have ONE of the following signs of inflammation:
  - C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - Sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You have tried or have a contraindication to ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa
- You have tried or have a contraindication to (harmful for you to use) ONE topical therapy (such as clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (such as tetracycline, dapsone)
- You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), adalimumab-adaz, Simlandi

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**
   If no, continue to #6.

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
   The patient has shown improvement in HS symptoms
   Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), adalimumab-adaz, Simlandi
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   - Ankylosing spondylitis (AS: a type of joint condition)
   - Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

   If you have moderate to severe plaque psoriasis, renewal also requires:
   - You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
   - You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   - You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

   (Renewal denial text continued on next page)

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), adalimumab-adaz, Simlandi

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Bimzelx.

REFERENCES
Bimzelx [Prescribing Information]. Smyrna, GA: UCB, Inc.; November 2024.

Created: 10/23
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

BINIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BINIMETINIB	MEKTOVI	45040		GPI-10 (2153352000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
   - Mektovi will be used in combination with Braftovi (encorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Mektovi will be used in combination with Braftovi (encorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have a BRAF V600E or V600K mutation (types of gene mutations), as detected by a Food and Drug Administration (FDA)-approved test
      2. Mektovi will be used in combination with Braftovi (encorafenib)

   C. **If you have metastatic non-small cell lung cancer, approval also requires**:
      1. You are 18 years of age or older
      2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
      3. Mektovi will be used in combination with Braftovi (encorafenib)

   (Denial text continued on next page)

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BINIMETINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mektovi.

REFERENCES

- Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23
Created: 08/18
Client Approval: 10/23
P&T Approval: 01/24

BIRCH BARK EXTRACT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BIRCH BARK EXTRACT	FILSUVEZ	48746		GPI-10 (9094402000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epidermolysis bullosa (EB) (ICD-10 Q81.9) and meet **ALL** of the following criteria?
   The patient is 6 months of age or older
   Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BIRCH BARK EXTRACT (Filsuvez)** requires the following rule(s) be met for approval:
   You have epidermolysis bullosa (EB: a type of genetic skin disorder)
   You are 6 months of age or older
   Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa (types of genetic skin disorders)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Filsuvez.

REFERENCES
Filsuvez [Prescribing Information]. Wahlstedt, Germany: Lichtenheldt GmbH Pharmazeutische Fabrik; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

BOSENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSENTAN	TRACLEER, BOSENTAN	22990		GPI-10 (4016001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 3 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The patient does NOT have idiopathic pulmonary fibrosis (IPF)
   Tracleer will NOT be used concurrently with cyclosporine A or glyburide

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   62.5mg tablet: #2 per day.
   125mg tablet: #2 per day.
   32mg tablet for suspension: #4 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BOSENTAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for approval:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
You are 3 years of age and older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide
Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Tracleer will NOT be used concurrently with cyclosporine A or glyburide

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   62.5mg tablet: #2 per day.
   125mg tablet: #2 per day.
   32mg tablet for suspension: #4 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tracleer.

REFERENCES

Tracleer [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/22
Client Approval: 06/24
P&T Approval: 01/24

BOSUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSUTINIB	BOSULIF	39590		GPI-10 (2153181200)	

GUIDELINES FOR USE

1. Does the patient have chronic phase (CP) Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND** meet the following criterion?
   The patient is 1 year of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient newly diagnosed?

   If yes, **approve for 12 months by GPID or GPI-14, for the requested strength, with the following quantity limits:**
   500mg: #1 per day.
   400mg: #1 per day.
   100mg: #6 per day.
   50mg: #1 per day.

   If no, continue to #3.

3. Does the patient have resistance or intolerance to prior therapy [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)] and meet **ALL** of the following criteria?
   The patient had a mutational analysis prior to initiation
   Bosulif is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile
   (Please see header CML-5 of the current NCCN guidelines)

   If yes, **approve for 12 months by GPID or GPI-14, for the requested strength, with the following quantity limits:**
   500mg: #1 per day.
   400mg: #1 per day.
   100mg: #6 per day.
   50mg: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of accelerated phase (AP) or blast phase (BP) Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had resistance or intolerance to prior therapy [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   The patient had a mutational analysis prior to initiation
   Bosulif is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile
   (Please see header CML-5 of the current NCCN guidelines)

   If yes, **approve for 12 months by GPID or GPI-14, for the requested strength, with the following quantity limits:**
   500mg: #1 per day.
   400mg: #1 per day.
   100mg: #6 per day.
   50mg: #1 per day.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML; a type of blood cancer)
      Accelerated phase (AP) or blast phase (BP) Philadelphia chromosome-positive chronic myelogenous leukemia
   If you have chronic phase Philadelphia chromosome-positive chronic myeloid leukemia, approval also requires:
      You are 1 year of age or older
      You meet ONE of the following:
         You are newly diagnosed
         You had resistance or intolerance to prior therapy [such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)] AND you had a mutational analysis prior to initiation of therapy AND Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile
   (Denial text continued on next page)

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

If you have accelerated or blast phase Philadelphia chromosome-positive chronic myeloid leukemia, approval also requires:
You are 18 years of age or older
You had resistance or intolerance to prior therapy [such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
You had a mutational analysis prior to initiation of therapy
Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bosulif.

REFERENCES

Bosulif [Prescribing Information]. New York, NY: Pfizer Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/22/24
Created: 09/12
Client Approval: 01/24
P&T Approval: 04/24

BREMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BREMELANOTIDE	VYLEESI	45878		GPI-10 (6217351510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is Vyleesi (bremelanotide) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom causes marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is **NOT** currently using Addyi (flibanserin)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #2.4mL per month.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BREMELANOTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty

B. You are a premenopausal female

C. You are 18 years of age or older

D. You had a previous trial of bupropion, unless there is a medical reason why you cannot (contraindication)

E. You are **NOT** currently using Addyi (flibanserin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom causes marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BREMELANOTIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is **NOT** currently using Addyi (flibanserin)
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.4mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder [FSIAD] where you do not desire sexual activity), as defined by **ALL** of the following:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
      3. HSDD symptom causes marked distress or interpersonal difficulty
   B. You are a premenopausal female
   C. You are **NOT** currently using Addyi (flibanserin)
   D. You have experienced continued improvement in symptoms of HSDD/FSIAD such as increased sexual desire, lessened distress)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BREMELANOTIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyleesi.

REFERENCES

- Vyleesi [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

BRENTUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRENTUXIMAB VEDOTIN	ADCETRIS	37879		GPI-10 (2135322020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81)?

   If yes, continue #2.
   If no, continue to #7.

2. Is the patient's cancer at stage III or IV and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has not been previously treated
   Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer considered high-risk and the patient meets **ALL** of the following criteria?
   The patient is 2 years of age or older
   The patient has not been previously treated
   Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient at high risk for relapse or disease progression post-autologous hematopoietic stem cell transplant (auto-HSCT) (defined as refractory, relapse within 12 months, or relapse at least 12 months with extranodal disease) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has obtained complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy

   If yes, **approve for 12 months by HICL or GPI-10**.
   If no, continue to #5.

5. Has the patient's cancer relapsed **AND** the patient meets the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   The patient has failed an autologous hematopoietic stem cell transplant (auto-HSCT)
   The patient is not an auto-HSCT candidate AND has failed at least two multi-agent chemotherapy regimens (e.g., ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of systemic anaplastic large cell lymphoma (sALCL) (ICD-10 Groups C84.6, C84.7) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #8.
   If no, continue to #10.

8. Is the patient previously untreated **AND** Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Has the patient relapsed **AND** failed at least one multi-agent chemotherapy regimen (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma (ICD-10 C86.5) or PTCL not otherwise specified (ICD-10 Group C84.4), and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient has not been previously treated
    Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) (ICD-10 C86.6) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient has received prior systemic therapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of mycosis fungoides (MF) (Group C84.0) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient's cancer is CD30-positive
    The patient has received prior systemic therapy (e.g., Istodax [romidepsin], methotrexate)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #13.

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

13. Does the patient have a diagnosis of large B-cell lymphoma (LBCL) (ICD-10 Groups C83.3, C85.2), including diffuse large B-cell lymphoma (DLBCL) not other specified (ICD-10 Group C83.3), DLBCL arising from indolent lymphoma (ICD-10 Group C83.3), or high-grade B-cell lymphoma (HGBL), and meet **ALL** of the following criteria?
    The patent is 18 years of age or older
    The patient's cancer is relapsed or refractory
    Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (e.g., Rituxan [rituximab], Truxima [rituximab-abbs])
    The patient has tried at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
    The patient is not eligible for auto-HSCT or chimeric antigen receptor (CAR) T-cell therapy (e.g., Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

    Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:
    You have ONE of the following:
        Classical Hodgkin lymphoma (a type of blood cancer)
        Systemic anaplastic large cell lymphoma (a type of blood cancer)
        CD30-expressing peripheral T-cell lymphomas (a type of blood cancer)
        Primary cutaneous anaplastic large cell lymphoma (a type of blood cancer)
        Mycosis fungoides (a type of blood cancer affecting the skin)
        Large B-cell lymphoma (LBCL), which includes diffuse large B-cell lymphoma (DLBCL) not other specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) (types of blood cancer)
    (Denial text continued on next page)

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
- Your cancer is stage III or IV; you are 18 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine
- Your cancer is considered high-risk; you are 2 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
- You are at high risk for relapse (disease comes back) or disease progression (disease gets worse) after having autologous hematopoietic stem cell transplant (auto-HSCT) (defined as refractory [disease does not respond to treatment], relapse within 12 months, or relapse at least 12 months with extranodal [area outside of the lymph node] disease); you are 18 years of age or older; AND you have obtained complete/partial remission (little or no sign of cancer in your body), or stable disease to most recent pre-auto-HSCT salvage therapy
- Your cancer has relapsed; you are 18 years of age or older; AND you have failed autologous hematopoietic stem cell transplant (auto-HSCT: transplant cells are from your own body)
- Your cancer has relapsed; you are 18 years of age or older; you are not a candidate for auto-HSCT; AND you have failed at least two multi-agent chemotherapy regimens (such as ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If you have systemic anaplastic large cell lymphoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have not been previously treated AND Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone
  - Your cancer has relapsed (disease that has returned) AND you have failed at least one multi-agent chemotherapy regimen (such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

If you have CD30-expressing peripheral T-cell lymphomas, including angioimmunoblastic T-cell lymphoma or peripheral T-cell lymphoma not otherwise specified, approval also requires:
- You are 18 years of age or older
- You have not been previously treated
- Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

(Denial text continued on next page)

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

If you have primary cutaneous anaplastic large cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received prior systemic therapy (treatment that targets the entire body such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

If you have mycosis fungoides, approval also requires:
- You are 18 years of age or older
- Your cancer is CD30 (a type of protein)-positive
- You have received prior systemic therapy (treatment that targets the entire body such as Istodax [romidepsin], methotrexate)

If you have large B-cell lymphoma, which includes diffuse large B-cell lymphoma not other specified, diffuse large B-cell lymphoma arising from indolent lymphoma, or high-grade B-cell lymphoma, approval also requires:
- You are 18 years of age or older
- Your cancer is relapsed (disease that has returned) or refractory (did not respond to treatment)
- Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (such as Rituxan [rituximab], Truxima [rituximab-abbs])
- You have has tried at least two lines of systemic therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
- You are not eligible for autologous hematopoietic stem cell transplantation (auto-HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) or chimeric antigen receptor (CAR) T-cell therapy (such as Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcetris.

REFERENCES

Adcetris [Prescribing Information]. Bothell, WA: Seagen Inc.; February 2025.

Created: 09/11
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

BRIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRIGATINIB	ALUNBRIG	44226		GPI-10 (2153051000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Alunbrig 30mg: #120 per 30 days.**
   - **Alunbrig 90mg: #30 per 30 days.**
   - **Alunbrig 180mg: #30 per 30 days.**
   - **Alunbrig 90mg-180mg initiation pack: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA) as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alunbrig.

REFERENCES

- Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/17
Client Approval: 03/21
P&T Approval: 07/20

BRODALUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRODALUMAB	SILIQ	44102		GPI-10 (9025052000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
   The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
   Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for a total of 6 months by HICL or GPI-10. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #6mL.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #3mL per 28 days (Enter a start date that is 5 weeks AFTER the START date of the first approval).

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:
   You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
   You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
   You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   (Initial denial text continued on next page)

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:

- You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
- You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BRODALUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors
   Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:
   You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more
   You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq
   You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   (Renewal denial text continued on next page)

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BRODALUMAB

RENEWAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Siliq.

REFERENCES
Siliq [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; August 2024.

Created: 01/17
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

BUDESONIDE-EOHILIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	EOHILIA		55273	GPI-14 (22100012001820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
   The patient is 11 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist or allergist
   The patient has at least 15 eosinophils/hpf in the esophagus as confirmed by a biopsy
   The patient had a trial of or contraindication to one inhaled corticosteroid (e.g., Flovent [fluticasone], Pulmicort [budesonide]) OR one generic proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for approval:
   You have eosinophilic esophagitis (a type of immune system disorder)
   You are 11 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or allergist (a type of allergy doctor)
   You have at least 15 eosinophils/high powered field (a type of lab test) in the esophagus as confirmed by a biopsy (removal of cells or tissue from the body for examination)
   You have tried or have a contraindication to (harmful for you to use) one inhaled corticosteroid (such as Flovent [fluticasone], Pulmicort [budesonide]) OR one proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUDESONIDE-EOHILIA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ONE** of the following criteria?
   There is less than 15 eosinophils/hpf in the esophagus after treatment with Eohilia
   The patient has experienced an improvement in dysphagia compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for renewal:
   You have eosinophilic esophagitis (EoE: a type of immune system disorder)
   You meet ONE of the following:
   - You have less than 15 eosinophils/high powered field (eos/hpf: a type of lab test) in the esophagus after treatment with Eohilia
   - You have experienced an improvement in dysphagia (difficulty swallowing) compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eohilia.

REFERENCES

Eohilia [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/24
Client Approval: 06/24
P&T Approval: 07/21

BUDESONIDE - ORTIKOS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	ORTIKOS		46496 46497	GPI-14 (22100012007025) (22100012007030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate active Crohn's Disease and meet **ALL** of the following criteria?
   - The patient is 8 years of age or older
   - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mild to moderate Crohn's Disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used for the maintenance of clinical remission
   - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - ORTIKOS** requires the following rule(s) be met for approval:
   A. You have mild to moderate Crohn's Disease (a type of bowel disorder)
   B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
      1. You are 8 years of age or older
      2. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

   (Denial text continued on the next page)

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BUDESONIDE - ORTIKOS

GUIDELINES FOR USE (CONTINUED)

C. **If you have mild to moderate Crohn's Disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
   3. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ortikos.

REFERENCES

- Ortikos [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/17/22
Created: 11/20
Client Approval: 01/22
P&T Approval: 10/20

BUDESONIDE - TARPEYO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	TARPEYO		51745	GPI-14 (22100012006520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has a progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g., greater than 1 gram protein/24-hour urine collection or UPCR [urine protein to creatinine ratio] of at least 1 g/g)
   - The patient has an eGFR of at least 35 mL/min/1.73m^2
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   - The patient has tried an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR has a contraindication to an SGLT2 inhibitor

   If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   D. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
   E. You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (increased levels of protein in the urine, such as greater than 1 gram protein in a 24-hour urine collection or at least 1 g/g urine protein to creatinine ratio [UPCR: a test that measures the amount of protein in urine])

   (Initial denial text continued on the next page)

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BUDESONIDE - TARPEYO

INITIAL CRITERIA (CONTINUED)

F. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 35 mL/min/1.73m^2
G. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
H. You have tried a sodium-glucose cotransporter-2 inhibitor (SGLT2 inhibitor: a type of medication used to protect kidneys, such as Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR you have a contraindication to an SGLT2 inhibitor

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUDESONIDE - TARPEYO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
   - The patient has improved or stable kidney function compared to baseline
   - The patient has a reduction in proteinuria

   If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You have improved or stable kidney function compared to baseline (before starting Tarpeyo) OR you have a reduction in proteinuria (lowered levels of protein in the urine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarpeyo.

REFERENCES

- Tarpeyo [Prescribing Information]. Stockholm, Sweden: Calliditas Therapeutics AB; June 2024.

Created: 01/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

BUPRENORPHINE EXTENDED-RELEASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUPRENORPHINE	SUBLOCADE		44186 44187	GPI-14 (6520001000E530, 6520001000E520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe opioid use disorder (ICD-10 Group F11) **AND** meet the following criterion?
   The patient initiated treatment with a single dose of a transmucosal buprenorphine product (e.g., Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]) OR is already being treated with buprenorphine

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: Approve all strengths for 1 month by GPID or GPI-14 as follows:
   100 mg/0.5 mL syringe: #0.5 mL per 30 days.
   300 mg/1.5 mL syringe: #3 mL per 30 days.
   SECOND APPROVAL: Approve the requested strength for 11 months by GPID or GPI-14 as follows (please enter a start date of 1 MONTH AFTER the START date of the first approval):
   100 mg/0.5 mL syringe: #0.5 mL per 30 days.
   300 mg/1.5 mL syringe: #1.5 mL per 30 days.
   SUBSEQUENT REQUESTS:
   Approve the requested strength for 12 months by GPID or GPI-14 as follows:
   100 mg/0.5 mL syringe: #0.5 mL per 30 days.
   300 mg/1.5 mL syringe: #1.5 mL per 30 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires the following rule(s) be met for approval:
   You have moderate to severe opioid use disorder (misuse of a type of pain medication)
   You started treatment with a single dose of a transmucosal (medication that enters the body through a mucous layer like those in the mouth) buprenorphine product (such as Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]), OR you are already being treated with buprenorphine

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUPRENORPHINE EXTENDED-RELEASE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sublocade.

REFERENCES

Sublocade [Prescribing Information]. North Chesterfield, VA: Indivior, Inc.; February 2025.

Created: 05/18
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 04/25

C1 ESTERASE INHIBITOR - BERINERT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	BERINERT	18568		GPI-10 (8580202200)	FDB & MEDI-SPAN: BRAND = BERINERT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - Berinert is being used for acute attacks of hereditary angioedema
   - Berinert will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   If yes, **approve for 12 months by NDC.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   C. Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of lab test)
   D. Berinert is being used for acute (short term) attacks of hereditary angioedema
   E. You will NOT be using Berinert concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - BERINERT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - Berinert will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   If yes, **approve for 12 months by NDC.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT be using Berinert concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Berinert.

REFERENCES

- Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC. May 2019.

Created: 04/09
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 04/22

C1 ESTERASE INHIBITOR - CINRYZE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	CINRYZE	18568		GPI-10 (8580202200)	BRAND = CINRYZE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Cinryze will be used for prophylaxis against HAE attacks
   The patient's diagnosis of HAE is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
   Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   If yes, **approve for 12 months for all NDCs with a quantity limit of #40 vials per 28 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for approval:
   You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   You are 6 years of age or older
   Cinryze will be used for the prevention of hereditary angioedema attacks
   Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of blood test)
   Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - CINRYZE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   The patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline
   Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   If yes, **approve for 12 months for all NDCs with a quantity limit of #40 vials per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for renewal:
   You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
   You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cinryze.

REFERENCES

Cinryze [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals, Inc.; February 2023.

Created: 10/22
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 07/24

C1 ESTERASE INHIBITOR - HAEGARDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	HAEGARDA	18568		GPI-10 (8580202200)	BRAND = HAEGARDA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Haegarda will be used for prophylaxis against HAE attacks
   - The patient's diagnosis of HAE is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
   - Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 6 years of age or older
   C. Haegarda will be used for the prevention of hereditary angioedema attacks
   D. Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of blood test)
   E. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   F. You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - HAEGARDA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline
   - Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
   C. You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Haegarda.

REFERENCES

- Haegarda [Prescribing Information]. Marburg, German: CSL Behring LLC; January 2022.

Created: 10/22
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 07/24

C1 ESTERASE INHIBITOR - RUCONEST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST	37766		GPI-10 (8580202210)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - Ruconest is being used for acute attacks of hereditary angioedema
   - Ruconest will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials per fill.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   C. Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of lab test)
   D. Ruconest is being used for acute (short term) attacks of hereditary angioedema
   E. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - RUCONEST

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - Ruconest will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8 vials per fill.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruconest.

REFERENCES

- Ruconest [Prescribing Information]. Raleigh, NC: Salix Pharmaceuticals; December 2019.

Created: 10/22
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 04/22

CABOZANTINIB S-MALATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ, CABOMETYX	39815		GPI-10 (2153301010)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

COMETRIQ

1. Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #112 per 28 days for the requested daily dose pack. (NOTE: Cometriq is available in three dosage packs each containing 7 days supply)**
   - **Cometriq 140mg daily dose pack.**
   - **Cometriq 100mg daily dose pack.**
   - **Cometriq 60mg daily dose pack.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:
   A. You have progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

GUIDELINES FOR USE (CONTINUED)

CABOMETYX

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - Cabometyx will be used as a single agent
   - Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (no prior treatment for advanced RCC)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has previously been treated with Nexavar (sorafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #3.

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CABOZANTINIB S-MALATE

GUIDELINES FOR USE - CABOMETYX (CONTINUED)

3. Does the patient have a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy
   - The patient is radioactive iodine-refractory or ineligible

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Hepatocellular carcinoma (HCC: type of liver cancer)
      3. Locally advanced or metastatic differentiated thyroid cancer (DTC: type of thyroid cancer)
   B. **If you have advanced renal cell carcinoma, approval also requires ONE of the following:**
      1. Cabometyx will be used as a single agent (used alone)
      2. Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (You have not received prior treatment for advanced renal cell carcinoma)
   C. **If you have hepatocellular carcinoma, approval also requires:**
      1. You have previously been treated with Nexavar (sorafenib)
   D. **If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:**
      1. You are 12 years of age or older
      2. You have disease progression (disease has gotten worse) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (a type of cancer therapy)
      3. You are radioactive iodine-refractory (resistant to) or ineligible

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq or Cabometyx.

REFERENCES

- Cometriq [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; February 2020.
- Cabometyx [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/04/21
Created: 01/13
Client Approval: 09/21
P&T Approval: 10/21

CALASPARGASE PEGOL-MKNL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CALASPARGASE PEGOL-MKNL	ASPARLAS	45566		GPI-10 (2125003050)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   The patient is 1 month to 21 years of age
   Asparlas will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CALASPARGASE PEGOL-MKNL (Asparlas)** requires the following rule(s) be met for approval:
   You have acute lymphoblastic leukemia (ALL: a type of blood cancer)
   You are 1 month to 21 years of age
   Asparlas will be used as a part of a chemotherapeutic (medications used to treat cancer) plan that contains multiple medications

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Asparlas.

REFERENCES

Asparlas [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; November 2023.

Created: 10/19
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/19

CANAKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANAKINUMAB/PF	ILARIS	36497		GPI-10 (6646002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) (ICD-10 M04.2), including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), and meet **ALL** of the following criteria?
   The patient is 4 years of age or older
   The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
   The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   Ilaris will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS, including FCAS or MWS

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) (ICD-10 M04.1) **AND** meet the following criterion?
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of TRAPS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (ICD-10 M04.1) **AND** meet the following criterion?
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HIDS/MKD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, continue to #4.

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of Familial Mediterranean Fever (FMF) (ICD-10 M04.1) **AND** meet the following criterion?
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of FMF

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Adult-Onset Still's Disease (AOSD) (ICD-10 M06.1) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of AOSD
   The patient had a trial of or contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, continue to #6.

6. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   Ilaris will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   The patient had a trial of or contraindication to the following preferred agent: Tyenne (tocilizumab-aazg)
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, continue to #7.

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of gout flares (ICD-10 Group M10) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of gout flares

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Has the patient had a trial of or contraindication to **ALL** of the following?
   Colchicine
   An NSAID (non-steroidal anti-inflammatory drug) (e.g., ibuprofen, naproxen, indomethacin)
   A corticosteroid (e.g., triamcinolone, methylprednisolone, prednisone, prednisolone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Cryopyrin-Associated Periodic Syndromes (CAPS: a type of immune disorder), including Familial Cold Auto-inflammatory Syndrome (FCAS: a type of immune disorder) or Muckle-Wells Syndrome (MWS: a type of immune disorder)
   - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: a type of genetic disease)
   - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (types of genetic disorders)
   - Familial Mediterranean Fever (FMF: a type of genetic disorder)
   - Adult-Onset Still's Disease (AOSD: an autoinflammatory disease)
   - Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   - Gout flares (episodes of pain or swelling associated with a type of joint condition)

   (Initial denial text continued on next page)

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:
- You are 4 years of age or older
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome or Muckle-Wells Syndrome

If you have Tumor Necrosis Factor Receptor Associated Periodic Syndrome, approval also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Tumor Necrosis Factor Receptor Associated Periodic Syndrome

If you have Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency, approval also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency

If you have Familial Mediterranean Fever, approval also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Familial Mediterranean Fever

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have Adult-Onset Still's Disease, approval also requires:
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Adult-Onset Still's Disease
- You have tried or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

If you have systemic juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)

If you have gout flares, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of gout flares
- You have tried or have a contraindication to (harmful for you to use) **ALL** of the following:
  - Colchicine
  - An NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, indomethacin)
  - A corticosteroid (such as triamcinolone, methylprednisolone, prednisone, prednisolone)

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CANAKINUMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of Adult-Onset Still's Disease (AOSD) (ICD-10 M06.1) **AND** meet the following criterion?
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of AOSD

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   Ilaris will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   The patient had a trial of or contraindication to the following preferred agent: Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

   If yes, continue to #4.
   If no, continue to #5.

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CANAKINUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of gout flares (ICD-10 Group M10) and meet **ALL** of the following criteria?
   The patient has shown improvement of gout flares while on Ilaris
   Therapy is prescribed by or in consultation with a rheumatologist
   Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of gout flares

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Adult-Onset Still's Disease (AOSD: an autoinflammatory disease)
   - Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   - Gout flares (episodes of pain or swelling associated with a type of joint condition)

   If you have Adult-Onset Still's Disease, renewal also requires:
   - You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Adult-Onset Still's Disease
   - You meet ONE of the following:
     - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
     - You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

   (Renewal denial text continued on next page)

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CANAKINUMAB

RENEWAL CRITERIA (CONTINUED)

If you have systemic juvenile idiopathic arthritis, renewal also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)
- You meet ONE of the following:
  - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
  - You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

If you have gout flares, renewal also requires:
- You have shown improvement of gout flares while on Ilaris
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of gout flares

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilaris.

REFERENCES
Ilaris [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; November 2024.

Created: 08/13
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANTHARIDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANTHARIDIN	YCANTH	02578		GPI-10 9075001000	BRAND = YCANTH

GUIDELINES FOR USE

1. Does the plan benefit include non-self-administered (NSA) medications?

   If yes, continue to #2.
   If no, guideline does not apply.

2 . Does the patient have a diagnosis of molluscum contagiosum **AND** meet the following criterion?
- The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL with a quantity limit of #2 per 21 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANTHARIDIN (Ycanth)** requires the following rule(s) be met for approval:
   A. You have molluscum contagiosum (a viral skin infection)
   B. You are 2 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ycanth.

REFERENCES

- Ycanth [Prescribing Information]. West Chester, PA: Verrica Pharmaceuticals Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval:10/23

CAPECITABINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPECITABINE	XELODA, CAPECITABINE	18385		GPI-10 (2130000500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Stage III colon cancer **AND** meet the following criterion?
   - The requested medication will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10 for 8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced rectal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as perioperative treatment
   - The requested medication will be used as part of chemoradiotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ONE** of the following criteria?
   - The requested medication will be used as a single agent, if an anthracycline- or taxane-containing chemotherapy is not indicated
   - The requested medication will be used in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as part of a combination chemotherapy regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has not received prior treatment for metastatic disease
   - The requested medication will be used as part of a combination regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as adjuvant treatment
   - The requested medication will be used as part of a combination chemotherapy regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:
   A. You have ONE of the following diagnoses:
      1. Stage III colon cancer (colon cancer that has spread to lymph nodes)
      2. Locally advanced rectal cancer (cancer that has spread from where it started to nearby tissue or lymph nodes)
      3. Unresectable (unable to remove by surgery) or metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
      4. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
      5. Unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (a type of digestive system cancer that has spread to other parts of the body)
      6. HER2 (a type of protein)-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
      7. Pancreatic adenocarcinoma (a type of cancer of the pancreas)
   B. **If you have Stage III colon cancer, approval also requires:**
      1. The requested medication will be used as adjuvant (add-on) treatment

   (Denial text continued on next page)

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have locally advanced rectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as perioperative (the time period before and after surgery) treatment
   3. The requested medication will be used as part of chemoradiotherapy (a type of cancer treatment)

D. **If you have advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used as a single agent (used alone), if an anthracycline (such as doxorubicin, daunorubicin)- or taxane (such as paclitaxel, docetaxel)-containing chemotherapy is not indicated
   2. The requested medication will be used in combination with docetaxel after disease progression (worsens) on prior anthracycline (such as doxorubicin, daunorubicin)-containing chemotherapy

E. **If you have unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as part of a combination chemotherapy (drugs used to treat cancer) regimen

F. **If you have HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received prior treatment for metastatic disease
   3. The requested medication will be used as part of a combination regimen (such as with cisplatin, trastuzumab)

G. **If you have pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as adjuvant (add-on) treatment
   3. The requested medication will be used as part of a combination chemotherapy regimen (such as with gemcitabine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPECITABINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeloda.

REFERENCES

- Xeloda [Prescribing Information]. South San Francisco, CA: Genentech Inc., December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 02/13
Client Approval: 01/23
P&T Approval: 01/23

CAPIVASERTIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPIVASERTIB	TRUQAP	49313		GPI-10 (2153032000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   Truqap will be used in combination with Faslodex (fulvestrant)
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test
   The patient has disease progression on an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #64 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPIVASERTIB (Truqap)** requires the following rule(s) be met for approval:
   You have locally advanced or metastatic breast cancer (breast cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   Truqap will be used together with Faslodex (fulvestrant)
   Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, with one or more PIK3CA/AKT1/PTEN-mutations (abnormal changes in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
   You have experienced disease progression (your condition has worsened) on an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPIVASERTIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truqap.

REFERENCES

Truqap [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

CAPLACIZUMAB-YHDP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		GPI-10 (8515102080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Is the request for continuation of Cablivi therapy from inpatient (hospital) setting **AND** the patient meets the following criterion?
   - Cablivi was previously initiated as part of the FDA approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting

   If yes, **approve for 1 month by HICL or GPI-10 for a maximum quantity of #30 vials.**
   If no, continue to #4.

4. Is the request for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and the patient meets **ALL** of the following criteria?
   - The patient is receiving immunosuppressive therapy
   - The patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

   If yes, **approve for 1 month by HICL or GPI-10 for a maximum quantity of #28 vials.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CAPLACIZUMAB-YHDP

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi**) requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP- a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
D. You have NOT experienced more than two recurrences of acquired thrombotic thrombocytopenia purpura, while on Cablivi therapy. For example there's a new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (process of replacing a liquid part of the blood) and up to 28 days of extended therapy
E. You also meet ONE of the following:
    1. Your request is for continuation of Cablivi therapy from inpatient (hospital) setting and you previously received plasma exchange and immunosuppressive therapy (treatment that weakens your immune system) within the inpatient setting
    2. Your request is for continuation of Cablivi therapy from the initial 30 days treatment course (no break in therapy) AND:
        a. You are receiving immunosuppressive therapy, and
        b. You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13: type of blood clot disorder] activity level remain present)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

- Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/21/22
Created: 05/19
Client Approval: 11/22
P&T Approval: 04/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPMATINIB HYDROCHLORIDE	TABRECTA	46519		GPI-10 (2153371620)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tabrecta.

REFERENCES

- Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 08/20
Client Approval: 03/21
P&T Approval: 07/20

CAPSAICIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPSAICIN 8% PATCH	QUTENZA	36916		GPI-10 (9085002530)	

GUIDELINES FOR USE

1. Does the patient have neuropathic pain associated with **ONE** of the following conditions?
   - Postherpetic neuralgia (PHN)
   - Diabetic peripheral neuropathy (DPN) of the feet

   If yes, **approve for 12 months by HICL or GPI-10 for 4 fills with a quantity limit of up to #4 patches per fill (maximum dose is 4 patches every 3 months).**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPSAICIN (Qutenza)** requires the following rule be met for approval:
   A. You have a diagnosis of neuropathic pain associated with ONE of the following conditions:
      - Postherpetic neuralgia (PHN) (painful condition that affects the nerve fibers and skin after having shingles)
      - Diabetic peripheral neuropathy (DPN) of the feet (numbness of the feet that is caused by diabetes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qutenza.

REFERENCES

- Qutenza [Prescribing Information]. Ardsley, NY. Acorda Therapeutics, Inc. July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/24/20
Created: 05/10
Client Approval: 07/20
P&T Approval: 10/20

CARBIDOPA-LEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBIDOPA/ LEVODOPA	DUOPA		37829	GPI-14 (73209902101820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced Parkinson's disease?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #100mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:
   A. You have a diagnosis of advanced Parkinson's disease (nerve system disorder that affects movement)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Duopa.

REFERENCES

- Duopa [Prescribing Information]. North Chicago, IL: Abbvie, Inc. Februrary 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 05/15

CARBOXYMETHYLCELLULOSE-CITRIC

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBOXYMETHYLCELLULOSE /CITRIC	PLENITY	47522		GPI-10 (6120990202)	

GUIDELINES FOR USE

1. Is the request for weight management and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a body mass index (BMI) of 25 to 40 kg/m(2)
   - Plenity will be used in conjunction with diet and exercise

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #168 per 28 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARBOXYMETHYLCELLULOSE-CITRIC (Plenity)** requires the following rule(s) be met for approval:
   A. The request is for weight management
   B. You are 18 years of age or older
   C. You have a body mass index (BMI) of 25 to 40 kg/m(2)
   D. Plenity will be used in conjunction (together) with diet and exercise

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Plenity.

REFERENCES

- Plenity [Prescribing Information]. Boston, MA: Gelesis, Inc., 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/13/24
Created: 08/21
Client Approval: 03/24
P&T Approval: 07/21

CARGLUMIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARGLUMIC ACID	CARBAGLU CARGLUMIC ACID	25643		GPI-10 (3090823000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency **AND** meet the following criterion?
   - NAGS gene mutation is confirmed by biochemical or genetic testing

   If yes, continue to #2**.**
   If no, continue to #4.

2. Is the request for generic carglumic acid?

   If yes, **approve carglumic acid (generic only) by HICL or GPI-10 as follows:**
   Acute HA due to NAGS deficiency: approve for 7 days.
   Chronic HA due to NAGS deficiency: approve for 6 months.
   If no, continue to #3.

3. Is the request for brand Carbaglu **AND** the patient meets the following criterion?
   - The patient had a trial of generic carglumic acid

   If yes, **approve by HICL or GPI-10 as follows:**
   Acute HA due to NAGS deficiency: approve for 7 days.
   Chronic HA due to NAGS deficiency: approve for 6 months.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of acute hyperammonemia (HA) due to propionic acidemia (PA) **AND** meet following criterion?
   - The diagnosis is confirmed by the presence of elevated methylcitric acid and normal methylmalonic acid OR genetic testing confirming mutation in the PCCA or PCCB gene

   If yes, **approve for 7 days by HICL or GPI-10.**
   If no, continue to #5.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CARGLUMIC ACID

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of acute hyperammonemia (HA) due to methylmalonic acidemia (MMA) **AND** meet following criterion?
   - The diagnosis is confirmed by the presence of elevated methylmalonic acid, methylcitric acid OR genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes

   If yes, **approve for 7 days by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (short-term or long-term high ammonia blood levels due to a genetic disorder)
      2. Acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (short-term high ammonia blood levels due to a genetic disorder)
   B. **If you have acute or chronic hyperammonemia due to N-acetylglutamate synthase deficiency, approval also requires**:
      1. Your N-acetylglutamate synthase gene mutation is confirmed by biochemical or genetic testing (types of lab test)
      2. Requests for brand Carbaglu requires a trial of generic carglumic acid
   C. **If you have acute hyperammonemia due to propionic acidemia, approval also requires**:
      1. Your diagnosis is confirmed by the presence of elevated methylcitric acid and normal methylmalonic acid (substances that indicate presence of a disease) OR genetic testing confirming mutation in the PCCA or PCCB gene (types of abnormal genes)
   D. **If you have acute hyperammonemia due to methylmalonic acidemia, approval also requires**:
      1. Your diagnosis is confirmed by the presence of elevated methylmalonic acid, methylcitric acid OR genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes (types of abnormal genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CARGLUMIC ACID

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of acute hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency or acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic hyperammonemia (HA) due to N- acetylglutamate synthase (NAGS) deficiency **AND** meet the following criterion?
   - The patient has clinical improvement or improved plasma (blood) ammonia levels

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for renewal:
   A. You have chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) (long-term high ammonia blood levels due to a genetic disorder)
   B. You have clinical improvement or improved plasma (blood) ammonia levels

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carbaglu.

REFERENCES

- Carbaglu [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 01/22

CASIMERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CASIMERSEN	AMONDYS-45	47149		GPI-10 (7460002500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) **AND** meet the following criterion?
   The patient has a confirmed mutation in the DMD gene that is amenable to exon 45 skipping

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CASIMERSEN (Amondys-45)** requires the following rule(s) be met for approval:
   You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   You have a confirmed mutation in the DMD gene that is responsive to exon 45 skipping (a type of gene mutation)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Amondys-45.

REFERENCES
Amondys-45 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; July 2024.

Created: 05/21
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/21

CELECOXIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CELECOXIB	ELYXYB		48006	GPI-10 (6760403000)	

GUIDELINES FOR USE

1. Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of generic celecoxib AND OTC or generic aspirin, diclofenac, ibuprofen, or naproxen
   - The patient is unable to swallow pills (e.g., tablets or capsules)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #38.4 mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CELECOXIB (Elyxyb)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines
   B. You are 18 years of age or older
   C. You had a trial of generic celecoxib AND over-the-counter (OTC) or generic aspirin, diclofenac, ibuprofen, or naproxen
   D. You are unable to swallow pills (such as tablets or capsules)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Elyxyb.

REFERENCES

- Elyxyb [Prescribing Information]. Raleigh, NC: BioDelivery Sciences International, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/22
Client Approval: 02/22
P&T Approval: 01/22

CENEGERMIN-BKBJ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CENEGERMIN-BKBJ	OXERVATE	45258		GPI-10 (8677002020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurotrophic keratitis (NK) (ICD-10 Group H16.23) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an ophthalmologist
   The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
   The patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
   The patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

   If yes, **approve for 8 weeks per lifetime by HICL or GPI-10 as follows:**
   If treatment is for 1 eye: #14 vials per 14 days for 4 fills.
   If treatment is for 2 eyes: #28 vials per 14 days for 4 fills.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:
   You have neurotrophic keratitis (an eye disease due to a damaged eye nerve)
   Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor)
   You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) (such as herpes zoster infection [shingles virus], multiple sclerosis [type of nerve disorder], diabetes (a disorder with high blood sugar), ocular surgical [eye surgery] damage)
   You have loss of corneal (a part of the eye) sensitivity, corneal epithelium changes, and/or loss of tear production
   You are refractory (not fully responsive) to conservative management (artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CENEGERMIN-BKBJ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxervate.

REFERENCES

Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc., October 2023.

Created: 02/19
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/19

CEQUR SIMPLICITY INSULIN DEVICE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOLUS INSULIN PUMP, 200 UNIT	CEQUR SIMPLICITY	44109		GPI-10 (9705105012)	Medi-Span: BRAND = CEQUR SIMPLICITY
DIABETIC SUPPLIES,MISCELL	CEQUR SIMPLICITY INSERTER	04476		GPI-10 (9705105012)	FDB/Medi-Span: BRAND = CEQUR SIMPLICITY INSERTER

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of diabetes mellitus (type 1 or type 2) and meet **ALL** of the following criteria?
   The patient is 21 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient follows a maintenance program of at least 3 injections of insulin per day
   The patient has worked with the physician to adjust the dose of insulin for the past 6 months and has not met glucose goals
   The patient requires bolus insulin dosing in increments of 2 units per bolus
   The patient had a trial of ONE of the following preferred devices: Omnipod, Omnipod Dash, V-Go

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient on a multiple daily insulin injection regimen and meets **ONE** of the following criteria?
   - The patient's glycosylated hemoglobin level (HbA1c) is greater than 7%
   - The patient has a history of recurring hypoglycemia
   - The patient has wide fluctuations in blood glucose before mealtime
   - The patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL
   - The patient has a history of severe glycemic excursions (i.e., sudden spikes in blood sugar levels)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CEQUR SIMPLICITY INSULIN DEVICE

INITIAL CRITERIA (CONTINUED)

3. Is the request for more than 10 patches per month?

   If yes, continue to #4.
   If no, **approve for 12 months for both agents as follows:**
   - **CeQur Simplicity Inserter: Approve for 1 fill by NDC [FDB] or GPI-14.**
   - **CeQur Simplicity Patches: Approve by HICL or NDC [Medi-Span] with a quantity limit of #10 per 30 days.**

4. Is the patient using more than more than 180 units of insulin per 72 hours?

   If yes, **approve for 12 months for both agents as follows:**
   - **CeQur Simplicity Inserter: Approve for 1 fill by NDC [FDB] or GPI-14.**
   - **CeQur Simplicity Patches: Approve by HICL or NDC [Medi-Span] for the requested quantity per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   [PAC NOTE: Enter proactive PAs for 12 months for both agents as follows:
   - **CeQur Simplicity Inserter: Approve for 1 fill by NDC [FDB] or GPI-14.**
   - **CeQur Simplicity Patches: Approve by HICL or NDC [Medi-Span] with a quantity limit of #10 per 30 days.]**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CEQUR SIMPLICITY INSULIN DEVICE** requires the following rule(s) be met for approval:
   A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
   B. You are 21 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. You follow a maintenance program of at least 3 injections of insulin per day
   E. You have worked with the physician to adjust the dose of insulin for the past 6 months and have not met glucose (blood sugar) goals
   F. You require bolus insulin dosing in increments of 2 units per bolus
   G. You had a trial of ONE of the following preferred devices: Omnipod, Omnipod Dash, V-Go
   H. If requesting more than 10 patches per month, then you must be using more than 180 units of insulin per 72 hours
   (Initial denial text continued on next page)

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CEQUR SIMPLICITY INSULIN DEVICE

INITIAL CRITERIA (CONTINUED)

I. You are on a multiple daily insulin injection regimen and meet ONE of the following criteria:
   1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) greater than 7 percent
   2. You have a history of recurring hypoglycemia (low blood sugar)
   3. You have wide fluctuations (variations) in blood glucose before mealtime
   4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
   5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of diabetes mellitus (type 1 or type 2) and meet **ALL** of the following criteria?
   - The patient has shown a positive response to therapy
   - The patient is adherent to physician follow-up visits

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for more than 10 patches per month?

   If yes, continue to #3.
   If no, **approve 12 months for both as follows:**
   - **CeQur Simplicity Inserter: Approve for 1 fill by NDC [FDB] or GPI-14.**
   - **CeQur Simplicity Patches: Approve by HICL or NDC [Medi-Span] with a quantity limit of #10 per 30 days.**

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CEQUR SIMPLICITY INSULIN DEVICE

RENEWAL CRITERIA (CONTINUED)

3. Is the patient using more than more than 180 units of insulin per 72 hours?

If yes, **approve 12 months for both as follows:**
- **CeQur Simplicity Inserter: Approve for 1 fill by NDC [FDB] or GPI-14.**
- **CeQur Simplicity Patches: Approve by HICL or NDC [Medi-Span] for the requested quantity per 30 days.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.
[PAC NOTE: Enter proactive PAs for 12 months for both as follows:
- **CeQur Simplicity Inserter: Approve for 1 fill by NDC [FDB] or GPI-14.**
- **CeQur Simplicity Patches: Approve HICL or NDC [Medi-Span] with a quantity limit of #10 per 30 days.]**

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CEQUR SIMPLICITY INSULIN DEVICE** requires the following rule(s) be met for renewal:
A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You have shown a positive response to therapy
C. You are adherent to your doctor follow-up visits
D. If requesting more than 10 patches per month, you are using more than 180 units of insulin per 72 hours

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CEQUR SIMPLICITY INSULIN DEVICE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for CeQur Simplicity.

REFERENCES

- CeQur Simplicity. CeQur Corp. Available at: https://mycegursimplicity.com/healthcare-professionals/. [Accessed July 27, 2004].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 08/22
Client Approval: 02/23
P&T Approval: 07/22

CERITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERITINIB	ZYKADIA	41111		GPI-10 (2153051400)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zykadia.

REFERENCE
- Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 05/14
Client Approval: 10/21
P&T Approval: 10/21

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		GPI-10 (5250502010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   <u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.
   <u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (enter a start date of 1 week AFTER the END date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 kits.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 kit per 28 days (enter a start date of 1 week AFTER the END date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 kits.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 kit per 28 days (enter a start date of 1 week AFTER the END date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 kits.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 kit per 28 days (enter a start date of 1 week AFTER the END date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient meet **ONE** of the following criteria?
    The patient was previously stable on another biologic and is switching to Cimzia
    The patient has C-reactive protein (CRP) levels above the upper limit of normal
    The patient has sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
    FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 kits.
    SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 kit per 28 days (enter a start date of 1 week AFTER the END date of the first approval).

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

11. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Therapy is prescribed by or in consultation with a dermatologist
    The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
    Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

    If yes, continue to #12.
    If no, continue to #14.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

12. Does the patient meet **ONE** of the following criteria?
    The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
    The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of PsO
    The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

13. Does the patient meet **ONE** of the following criteria?
    The patient is pregnant, breastfeeding, or trying to become pregnant
    The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

14. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Therapy is prescribed by or in consultation with a gastroenterologist
    Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

    If yes, continue to #15.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

15. Does the patient meet **ONE** of the following criteria?
    The patient is pregnant, breastfeeding, or trying to become pregnant
    The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
    FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 kits.
    SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 kit per 28 days (enter a start date of 3 weeks AFTER the END date of the first approval).

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
    Psoriatic arthritis (PsA: a type of skin and joint condition)
    Ankylosing spondylitis (AS: a type of joint condition)
    Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
    Moderate to severe plaque psoriasis (PsO: a type of skin condition)
    Moderate to severe Crohn's disease (CD: a type of bowel disorder)
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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Cimzia
  - You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor) for the same indication

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are pregnant, breastfeeding, or trying to become pregnant
- You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have moderate to severe Crohn's disease, approval also requires:

You are 18 years of age or older

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)

You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

You meet ONE of the following:
- You are pregnant, breastfeeding, or trying to become pregnant
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, continue to #4.
   If no, continue to #5.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The patient is pregnant, breastfeeding, or trying to become pregnant
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Cimzia will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, continue to #10.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
    The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
    Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

    If yes, continue to #11.
    If no, continue to #12.

11. Does the patient meet **ONE** of the following criteria?
    The patient is pregnant, breastfeeding, or trying to become pregnant
    The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

12. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
    Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

13. Does the patient meet **ONE** of the following criteria?
    The patient is pregnant, breastfeeding, or trying to become pregnant
    The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.** If no, do not approve.

    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:
    You have ONE of the following:
        Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
        Psoriatic arthritis (PsA: a type of skin and joint condition)
        Ankylosing spondylitis (AS: a type of joint condition)
        Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
        Moderate to severe plaque psoriasis (PsO: a type of skin condition)
        Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    If you have moderate to severe rheumatoid arthritis, renewal also requires:
        You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
        You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
    (Renewal denial text continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are pregnant, breastfeeding, or trying to become pregnant
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
- You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:

You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

You meet ONE of the following:
- You are pregnant, breastfeeding, or trying to become pregnant
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

If you have psoriatic arthritis, renewal also requires:

You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

You meet ONE of the following:
- You are pregnant, breastfeeding, or trying to become pregnant
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cimzia.

REFERENCES
Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc.; September 2024.

Created: 05/08
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

CETUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CETUXIMAB	ERBITUX	25947		GPI-10 (2136001500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
   Erbitux will be used in combination with radiation therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
   Erbitux will be used in combination with platinum-based therapy (e.g., cisplatin, carboplatin, oxaliplatin) and 5-fluorouracil (5-FU)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
   The patient has failed prior platinum-based therapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Will Erbitux be used in combination with Krazati (adagrasib)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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CETUXIMAB

GUIDELINES FOR USE (CONTINUED)

6. Is the patient's cancer KRAS wild-type (without mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by an FDA-approved test, and the patient meets **ONE** of the following criteria?
   Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)
   Erbitux will be used in combination with irinotecan AND the patient is refractory to irinotecan-based chemotherapy
   The patient has failed oxaliplatin-based and irinotecan-based chemotherapy OR the patient is intolerant to irinotecan

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient's cancer have a BRAF V600E mutation, as determined by an FDA-approved test?

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Will Erbitux be used in combination with Braftovi (encorafenib) and mFOLFOX6 (fluorouracil, leucovorin and oxaliplatin)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Will Erbitux be used in combination with Braftovi (encorafenib) after prior therapy **AND** the patient meets the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CETUXIMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CETUXIMAB (Erbitux)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has spread from where it started to nearby tissue or lymph nodes)
- Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has returned or has spread to other parts of the body)
- Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has returned or has spread to other parts of the body)
- Metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)

If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:
Erbitux will be used in combination with radiation therapy

If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:
Erbitux will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin) and 5-fluorouracil (5-FU)

If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
You have previously failed platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin)

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CETUXIMAB

GUIDELINES FOR USE (CONTINUED)

If you have metastatic colorectal cancer (mCRC), approval also requires ONE of the following:

Erbitux will be used in combination with Krazati (adagrasib)

Your cancer is KRAS wild-type (a type of gene with no mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by a Food and Drug Administration (FDA)-approved test, AND you meet ONE of the following:

Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)

Erbitux will be used in combination with irinotecan and you are refractory (resistant) to irinotecan-based chemotherapy

You have failed oxaliplatin-based and irinotecan-based chemotherapy OR you are intolerant to irinotecan

Your cancer has a BRAF V600E mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test and you meet ONE of the following:

Erbitux will be used in combination with Braftovi (encorafenib) and mFOLFOX6 (fluorouracil, leucovorin and oxaliplatin)

Erbitux will be used in combination with Braftovi (encorafenib) after prior therapy, and you are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or Drug Monograph for Erbitux.

REFERENCES

Erbitux [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2021.
Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; December 2024.
Krazati [Prescribing Information]. San Diego, CA: Mirati Therapeutics, Inc.; June 2024.

Created: 02/13
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/25

CHENODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHENODIOL	CHENODAL	01364		GPI-10 (5210001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being prescribed for the treatment of cerebrotendinous xanthomatosis (CTX)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 daily.**
   If no, continue to #2.

2. Is the requested medication being prescribed for the treatment of radiolucent gallstones?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient received previous chenodiol therapy with a total duration exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #4.

4. Has the patient had a previous trial of or contraindication to ursodiol?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #7 daily.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for approval:
   A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
   B. **If you have radiolucent gallstones, approval also requires:**
      1. You have tried ursodiol, unless there is a medical reason why you cannot (contraindication)
      2. You have not received previous chenodiol therapy for more than a total of 24 months

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CHENODIOL

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the requested medication being used for radiolucent gallstones?

   If yes, continue to #2.
   If no, continue to #5.

2. Has the patient previously received a total duration of chenodiol therapy exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have complete or no gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #4.

4. Does the patient have partial gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #7 daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) **AND** meet the following criterion?
   - The patient has experienced improvement in **ONE** of the following:
     - Normalization of elevated serum or urine bile alcohols
     - Normalization of elevated serum cholestanol levels
     - Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHENODIOL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for renewal:

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)

B. **If you have radiolucent gallstones, renewal also requires:**
   1. You have **NOT** had chenodiol therapy for more than a total of 24 months
   2. You do **NOT** have complete or no gallstone dissolution (disappearance) seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
   3. You have partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy

C. **If you have cerebrotendinous xanthomatosis, renewal also requires you have experienced an improvement** in **ONE** of the following:
   1. Normalization of elevated serum or urine bile alcohols
   2. Normalization of elevated serum cholestanol levels
   3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Chenodal.

REFERENCES

- Chenodal [Prescribing Information]. Manchester Pharmaceuticals, Inc. Fort Collins, CO. July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/09
Client Approval: 04/20
P&T Approval: 07/18

CHOLIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHOLIC ACID	CHOLBAM	39124		GPI-10 (5270002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to **ONE** of the following conditions?
   - Bile acid synthesis disorders
   - Peroxisomal disorders (i.e., Zellweger spectrum disorders)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:
   A. You show signs of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins that occur from ONE of the following conditions:
      1. Bile acid synthesis disorders (your body has a problem making bile acid)
      2. Peroxisomal disorders (Zellweger spectrum disorders) (problems with a part of a cell that contains enzymes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Did the patient experience improvement in liver function (as defined by at least **ONE** of the following criteria)?
   - ALT or AST values reduced to less than 50 U/L or baseline levels reduced by 80%
   - Total bilirubin values reduced to less than 1 mg/dL
   - No evidence of cholestasis on liver biopsy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHOLIC ACID

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:

A. You have experienced an improvement in your liver function as defined by at least ONE of the following criteria:

1. ALT (alanine aminotransferase) or AST (aspartate transaminase) (types of liver enzymes) values have been lowered to less than 50 U/L or baseline levels reduced by 80%
2. Total bilirubin values reduced to less than 1 mg/dL
3. No evidence of cholestasis (condition where bile cannot flow from liver) on liver biopsy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cholbam.

REFERENCES

- Cholbam [Prescribing Information]. Baltimore, MD: Asklepion Pharmaceuticals, LLC; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/15
Client Approval: 04/20
P&T Approval: 05/15

CLADRIBINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLADRIBINE	MAVENCLAD		44338	GPI-10 (6240101500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 48 weeks by GPID or GPI-10.**
   APPROVAL TEXT: Renewal requires 1) physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline, 2) the patient does not have lymphopenia, and 3) the patient has not received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CLADRIBINE

RENEWAL CRITERIA (CONTINUED)

2. Has the patient received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, **approve for 48 weeks by GPID or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for renewal:
   A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
   B. You have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
   C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
   D. You have not received a total of two years of treatment with Mavenclad

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

- Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc., March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/19
Client Approval: 04/20
P&T Approval: 10/19

CLASCOTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLASCOTERONE	WINLEVI	46803		GPI-10 (9005001100)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acne vulgaris and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient had a trial of or contraindication to **BOTH** of the following:
     - ONE oral acne agent (e.g. oral antibiotics or oral isotretinoin)
     - TWO topical acne agents (e.g. topical retinoids, topical antibiotics, benzoyl peroxide)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**
   APPROVAL TEXT: Renewal requires the patient had improvement of acne lesions.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
   A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   D. You have previously tried BOTH of the following unless there is a medical reason why you cannot (contraindication):
   1. ONE oral acne agent (such as oral antibiotics or oral isotretinoin)
   2. TWO topical acne agents (such as topical retinoids, topical antibiotics, benzoyl peroxide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLASCOTERONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acne vulgaris **AND** meet the following criterion?
   - The patient had improvement of acne lesions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
   A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
   B. You had improvement of acne lesions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Winlevi.

REFERENCES

- Winlevi [Prescribing Information]. Milan, Italy: Cosmo S.p.A.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 12/20
Client Approval: 12/20
P&T Approval: 10/20

CLOBAZAM-SYMPAZAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLOBAZAM	SYMPAZAN	06536		GPI-10 (7210000700)	DOSAGE FORM = FILM

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - Sympazan will be used for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome
   - The patient is unable to take tablets or suspension
   - The patient had a trial of or contraindication to generic/branded clobazam products (Onfi)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths with a quantity limit of #2 per day:**
   - **5mg film**
   - **10mg film**
   - **20mg film**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for approval:
   A. You have Lennox-Gastaut Syndrome (a type of seizure disorder in young children)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. Sympazan will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome
   E. You are unable to take tablets or suspension
   F. You had a trial of or contraindication (harmful for) to generic/branded clobazam products (Onfi)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLOBAZAM-SYMPAZAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sympazan.

REFERENCES

- Sympazan [Prescribing Information]. Warren, NJ. Aquestive Therapeutics; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22

Created: 02/19
Client Approval: 05/22

P&T Approval: 04/22

COBIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		GPI-10 (2153353020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has a BRAF V600E OR V600K mutation
   - Cobimetinib will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of histiocytic neoplasms and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Cobimetinib will be used as a single agent

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
      2. Hystiocytic neoplasms (a type of white blood cell disorder)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You are 18 years of age or older
      2. Your tumor has a BRAF V600E OR V600K mutation (a type of gene mutation)
      3. Cobimetinib will be used in combination with vemurafenib (Zelboraf)
   C. **If you have histiocytic neoplasms, approval also requires:**
      1. You are 18 years of age or older
      2. Cobimetinib will be used as a single agent

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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COBIMETINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cotellic.

REFERENCES

- Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/21/22
Created: 11/15
Client Approval: 11/22
P&T Approval: 01/23

COLLAGENASE TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COLLAGENASE CLOSTRIDIUM HIST.	SANTYL		21190	GPI-14 (90700010004205)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic dermal ulcer(s) or severe burn(s) that require(s) debridement?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the requested quantity for one tube (30 grams) or less?

   If yes, **approve by GPID or GPI-14 for one fill with a quantity limit of #30 grams.**
   If no, continue to #3.

3. Are **BOTH** of the following provided?
   - The patient's wound size (width/length)
   - The anticipated duration of therapy

   If yes, **approve by GPID or GPI-14 for one fill with a quantity limit based on the Santyl dosing calculator (https://santyl.com/hcp/dosing).**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COLLAGENASE TOPICAL (Santyl)** requires the following rule(s) be met for approval:
   A. You have chronic dermal (skin) ulcer(s) or severe burn(s) that require(s) debridement (removal of damaged tissue from a wound)
   B. **If the requested quantity is more than one tube (30 grams), approval also requires:**
      1. The higher quantity is based on the size of your wound (width/length) and the anticipated duration of therapy, using the Santyl dosing calculator (https://santyl.com/hcp/dosing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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COLLAGENASE TOPICAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Santyl.

REFERENCES

- Santyl [Prescribing Information]. Fort Worth, TX: Smith & Nephew, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/21
Client Approval: 02/22
P&T Approval: 10/21

CONCIZUMAB-MTCI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONCIZUMAB-MTCI	ALHEMO	50125		GPI-10 (8510502505)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient's hemophilia has FVIII inhibitors
   Therapy is prescribed by or in consultation with a hematologist
   Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (congenital factor IX deficiency) (ICD-10 D67) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient's hemophilia has FIX inhibitors
   Therapy is prescribed by or in consultation with a hematologist
   Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CONCIZUMAB-MTCI

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONCIZUMAB-MTCI (Alhemo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
- Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

If you have hemophilia A (congenital factor VIII deficiency), approval also requires:
- You are 12 years of age or older
- Your hemophilia has FVIII inhibitors (a type of protein)
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

If you have hemophilia B (congenital factor IX deficiency), approval also requires:
- You are 12 years of age or older
- Your hemophilia has FIX inhibitors (a type of protein)
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CONCIZUMAB-MTCI

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   The patient's hemophilia has FVIII inhibitors
   Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
   The patient has shown a clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (congenital factor IX deficiency) (ICD-10 D67) and meet **ALL** of the following criteria?
   The patient's hemophilia has FIX inhibitors
   Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
   The patient has shown a clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CONCIZUMAB-MTCI

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONCIZUMAB-MTCI (Alhemo)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
- Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

If you have hemophilia A (congenital factor VIII deficiency), renewal also requires:
- Your hemophilia has FVIII inhibitors (a type of protein)
- You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
- You have shown a clinical benefit compared to baseline (before starting Alhemo)

If you have hemophilia B (congenital factor IX deficiency), renewal also requires:
- Your hemophilia has FIX inhibitors (a type of protein)
- You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
- You have shown a clinical benefit compared to baseline (before starting Alhemo)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alhemo.

REFERENCES
Alhemo [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; December 2024.

Created: 01/25
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 01/25

CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER	DEXCOM G4, DEXCOM G5	36756		GPI-10 (9720201202)	FDB & Medi-Span: BRAND = DEXCOM G4%, DEXCOM G5%
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, EVERSENSE SMART TRANSMITTER, EVERSENSE E3 SMART TRANSMITTER, EVERSENSE 365 TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER, GUARDIAN 4 TRANSMITTER	36760		GPI-10 (9720201206)	FDB & Medi-Span: BRAND = DEXCOM G4%, DEXCOM G5%, EVERSENSE SMART TRANSMITTER, EVERSENSE E3 SMART TRANSMITTER, EVERSENSE 365 TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER, GUARDIAN 4 TRANSMITTER
BLOOD-GLUCOSE SENSOR	DEXCOM G5-G4 SENSOR, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3, GUARDIAN 4 GLUCOSE SENSOR, EVERSENSE 365 SENSOR	36696 45253		GPI-10 (9720201204)	FDB & Medi-Span: BRAND = DEXCOM G5-G4%, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3, GUARDIAN 4 GLUCOSE SENSOR, EVERSENSE 365 SENSOR

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of type 1, type 2, or gestational diabetes?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient is being treated with insulin (e.g., Humalog [insulin lispro], Lantus [insulin glargine])
   The patient has a clinical need that cannot be managed with self-monitoring of blood glucose (SMBG) (e.g., frequent hypoglycemia, hypoglycemic unawareness, unable to achieve control of diabetes)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for Dexcom G4 or Dexcom G5 (i.e., meter, sensor, transmitter) **AND** the patient meets the following criterion?
   The patient is 2 years of age or older

   If yes, continue to #7.
   If no, continue to #4.

4. Is the request for Guardian Connect (i.e., sensor, transmitter) **AND** the patient meets the following criterion?
   The patient is 14 to 75 years of age

   If yes, continue to #7.
   If no, continue to #5.

5. Is the request for Guardian 3 (i.e., sensor, link transmitter) or Guardian 4 (i.e., sensor, transmitter) **AND** the patient meets the following criterion?
   The patient is 7 years of age or older

   If yes, continue to #7.
   If no, continue to #6.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

INITIAL CRITERIA (CONTINUED)

6. Is the request for Eversense Smart (i.e., transmitter), Eversense E3 Smart (i.e., transmitter), or Eversense 365 (i.e., sensor, transmitter) **AND** the patient meets the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to Dexcom G6 or Dexcom G7
   The patient had a trial of or contraindication to Freestyle Libre
   Dexcom G6, Dexcom G7, and Freestyle Libre are not compatible with the patient's current insulin pump

   If yes, **approve the requested agent for 12 months by NDC as follows:**
   Dexcom G4: approve all of the following:
   Receiver: #1 per 12 months.
   Transmitter: #1 per 180 days.
   Sensor: #4 per 28 days.
   Dexcom G5: approve all of the following:
   Receiver: #1 per 12 months.
   Transmitter: #1 per 90 days.
   Sensor: #4 per 28 days.
   Guardian Connect: approve all of the following:
   Transmitter: #1 per 12 months.
   Sensor: #5 per 35 days.
   Guardian 3: approve all of the following:
   Link Transmitter: #1 per 12 months.
   Sensor: #5 per 35 days.
   Guardian 4: approve all of the following:
   Transmitter: #1 per 12 months.
   Sensor: #5 per 35 days.
   Eversense Smart transmitter or Eversense E3 Smart transmitter: approve with a quantity limit of #1 per 12 months.
   Eversense 365: approve all of the following:
   Transmitter: #1 per 12 months.
   Sensor: #1 per 12 months.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for approval:

You have type 1, type 2, or gestational (during pregnancy) diabetes (a disorder with high blood sugar)

You have tried or have a contraindication to (harmful for you to use) Dexcom G6, Dexcom G7, or Freestyle Libre, OR all three products are not compatible with your current insulin pump

You meet ONE of the following:

- You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
- You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)

If you are requesting Dexcom G4 or Dexcom G5 system (meter, sensor, transmitter), approval also requires:

You are 2 years of age or older

If you are requesting Guardian Connect (sensor, transmitter), approval also requires:

You are 14 to 75 years of age

If you are requesting Guardian 3 (sensor, link, transmitter) or Guardian 4 (sensor, transmitter), approval also requires:

You are 7 years of age or older

If you are requesting Eversense Smart (transmitter), Eversense E3 Smart (transmitter) or Eversense 365 (sensor, transmitter), approval also requires:

You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

RENEWAL CRITERIA

1. Does the patient continue to require continuous glucose monitoring?

If yes, **approve the requested agent for 12 months by NDC as follows:**
Dexcom G4: approve all of the following:
Receiver: #1 per 12 months.
Transmitter: #1 per 180 days.
Sensor: #4 per 28 days.
Dexcom G5: approve all of the following:
Receiver: #1 per 12 months.
Transmitter: #1 per 90 days.
Sensor: #4 per 28 days.
Guardian Connect: approve all of the following:
Transmitter: #1 per 12 months.
Sensor: #5 per 35 days.
Guardian 3: approve all of the following:
Link Transmitter: #1 per 12 months.
Sensor: #5 per 35 days.
Guardian 4: approve all of the following:
Transmitter: #1 per 12 months.
Sensor: #5 per 35 days.
Eversense Smart transmitter or Eversense E3 Smart transmitter: approve with a quantity limit of #1 per 12 months.
Eversense 365: approve all of the following:
Transmitter: #1 per 12 months.
Sensor: #1 per 12 months.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for renewal:
You continue to require continuous glucose monitoring

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CONTINUOUS GLUCOSE MONITORS – STAND-ALONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related continuous glucose monitor.

REFERENCES

Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Available at: https://www.dexcom.com/

Medtronic. Medtronic MiniMed, Inc. Available at: https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system

Eversense Continuous Glucose Monitoring System. Senseonics, Inc. Available at: https://www.eversensediabetes.com/

Created: 02/18
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

CORTICOTROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CORTICOTROPIN	ACTHAR , ACTHAR SELFJECT, CORTROPHIN	02830		GPI-10 (3030001000)	

GUIDELINES FOR USE

1. Is the request for Acthar pre-filled SelfJect for any indication?

   If yes, do not approve.
   Note: Off-label guideline should not be used for Acthar because it hasn't demonstrated proven benefits in the other indications and has no proven advantage over synthetic steroids. Therefore, there isn't a pathway to approval for any other listed indications.

   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for Acthar vial?

   If yes, continue to #3.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   The patient is less than 2 years of age

   If yes, **approve Acthar vial for 28 days by GPID or GPI-14 for #8 vials.**
   If no, continue to #4.

4. Is the request for any other indications other than infantile spasms?

   If yes, do not approve. See note below and use the denial text at the end of the guideline.
   Note: Off-label guideline should not be used for Acthar because it hasn't demonstrated proven benefits in the other indications and has no proven advantage over synthetic steroids. Therefore, there isn't a pathway to approval for any other listed indications.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CORTICOTROPIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CORTICOTROPIN (Acthar, Cortrophin)** requires the following rule(s) be met for approval:
You have infantile spasms (a type of seizure disorder in infancy and childhood)
You are less than 2 years of age
Your request is for Acthar vial

Acthar vial will not be approved for any other indication other than infantile spasms. Acthar has not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Acthar pre-filled SelfJect will not be approved for infantile spasms (not Food and Drug Administration (FDA)-indicated) or any other indication. Acthar has not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Acthar Gel.

REFERENCES

Acthar Gel [Prescribing Information]. Bridgewater, NJ: Mallinckrodt ARD LLC; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 11/07
Client Approval: 07/24
P&T Approval: 04/20

CRINECERFONT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRINECERFONT	CRENESSITY	50097		GPI-10 (3032102000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of classic congenital adrenal hyperplasia (CAH) (ICD-10 E25.0) and meet **ALL** of the following criteria?
   The patient is 4 years of age or older
   Crenessity will be used as adjunctive treatment with glucocorticoid replacement therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Crenessity capsule?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   50mg: #3 per day.
   100mg: #4 per day.

   If no, continue to #3.

3. Is the request for Crenessity solution **AND** the patient meets the following criterion?
   The patient is unable to swallow Crenessity capsules

   If yes, **approve the solution for 12 months by GPID or GPI-14 with a quantity limit of #8mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CRINECERFONT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CRINECERFONT (Crenessity)** requires the following rule(s) be met for approval:
You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
You are 4 years of age or older
Crenessity will be used as adjunctive (additional) treatment with glucocorticoid replacement therapy
If the request is for Crenessity solution, approval also requires that you are unable to swallow Crenessity capsules

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Crenessity.

REFERENCES

Crenessity [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.

Created: 12/24
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

CRIZOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRIZOTINIB	XALKORI	37916		GPI-10 (2153051700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient's tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
   The patient's tumors are ROS1-positive as detected by an FDA-approved test

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient unable to swallow capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   50mg pellet: #4 per day.
   150mg pellet: #2 per day.

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   200mg capsule: #2 per day.
   250mg capsule: #2 per day.

4. Does the patient have a diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient's tumors are anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #6.
   If no, continue to #5.

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CRIZOTINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient's tumors are anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient unable to swallow capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   20mg pellet: #8 per day.
   50mg pellet: #4 per day.
   150mg pellet: #6 per day.

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   200mg capsule: #4 per day.
   250mg capsule: #4 per day.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   - Relapsed (disease that has returned) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: a type of blood cell cancer)
   - Unresectable (unable to remove by surgery), recurrent, or refractory (disease does not respond to treatment) inflammatory myofibroblastic tumor (IMT: a rare type of tumor)

   If you have metastatic non-small cell lung cancer, approval also requires:
   - You are 18 years of age or older
   - Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive or ROS1 (a type of gene)-positive as detected by a Food and Drug Administration (FDA)-approved test

   If you have relapsed or refractory systemic anaplastic large cell lymphoma, approval also requires:
   - You are 1 year of age or older
   - Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

   (Denial text continued on next page)

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CRIZOTINIB

GUIDELINES FOR USE (CONTINUED)

If you have unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires:
You are 1 year of age or older
Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive
If the request is for Xalkori oral pellets, approval also requires:
You are unable to swallow capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xalkori.

REFERENCE

Xalkori [Prescribing Information]. New York, New York: Pfizer Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 09/11
Client Approval: 11/23
P&T Approval: 01/24

CYCLOSPORINE - VERKAZIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYCLOSPORINE	VERKAZIA		46848	GPI-14 (86720020001630)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of vernal keratoconjunctivitis **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (e.g., ketotifen) or mast cell stabilizers (e.g., cromolyn)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 vials per day.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VERKAZIA** requires the following rule(s) be met for approval:
   A. You have vernal keratoconjunctivitis (allergic eye disease)
   B. You have tried or have a contraindication to (harmful for you to use) TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (such as ketotifen) or mast cell stabilizers (such as cromolyn)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Verkazia.

REFERENCES

- Verkazia [Prescribing Information]. Emeryville, CA: Santen Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 08/22
Client Approval: 12/23
P&T Approval: 07/22

CYCLOSPORINE - VEVYE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYCLOSPORINE	VEVYE	04524		GPI-10 (8672002000)	BRAND = VEVYE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (DED) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   The patient has ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
   The patient had a trial of or contraindication to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, TheraTears], polyvinyl alcohol [LiquiTears, Refresh Classic], or wetting agent [Systane, Lacri-Lube])
   The patient had a trial of or contraindication to BOTH of the following preferred agents: Restasis (cyclosporine) and Xiidra (lifitegrast)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2mL per 50 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for approval:
   You have dry eye disease (DED: a type of eye condition)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
   You have ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
   You have tried or have a contraindication to (harmful for you to use) ONE ocular lubricant (such as carboxymethylcellulose [such as Refresh, Celluvisc, TheraTears], polyvinyl alcohol [such as LiquiTears, Refresh Classic], or a wetting agent [such as Systane, Lacri-Lube])
   You have tried or have a contraindication to BOTH of the following preferred medications: Restasis (cyclosporine) and Xiidra (lifitegrast)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CYCLOSPORINE – VEVYE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (DED) **AND** meet the following criterion?
   The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 50 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for renewal:
   You have dry eye disease (DED: a type of eye condition)
   You have demonstrated improvement of your dry eye disease (the treatment is working)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vevye.

REFERENCES

Vevye [Prescribing Information]. Nashville, TN: Harrow Eye, LLC.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 04/23

CYSTEAMINE BITARTRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE BITARTRATE	PROCYSBI		34656 34657 47723 47724	GPI-14 (56400030106520) (56400030106530) (56400030103020) (56400030103040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of nephropathic cystinosis and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:
   A. You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
   B. You are 1 year of age or older
   C. You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Procysbi.

REFERENCES

- Procysbi [Prescribing Information]. Novato, CA: Raptor Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/13
Client Approval: 04/20
P&T Approval: 11/15

CYSTEAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE HCL	CYSTARAN, CYSTADROPS		33485 40466	GPI-10 (8680552510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient require treatment for corneal cystine crystal accumulation or deposits?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Cystaran: #60mL(4 bottles) per 28 days.**
   - **Cystadrops: #20mL (4 bottles) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:
   A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
   B. You require treatment for corneal cystine crystal accumulation or deposits (build up of cysteine in the eye)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CYSTEAMINE HYDROCHLORIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran/Cystadrops.

REFERENCES

- Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2018.
- Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20

Created: 05/13
Client Approval: 09/20

P&T Approval: 05/13

DABIGATRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABIGATRAN ETEXILATE MESELATE	PRADAXA	35604		GPI-10 (8333703020)	DOSAGE FORM = PELET PACK

GUIDELINES FOR USE

1. Is the request for the treatment of a venous thromboembolic event (VTE) **AND** the patient meets the following criterion?
   - The patient has been treated with a parenteral anticoagulation agent for at least 5 days

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request to reduce the risk of venous thromboembolic event (VTE) recurrence **AND** the patient meets the following criterion?
   - The patient has been previously treated

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 months to 7 years of age
   - The patient is 8 to 11 years of age AND unable to swallow dabigatran (Pradaxa) capsule

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

4. Has the patient had a trial of or contraindication to rivaroxaban (Xarelto) suspension?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

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DABIGATRAN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABIGATRAN (Pradaxa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of a venous thromboembolic event (VTE: a type of blood clot disease in your veins)
   2. Reduce the risk of venous thromboembolic event recurrence (happening again)

B. You meet ONE of the following:
   1. You are 3 months to 7 years of age
   2. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules

C. You have tried or have a contraindication (harmful for) to rivaroxaban (Xarelto) suspension

D. **If the request is for the treatment of a venous thromboembolic event, approval also requires:**
   1. You have been treated with parenteral anticoagulation agent (type of medication) for at least 5 days

E. **If the request is to reduce the risk of venous thromboembolic event recurrence, approval also requires:**
   1. You have been previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pradaxa.

REFERENCES

- Pradaxa [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/10
Client Approval: 05/23
P&T Approval: 04/23

DABRAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		GPI-10 (2153202510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ONE** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test AND the requested medication will be used as a single agent
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The requested medication has not previously been used for more than one year
   - The requested medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - The requested medication will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Mekinist (trametinib)
   - The patient's disease has progressed following prior treatment and have no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Mekinist (trametinib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the capsule formulation?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Is the request for the tablet for oral suspension **AND** the patient meets the following criterion?
   - The patient cannot swallow Tafinlar (dabrafenib) capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Melanoma (a type of skin cancer)
   3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires ONE of the following:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent (by itself)
   2. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

C. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication has not previously been used for more than one year
   3. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
   4. There is involvement of lymph node(s) following complete resection (removal by surgery)

D. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)

(Denial text continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the tablet for oral suspension, approval also requires:**
   1. You cannot swallow Tafinlar (dabrafenib) capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tafinlar.

REFERENCES

- Tafinlar [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 06/13
Client Approval: 09/23
P&T Approval: 10/23

ACOMITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DACOMITINIB	VIZIMPRO	45283		GPI-10 (2136001900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
   - Vizimpro will be used as first-line treatment
   - Vizimpro will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of cancer that has spread) to other parts of the body)
   B. You have epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   C. Vizimpro will be used as first-line treatment
   D. You will NOT be using Vizimpro concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DACOMITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vizimpro.

REFERENCES

- Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/18
Client Approval: 05/22
P&T Approval: 04/22

DALFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DALFAMPRIDINE	AMPYRA, DALFAMPRIDINE ER	13907		GPI-10 (6240603000)	FDB: ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple sclerosis (MS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has symptoms of a walking disability such as mild to moderate bilateral lower extremity weakness or unilateral weakness plus lower extremity or truncal ataxia

   If yes, **approve for 3 months by HICL or GPI-10 for #2 tablets per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You have symptoms of a walking disability such as mild to moderate bilateral (both sides) lower extremity weakness or unilateral (one side) weakness plus lower extremity or truncal ataxia (impaired balance or coordination)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DALFAMPRIDINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of multiple sclerosis (MS) **AND** meet the following criterion?
   - The patient has experienced or maintained at least a 15% improvement in walking ability

   If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You have experienced or maintained at least a 15% improvement in walking ability

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ampyra.

REFERENCES

- Ampyra [Prescribing Information]. Ardsley, NY: Acorda Therapeutics; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 02/10
Client Approval: 07/22
P&T Approval: 07/22

DANICOPAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DANICOPAN	VOYDEYA	49483		GPI-10 (8580852000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a hematologist
   Voydeya will be used for the treatment of extravascular hemolysis (EVH)
   The patient has anemia (Hgb level less than or equal to 9.5 g/dL) with an absolute reticulocyte count of at least 120 x 10^9/L
   The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   The patient had a trial of or contraindication to Fabhalta (iptacopan)
   Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for approval:
   You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   You will use Voydeya for the treatment of extravascular hemolysis (EVH: break down of blood cells outside of your blood stream)
   You have anemia (a hemoglobin [Hgb: a type of protein in red blood cells] level less than or equal to 9.5 g/dL) with an absolute reticulocyte (immature red blood cell) count of at least 120 x 10(9)/L
   (Initial denial text continued on next page)

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DANICOPAN

INITIAL CRITERIA (CONTINUED)

You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
You have tried or have a contraindication to (harmful for you to use) Fabhalta (iptacopan)
You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DANICOPAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient has experienced a clinical benefit (e.g., improvement in hemoglobin levels) compared to baseline
   Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for renewal:
   You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   You have experienced a clinical benefit (such as an improvement in hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before you started treatment)
   You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DANICOPAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voydeya.

REFERENCES

Voydeya [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 04/24
Client Approval: 08/24
P&T Approval: 07/24

DAPRODUSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAPRODUSTAT	JESDUVROQ	48668		GPI-10 (8240252000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist
   The patient has been receiving dialysis for at least 4 months
   The patient has an eGFR of less than 60 mL/min/1.73m(2) corresponding to stage 3, 4, or 5 chronic kidney disease (CKD)
   Jesduvroq will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Vafseo [vadadustat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient currently being treated with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit)?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a hemoglobin level of less than 11 g/dL?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   1mg: #1 per day.
   2mg: #1 per day.
   4mg: #1 per day.
   6mg: #2 per day.
   8mg: #3 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DAPRODUSTAT

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   The patient has a hemoglobin level of less than 12 g/dL
   The patient will discontinue the erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit) prior to starting Jesduvroq

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   1mg: #1 per day.
   2mg: #1 per day.
   4mg: #1 per day.
   6mg: #2 per day.
   8mg: #3 per day.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for approval:
   You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 4 months
   You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic kidney disease (CKD)
   You will NOT use Jesduvroq concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Vafseo [vadadustat])
   If you are NOT currently being treated with an erythropoiesis-stimulating agent (ESA: drugs used to treat anemia such as Epogen or Procrit), approval also requires:
   You have a hemoglobin level (a type of blood test) of less than 11 g/dL
   If you are currently being treated with an erythropoiesis-stimulating agent (ESA: drugs used to treat anemia such as Epogen or Procrit), approval also requires:
   You have a hemoglobin level (a type of blood test) of less than 12 g/dL
   You will discontinue ESA therapy before starting Jesduvroq

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAPRODUSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ONE** of the following criteria?
   The patient has a hemoglobin level of at least 10 g/dL
   The patient's hemoglobin level has increased by at least 2 g/dL from their baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   1mg: #1 per day.
   2mg: #1 per day.
   4mg: #1 per day.
   6mg: #2 per day.
   8mg: #3 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for renewal:
   You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
   You meet ONE of the following:
   You have a hemoglobin level (a type of blood test) of at least 10 g/dL
   Your hemoglobin level has increased by at least 2 g/dL from your baseline level

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jesduvroq.

REFERENCES

Jesduvroq [Prescribing Information]. Durham, NC: GlaxoSmithKline; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/05/24
Created: 09/23
Client Approval: 07/24
P&T Approval: 01/24

DARBEPOETIN ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARBEPOETIN ALFA IN POLYSORBAT	ARANESP	22890		GPI-10 (8240101510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, continue to #2.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, continue to #3.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 10g/dL
   The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
- Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
- Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

If you have anemia due to chronic kidney disease, approval also requires:
- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 10g/dL

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
- Your hemoglobin level is less than 10g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DARBEPOETIN ALFA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL if not on dialysis
   The patient's hemoglobin level is less than 11g/dL if on dialysis
   The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, continue to #3.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL
   The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, continue to #4.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy **AND** meet the following criterion?
   The patient's a hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, continue to #5.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
   The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   25mcg/mL vial: #4mL per 28 days.
   40mcg/mL vial: #4mL per 28 days.
   60mcg/mL vial: #4mL per 28 days.
   100mcg/mL vial: #4mL per 28 days.
   200mcg/mL vial: #4mL per 28 days.
   300mcg/mL vial: #4mL per 28 days.
   10mcg/0.4mL syringe: #1.6mL per 28 days.
   25mcg/0.42mL syringe: #1.68mL per 28 days.
   40mcg/0.4mL syringe: #1.6mL per 28 days.
   60mcg/0.3mL syringe: #1.2mL per 28 days.
   100mcg/0.5mL syringe: #2mL per 28 days.
   150mcg/0.3mL syringe: #1.2mL per 28 days.
   200mcg/0.4mL syringe: #1.6mL per 28 days.
   300mcg/0.6mL syringe: #2.4mL per 28 days.
   500mcg/mL syringe: #4mL per 28 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   - Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   - Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

   (Renewal denial text continued on next page)

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:
- Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level is less than 11g/dL if you are on dialysis
- Your hemoglobin has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions
- Your hemoglobin has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:
- Your hemoglobin level is less than 10g/dL
- Your hemoglobin level has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Aranesp.

REFERENCES
Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/24
Created: 02/11
Client Approval: 05/24
P&T Approval: 10/23

DARIDOREXANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARIDOREXANT HCL	QUVIVIQ	47751		GPI-10 (6050002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of insomnia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has premature awakening and/or abnormal sleep onset delay lasting 30 minutes or longer, occurring 3 or more times weekly for the last month for acute insomnia or for at least 3 months for chronic insomnia
   - The patient has daytime impairment despite adequate time attempting to sleep and treatment of any treatable causes
   - The patient is NOT concurrently using Z hypnotics (e.g., eszopiclone, zaleplon, zolpidem) or benzodiazepines (e.g., estazolam, temazepam, triazolam) for sleep
   - The patient does NOT have narcolepsy
   - The patient had a trial of or contraindication to TWO generic insomnia medications (e.g., eszopiclone, zaleplon, zolpidem) AND Belsomra

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARIDOREXANT (Quviviq)** requires the following rule(s) be met for approval:
   A. You have insomnia (a type of sleep condition)
   B. You are 18 years of age or older
   C. You have premature awakening (waking up too early) and/or abnormal sleep onset delay (cannot fall asleep) lasting 30 minutes or longer, occurring 3 or more times weekly for the last month for acute (short-term) insomnia or for at least 3 months for chronic (long-term) insomnia
   D. You have daytime impairment despite adequate time attempting to sleep and treatment of any treatable causes
   E. You are NOT using Quviviq at the same time with Z hypnotics (such as eszopiclone, zaleplon, zolpidem) or benzodiazepines (such as estazolam, temazepam, triazolam) for sleep
   F. You do NOT have narcolepsy (a type of sleep condition)
   G. You had a trial of or contraindication (harmful for) to TWO generic insomnia medications (such as eszopiclone, zaleplon, zolpidem) AND Belsomra

   (Initial denial text continued on next page)

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DARIDOREXANT

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of insomnia and meet **ALL** of the following criteria?
   - The patient has demonstrated improvement of insomnia symptoms but is not currently a candidate for discontinuation
   - The patient is NOT concurrently using Z hypnotics (e.g., eszopiclone, zaleplon, zolpidem) or benzodiazepines (e.g., estazolam, temazepam, triazolam) for sleep

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARIDOREXANT (Quviviq)** requires the following rule(s) be met for renewal:
   A. You have insomnia (a type of sleep condition)
   B. You have demonstrated improvement of insomnia symptoms but are not currently a candidate for discontinuation
   C. You are NOT using Quviviq at the same time with Z hypnotics (such as eszopiclone, zaleplon, zolpidem) or benzodiazepines (such as estazolam, temazepam, triazolam) for sleep

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DARIDOREXANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Quviviq.

REFERENCES

- Quviviq [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US, Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/09/22
Created: 04/22
Client Approval: 04/22
P&T Approval: 10/21

DAROLUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		GPI-10 (2140242500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** meet the following criterion?
   - The requested medication will be used in combination with docetaxel

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DAROLUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have non-metastatic castration resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)

D. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
   1. The requested medication will be used in combination with docetaxel

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC)?

   If yes, continue to #3.
   If no, continue to #2.

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DAROLUTAMIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** meet the following criterion?
   - The requested medication will be used in combination with docetaxel

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
      2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

   B. You meet ONE of the following:
      1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

   C. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
      1. The requested medication will be used in combination with docetaxel

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAROLUTAMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

- Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 11/19
Client Approval: 11/22
P&T Approval: 10/22

DASATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	SPRYCEL	33855		GPI-10 (2153182000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) in chronic phase (CP) and meet **ONE** of the following criteria?
   - The patient is 18 years of age or older AND is newly diagnosed
   - The patient is between 1 and 17 years of age

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in chronic, accelerated, myeloid or lymphoid blast phase
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND Sprycel is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

4. Is the patient 18 years of age or older **AND** has a resistance or intolerance to prior therapy (e.g., imatinib [Gleevec], nilotinib [Tasigna])?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #5.

5. Is the patient between 1 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is newly diagnosed
   - Sprycel will be used in combination with chemotherapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic, accelerated, myeloid or lymphoid blast phase
      2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

   B. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:**
      1. You are 18 years of age or older AND you are newly diagnosed
      2. You are between 1 and 17 years of age

   (Denial text continued on the next page)

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance (medication no longer works as well) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
   3. You had a mutational analysis (a type of lab test) prior to start of therapy AND Sprycel is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance (medication no longer works as well) or intolerance (side effect) to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are between 1 and 17 years of age, you are newly diagnosed, AND you will be using Sprycel in combination with chemotherapy (drugs used to treat cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sprycel.

REFERENCES

- Sprycel [Prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/23/24
Created: 05/12
Client Approval: 09/24
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DATOPOTAMAB DERUXTECAN-DLNK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DATOPOTAMAB DERUXTECAN-DLNK	DATROWAY	50179		GPI-10 (2155102020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic breast cancer (ICD-10 C79.81; Group C50) and meet **ALL** of the following criteria?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH-)
   The patient has received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen) and chemotherapy for unresectable or metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DATOPOTAMAB DERUXTECAN-DLNK (Datroway)** requires the following rule(s) be met for approval:
   You have unresectable or metastatic breast cancer (a type of breast cancer that cannot be removed by surgery or has spread to other parts of the body)
   Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+, or IHC 2+/ISH- [type of lab test])
   You had prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) and chemotherapy (medications used to treat cancer) for unresectable or metastatic disease

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Datroway.

REFERENCES
Datroway [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2025.

Created: 01/25
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 04/25

DECITABINE/CEDAZURIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DECITABINE/ CEDAZURIDINE	INQOVI	46686		GPI-10 (2199000225)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **ONE** of the following International Prognostic Scoring System groups: intermediate-1, intermediate-2, or high-risk

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic myelomonocytic leukemia (CMML) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Myelodysplastic syndromes (MDS: type of blood cancer)
      2. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)
   B. You are 18 years of age or older
   C. **If you have myelodysplastic syndromes (MDS), approval also requires:**
      1. You meet ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
         a. Intermediate-1
         b. Intermediate-2
         c. High-risk

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DECITABINE/CEDAZURIDINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inqovi.

REFERENCES

- Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 10/20
Client Approval: 11/20
P&T Approval: 10/20

DEFERASIROX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX	33337		GPI-10 (9310002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request prescribed by or given in consultation with a hematologist or hematologist-oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of chronic iron overload due to blood transfusions?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's serum ferritin levels are consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 5mg Fe/g dry weight

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for Exjade or Jadenu tablets?

   If yes, **approve Exjade or Jadenu tablets for all strengths of the requested drug for 6 months by GPID or GPI-14.**
   If no, continue to #7.

7. Is the request for Jadenu sprinkle packets **AND** the patient has tried a generic equivalent of Exjade or Jadenu tablets?

   If yes, **approve Jadenu Sprinkle for all strengths for 6 months by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for approval:
   A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
   B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
   C. **If you have chronic iron overload due to blood transfusions, approval also requires:**
      1. You are 2 years of age or older
      2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values taken within the previous 3 months)

   (Initial denial text continued on next page)

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

D. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:**
   1. You are 10 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater

E. Requests for Jadenu sprinkle packets require a trial of equivalent generic Exjade or Jadenu tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions **AND** meet the following criterion?
   - The patient's serum ferritin levels are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT) and meet **ONE** of the following criteria?
   - The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 3mg Fe/g dry weight (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERASIROX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (we need at least 2 lab values taken within the previous 3 months)
C. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exjade and Jadenu.

REFERENCES

- Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
- Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 08/17
Client Approval: 08/20
P&T Approval: 01/20

DEFERIPRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERIPRONE	FERRIPROX, DEFERIPRONE	18544		GPI-10 (9310002800)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Transfusional iron overload due to thalassemia syndrome
   - Transfusional iron overload due to sickle cell disease or other anemias

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a hematologist or hematologist/oncologist
   - The patient had a trial of or contraindication to at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient experiencing intolerable toxicities, clinically significant adverse effects, has a contraindication to current chelators: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine), **OR** current chelation therapy is inadequate?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets **AND** the patient is 8 years of age or older
   - The request is for Ferriprox oral solution **AND** the patient is 3 years of age or older

   If yes, **approve for 6 months for all strengths of the requested formulation by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERIPRONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a type of blood disorder)
   2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a type of blood disorder)

B. Therapy is prescribed by or given in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of cancer doctor)

C. You have tried or have a contraindication (harmful for) to at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

D. You meet ONE of the following:
   1. You are experiencing intolerable toxicities or clinically significant adverse effects or have a contraindication (harmful for) to current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   2. Current chelation therapy (therapy that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough

E. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
   1. You are 8 years of age or older

F. **If the request is for Ferriprox oral solution, approval also requires:**
   1. You are 3 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Transfusional iron overload due to thalassemia syndrome
   - Transfusional iron overload due to a sickle cell disease or other anemias

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERIPRONE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet the following criterion?
   - The patient has serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets **AND** the patient is 8 years of age or older
   - The request is for Ferriprox oral solution **AND** the patient is 3 years of age or older

   If yes, **approve for 12 months for all strengths of the requested formulation by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Transfusional iron overload due to thalassemia syndrome (you have too much iron in your body due to a type of blood disorder)
      2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a type of blood disorder)
   B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay above 500mcg/L (at least 2 lab values in the previous 3 months)
   C. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
      1. You are 8 years of age or older
   D. **If the request is for Ferriprox oral solution, approval also requires:**
      1. You are 3 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERIPRONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ferriprox.

REFERENCES

- Ferriprox [Prescribing Information]. Weston, FL: ApoPharma USA, Inc.; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/17
Client Approval: 02/22
P&T Approval: 01/22

DEFEROXAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFEROXAMINE MESYLATE	DESFERAL, DEFEROXAMINE MESYLATE	01104		GPI-10 (9300002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a hematologist or hematologist-oncologist
   - The patient is 3 years of age or older
   - The patient has a serum ferritin levels that are consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:
   A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
   B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
   C. You are 3 years of age or older
   D. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 1000mcg/L (shown by at least 2 lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFEROXAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet the following criterion?
   - The patient has a serum ferritin levels that are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rules be met for renewal:
   A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
   B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Desferal.

REFERENCES

- Desferal [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 08/17
Client Approval: 03/23
P&T Approval: 07/17

DEFLAZACORT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFLAZACORT	EMFLAZA, DEFLAZACORT	11668		GPI-10 (2210001700)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

3. Did the patient experience a lack of efficacy with prednisone or prednisolone and meets **ALL** of the following criteria?
   The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   Steroid myopathy has been ruled out
   The patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA], pulmonary function tests [FVC, PFTs], upper limb strength [propelling a wheelchair 30 feet])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   6mg tablet: #2 per day.
   18mg tablet: #1 per day.
   30mg tablet: #2 per day.
   36mg tablet: #2 per day.
   22.75mg/mL oral suspension: #1.3mL per day.

   If no, continue to #4.

4. Did the patient experience a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes)?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   6mg tablet: #2 per day.
   18mg tablet: #1 per day.
   30mg tablet: #2 per day.
   36mg tablet: #2 per day.
   22.75mg/mL oral suspension: #1.3mL per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rule(s) be met for approval:
You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
You are 2 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
Your diagnosis of DMD is confirmed by genetic testing
You have tried prednisone or prednisolone for at least 6 months
You meet ONE of the following:
- Prednisone or prednisolone did not work for you, and you meet **ALL** of the following:
  - You are not in Stage 1 of the disease (the pre-symptomatic phase)
  - There is no steroid myopathy (muscle disease due to steroid use)
  - You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician], pulmonary function [forced vital capacity, lung function tests], upper limb strength [moving a wheelchair 30 feet])
- You have experienced a significant adverse effect (such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFLAZACORT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   The patient has shown function or improvement since being on Emflaza, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   6mg tablet: #2 per day.
   18mg tablet: #1 per day.
   30mg tablet: #2 per day.
   36mg tablet: #2 per day.
   22.75mg/mL oral suspension: #1.3mL per day.

   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since being on Emflaza, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength measures [propelling a wheelchair 30 feet], Physician Global Assessment [PGA])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   6mg tablet: #2 per day.
   18mg tablet: #1 per day.
   30mg tablet: #2 per day.
   36mg tablet: #2 per day.
   22.75mg/mL oral suspension: #1.3mL per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFLAZACORT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rule(s) be met for renewal:
You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
If you are currently ambulatory (can walk), approval also requires:
You have shown function or improvement since being on Emflaza as measured by a standard set of ambulatory or functional status measures (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician])
If you are currently non-ambulatory (cannot walk), approval also requires:
You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since being on Emflaza as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength measures [moving in a wheelchair 30 feet], Physician Global Assessment [PGA: an evaluation by a physician])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emflaza.

REFERENCES

Emflaza [Prescribing Information]. Warren, NJ: PTC Therapeutics, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/17
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

DELAFLOXACIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELAFLOXACIN MEGLUMINE	BAXDELA		43532	GPI-14 (05000025100320)	

GUIDELINES FOR USE

1. Is therapy prescribed by or in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve as follows:**
   Acute bacterial skin or skin structure infection (ABSSSI): Approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #28 per 14 days.
   Community-acquired bacterial pneumonia (CABP): Approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #20 per 10 days.
   Other indications: Approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #28 per 14 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of an acute bacterial skin and skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The infection is caused by **ONE** of the following susceptible organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus Group* (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* or *Pseudomonas aeruginosa*

   If yes, continue to #3.
   If no, continue to #6.

3. Is Baxdela being used for an animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitus ulcer formation, myonecrosis or ecthyma gangrenosum?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

4. Has antimicrobial susceptibility testing been performed that meets **ALL** of the following criteria?
   The results from the infection site culture indicate pathogenic organism(s) with resistance to ONE standard of care agent for acute bacterial skin and skin structure infections (ABSSSI) (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)
   The results from the infection site culture indicate pathogenic organism(s) that are susceptible to Baxdela (delafloxacin)

   If yes, **approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #28 per 14 days.**

   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   Antimicrobial susceptibility results are unavailable
   The patient had a trial of or contraindication to ONE of the following agents: gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin), penicillin antibiotic (e.g., amoxicillin), fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin), cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)

   If yes, **approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #28 per 14 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates* only*), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila* or *Mycoplasma pneumoniae*

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

7. Has antimicrobial susceptibility testing been performed that meets **ALL** of the following criteria?
   The results from the infection site culture indicate pathogenic organism(s) with resistance to TWO standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)
   The results from the infection site culture indicate pathogenic organism(s) that are susceptible to Baxdela (delafloxacin)

   If yes, **approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #20 per 10 days.**

   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   Antimicrobial susceptibility results are unavailable
   The patient had a trial of or contraindication to TWO standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)

   If yes, **approve the 450mg tablets for 1 fill by GPID or GPI-14 with a quantity limit of #20 per 10 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - The requested medication is prescribed by or in consultation with an infectious disease (ID) specialist
   - You have an acute bacterial skin and skin structure infection (ABSSSI: a type of skin condition)
   - You have community-acquired bacterial pneumonia (CABP: type of lung infection)

   (Denial text continued on next page)

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

If you have an acute bacterial skin or skin structure infection, approval also requires:

You are 18 years of age or older

The infection is caused by any of the following bacteria: *Staphylococcus aureus* (including methicillin-resistant [MRSA] *and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, or Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa*

You are NOT using Baxdela for an animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitus ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum (a type of skin lesion)

You meet ONE of the following:

If an antimicrobial susceptibility test (a type of lab test) is available, your results of the test from the infection site show both of the following:

The bacteria is resistant to ONE standard of care medication for acute bacterial skin and skin structure infections (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)

Baxdela (delafloxacin) will work to treat the bacteria

b. If an antimicrobial susceptibility test (a type of lab test) is NOT available, you have tried or have a contraindication to (harmful for you to use) ONE of the following medications: a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin), a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin)

(Denial text continued on next page)

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

If you have community-acquired bacterial pneumonia, approval also requires:

- You are 18 years of age or older
- The infection is caused by any of the following bacteria: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae
- You meet ONE of the following:
  - If an antimicrobial susceptibility test (a type of lab test) is available, your results of the test from the infection site show both of the following:
    - The bacteria is resistant to TWO standard of care medications for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
    - Baxdela (delafloxacin) will work to treat the bacteria
  - If an antimicrobial susceptibility test (a type of lab test) is NOT available, you have tried or have a contraindication to (harmful for you to use) TWO standard of care medications for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxdela.

REFERENCES

Baxdela [Prescribing Information]. Lincolnshire, Illinois: Melinta Therapeutics, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/17
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DESIRUDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DESIRUDIN	IPRIVASK	19072		GPI-10 (8333403000)	

GUIDELINES FOR USE

1. Is the request for Iprivask for the prevention (prophylaxis) of deep vein thrombosis (DVT) for a patient undergoing elective hip replacement surgery?

   If yes, **approve for a total of 35 days of treatment. Enter two authorizations as follows:**
   - **Approve for 12 days by HICL or GPI-10 for #24 vials.**
   - **Also enter one fill for 23 days by HICL or GPI-10 for #46 vials with a start date of 7 days following the initial approval.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iprivask.

REFERENCES

- Iprivask [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals; November 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/10
Client Approval: 04/20
P&T Approval: 11/13

DEUCRAVACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEUCRAVACITINIB	SOTYKTU	48292		GPI-10 (9025052400)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   Sotyktu will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEUCRAVACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for approval:
You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
You meet ONE of the following:
- You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
- You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEUCRAVACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Sotyktu will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for renewal:
   You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
   You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sotyktu.

REFERENCES

Sotyktu [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.

Created: 09/22
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

DEXTROMETHORPHAN-QUINIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEXTROMETHORPHAN HBR/QUINIDINE	NUEDEXTA	37278		GPI-10 (6260990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pseudobulbar affect (PBA) (ICD-10 F48.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN-QUINIDINE (Nuedexta)** requires the following rule(s) be met for approval:
   You have pseudobulbar affect (uncontrollable, inappropriate laughing and/or crying due to a nervous system disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuedexta.

REFERENCES

Nuedexta [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceuticals, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/15

DIABETIC TEST STRIPS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BLOOD SUGAR DIAGNOSTIC, BLOOD SUGAR DIAGNOSTIC, DISC, BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS		25200	GPI-14 (94100030006100)	

CSR NOTE: Requests for blood glucose (diabetic) test strips manufactured by Abbott (FreeStyle and Precision) will adjudicate at the point of service with no restrictions. Non-formulary test strips will require prior authorization.

GUIDELINES FOR USE

1. Has the patient tried one of the following preferred blood glucose (diabetic) meters and test strips by Abbott: FreeStyle or Precision?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient require the use of a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, continue to #3.

3. Is the prescriber requesting a non-preferred test strip due to a need for data management software? [**Note:** The preferred test strips include FreeStyle and Precision by Abbott]

   If yes, do not approve, and recommend the prescriber contact Abbott for data management software and a connection cable for the meter.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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DIABETIC TEST STRIPS

GUIDELINES FOR USE (CONTINUED)

4. Does the patient require the use of a non-preferred blood glucose test strip based on his/her use of another manufacturer's companion insulin pump?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:
   A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott
   B. You require a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment (problems with sight and/or memory and thinking)
   C. You require a non-preferred blood glucose test strip because you use another manufacturer's companion insulin pump

   Request for non-preferred test strips will not be approved if due to a need for data management software. Please note that data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of non-preferred alternatives.

REFERENCES

- Drug Facts and Comparisons (online version), Blood Glucose Meters. Available at http://online.factsandcomparisons.com.
- American Diabetes Association. Standards of Medical Care in Diabetes- 2017. Diabetes Care 2017; 40 (suppl 1): S11-S135.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/08/21
Created: 01/12
Client Approval: 01/21
P&T Approval: 08/14

DICHLORPHENAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICHLORPHENAMIDE	KEVEYIS, ORMALVI, DICHLORPHENAMIDE	03642		GPI-10 (3710002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis or related variants (ICD-10 G72.3), and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist
   The patient has tried acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide)
   The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary hypokalemic periodic paralysis or related variants (ICD-10 G72.3), and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist
   The patient has tried acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene)
   The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DICHLORPHENAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood) or related variants
- Primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood) or related variants

If you have primary hyperkalemic periodic paralysis or related variants, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)
- You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

If you have primary hypokalemic periodic paralysis or related variants, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
- You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants (ICD-10 G72.3) **AND** meet the following criterion?
   The patient has experienced at least TWO fewer attacks per week from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for renewal:
   You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
   You have experienced at least TWO fewer attacks per week from baseline (before you started treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keveyis or Ormalvi.

REFERENCES

Keveyis [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; August 2024.
Ormalvi [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 09/15
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 11/15

DICLOFENAC TOPICAL GEL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC SODIUM	SOLARAZE, DICLOFENAC SODIUM		86831	GPI-10 (9037403530)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a dermatologist or oncologist
   - The patient had a trial of or contraindication to topical fluorouracil (e.g., Efudex, Fluoroplex, Carac)

   If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit of #100 grams per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC TOPICAL GEL (Solaraze)** requires the following rule(s) be met for approval:
   A. You have actinic keratosis (a type of skin condition)
   B. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor) or oncologist (a type of cancer doctor)
   C. You had a trial of or contraindication (harmful for) to topical fluorouracil (such as Efudex, Fluoroplex, Carac)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Solaraze.

REFERENCES

- Solaraze [Prescribing Information]. PharmaDerm: Melville, NY; May 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/22

DICLOFENAC TOPICAL SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC SODIUM	PENNSAID, DICLOFENAC SODIUM		35936 43213	GPI-14 (90210030302030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of osteoarthritis of the knee(s) **AND** meet the following criterion?
   - The patient had a trial of diclofenac 1% gel AND diclofenac 1.5% drops

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #224 grams per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC TOPICAL SOLUTION (Pennsaid)** requires the following rule(s) be met for approval:
   A. You have osteoarthritis (a type of joint condition) of the knee(s)
   B. You had a trial of diclofenac 1% gel AND diclofenac 1.5% drops

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pennsaid.

REFERENCES

- Pennsaid [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/22

DIGOXIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIGOXIN	DIGOXIN		00130	GPI-14 (31200010000303)	GENERIC ONLY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of heart failure?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic atrial fibrillation **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIGOXIN** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Heart failure (a type of heart condition)
      2. Chronic atrial fibrillation (a type of heart condition)
   B. **If you have chronic atrial fibrillation, approval also requires:**
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lanoxin.

REFERENCES

- Lanoxin [Prescribing Information]. 17 Northwood House, Dublin 9, Ireland: Concordia Pharmaceuticals, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

DIMETHYL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIMETHYL FUMARATE	TECFIDERA, DIMETHYL FUMARATE	40168		GPI-10 (6240552500)	FDB ROUTE ≠ MISCELL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for generic dimethyl fumarate?

   If yes, **approve generic dimethyl fumarate for 12 months by HICL or GPI-10 with a quantity limit of #2 per day and override 'Generic Only' field.**
   If no, continue to #3.

3. Is the request for brand Tecfidera **AND** the patient meets the following criterion?
   The patient had a trial of generic dimethyl fumarate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rule(s) be met for approval:
   You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
   You are 18 years of age or older
   If you are requesting brand Tecfidera, approval also requires:
   You have tried generic dimethyl fumarate

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DIMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tecfidera.

REFERENCES

Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/13
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/20

DIROXIMEL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164		GPI-10 (6240553000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vumerity.

REFERENCES

- Vumerity [Prescribing Information]. Cambridge, MA: Biogen Inc.; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/19
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/20

DONEPEZIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONEPEZIL HCL	ADLARITY		52053 52054	GPI-14 (62051025108820, 62051025108830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dementia associated with Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   The patient had a trial of or contraindication to TWO generic oral acetylcholinesterase inhibitors (e.g., donepezil, galantamine)
   The patient had a trial of or contraindication to ONE generic acetylcholinesterase inhibitor patch (e.g., rivastigmine)

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONEPEZIL (Adlarity)** requires the following rule(s) be met for approval:
   You have dementia (a type of memory disorder) associated with Alzheimer's disease (a type of brain disorder)
   You have tried or have a contraindication to (harmful for you to use) TWO generic oral acetylcholinesterase inhibitors (such as donepezil, galantamine)
   You have tried or have a contraindication to (harmful for you to use) ONE generic acetylcholinesterase inhibitor patch (such as rivastigmine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlarity.

REFERENCES
Adlarity [Prescribing Information]. Grand Rapids, MI: Astellas Corium, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 06/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/22

DORNASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DORNASE ALFA	PULMOZYME	08832		GPI-10 (4530402000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for once daily dosing (30 ampules per month)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 ampules per month.**
   If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 ampules per month.**
   If no, do not approve. **Enter a proactive authorization for 12 months by HICL or GPI-10 with a quantity limit of #30 ampules per month.**
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: an inherited disorder that damages lung and digestive system with fluid build up)
   B. If you are requesting twice daily dosing, we require that you have tried and failed once daily dosing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DORNASE ALFA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pulmozyme.

REFERENCE

- Pulmozyme [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/12
Client Approval: 04/20
P&T Approval: 05/12

DROXIDOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DROXIDOPA	NORTHERA, DROXIDOPA	40936		GPI-10 (3870003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist or cardiologist
   - The patient had a previously had a trial of or contraindication to midodrine **OR** fludrocortisone

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the prescriber performed baseline blood pressure readings while the patient is sitting and also within minutes of standing from a supine (lying face up) position?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DROXIDOPA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'?

   If yes, **approve for 1 month by HICL or GPI-10 for #180 per 30 days.**
   APPROVAL TEXT: Renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:
   - Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **DROXIDOPA (Northera)** requires the following rules be met for approval:
   A. You have neurogenic orthostatic hypotension (a type of low blood pressure)
   B. You are 18 years of age or older
   C. You have a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency (you are missing a type of enzyme), or non-diabetic autonomic neuropathy (nerve pain/damage)
   D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
   E. Theray is prescribed or given in consultation with a neurologist (nerve doctor) or cardiologist (heart doctor)
   F. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
   G. You have a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
   H. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DROXIDOPA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (NOH) and meets **ALL** of the following criteria?
   - The patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - The patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

   If yes, **approve for 3 months by HICL or GPI-10 for #180 per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:
   A. You have neurogenic orthostatic hypotension (NOH)
   B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
   C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Northera.

REFERENCES

- Northera [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/15/21
Created: 9/14
Client Approval: 03/21
P&T Approval: 11/14

DULOXETINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DULOXETINE HCL	DRIZALMA SPRINKLE		46703 46713 46714 46715	GPI-14 (5818002510H120) (5818002510H130) (5818002510H140) (5818002510H160)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   Major depressive disorder (MDD) (ICD-10 Groups F32, F33)
   Diabetic peripheral neuropathy (DPNP)
   Fibromyalgia (FM) (ICD-10 M79.7)
   Chronic musculoskeletal pain

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of, or contraindication to, or is unable to swallow duloxetine capsules

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   20 mg, 30 mg, 40 mg: #1 per day.
   60 mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of generalized anxiety disorder and meet **ALL** of the following criteria?
   The patient is 7 years of age or older
   The patient had a trial of, or contraindication to, or is unable to swallow duloxetine capsules

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   20 mg, 30 mg, 40 mg: #1 per day.
   60 mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DULOXETINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DULOXETINE (Drizalma Sprinkle)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Major depressive disorder (MDD: a type of mental illness)
- Diabetic peripheral neuropathy (DPNP: a type of nerve damage caused by high blood sugar)
- Fibromyalgia (FM: a type of pain disorder)
- Chronic musculoskeletal pain (severe pain relating to muscles and bones)
- Generalized anxiety disorder (GAD: a type of mental illness)

If you have major depressive disorder, diabetic peripheral neuropathy, fibromyalgia, or chronic musculoskeletal pain, approval also requires:
- You are 18 years of age or older
- You had tried, or have a contraindication to (harmful for you to use), or are unable to swallow duloxetine capsules

If you have generalized anxiety disorder, approval also requires:
- You are 7 years of age or older
- You had tried, or have a contraindication to (harmful for you to use), or are unable to swallow duloxetine capsules

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Drizalma Sprinkle.

REFERENCES
Drizalma Sprinkle [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2024.

Created:11/22
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 03/25

DUPILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUPILUMAB	DUPIXENT	44180		GPI-10 (9027302000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 6 months of age or older
   Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   Dupixent will NOT be used concurrently with another systemic biologic (e.g., Adbry [tralokinumab-ldrm]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic (e.g., Rinvoq [upadacitinib]) and is switching to Dupixent
   The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA)
   The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **ONE** of the following?
   Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole])
   Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   Phototherapy

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   200mg/1.14mL: #4.56mL.
   300mg/2mL: #8mL.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 1 week after the end date of the first approval):
   200mg/1.14mL: #2.28mL per 28 days.
   300mg/2mL: #4mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   The patient has a pre-treatment blood eosinophil level of 150 to 1500 cells/mcL
   Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma (ICD-10 J45.909) **AND** meet the following criterion?
   Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of oral corticosteroid-dependent asthma

   If yes, continue to #6.
   If no, continue to #10.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   Dupixent will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, continue to #9.
   If no, continue to #8.

8. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   Daytime asthma symptoms more than twice per week
   Any night waking due to asthma
   Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   Any activity limitation due to asthma

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

9. Is the request for the 100mg/0.67mL strength?

   If yes**, approve 100mg/0.67mL for 4 months by GPID or GPI-14 with a quantity limit of #1.34mL per 28 days.**

   If no, **approve for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   200mg/1.14mL: #4.56mL.
   300mg/2mL: #8mL.
   SECOND APPROVAL: Approve all formulations of the requested strength for 3 months as follows (enter a start date of 1 week after the end date of the first approval):
   200mg/1.14mL: #2.28mL per 28 days.
   300mg/2mL: #4mL per 28 days.

10. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
    The patient is 12 years of age or older
    Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
    There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
    The patient has inadequately controlled disease
    The patient had a 56-day trial of ONE intranasal corticosteroid (e.g., mometasone nasal spray)
    Dupixent will be used as add-on maintenance treatment (i.e., in conjunction with maintenance intranasal steroids)
    Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

    If yes, **approve all formulations of the 300mg/2mL strength for 6 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

    If no, continue to #11.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
    The patient is 1 year of age or older
    The patient weighs at least 15 kg (33 lbs)
    Therapy is prescribed by or in consultation with a gastroenterologist, allergist, or immunologist
    The patient had a trial of or contraindication to dietary therapy
    The patient had a trial of or contraindication to a proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)
    Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EoE

    If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
    200mg/1.14mL: #2.28mL per 28 days.
    300mg/2mL: #8mL per 28 days.

    If no, continue to #12.

12. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Therapy is prescribed by or in consultation with a dermatologist, immunologist, or allergist
    The patient has the presence of multiple pruriginous lesions (localized or general)
    The patient had a trial of or contraindication to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine
    Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nemluvio [nemolizumab-ilto]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

    If yes, **approve all formulations of the 300mg/2mL strength for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
    FIRST APPROVAL: Approve for 1 month with a quantity limit of #8mL.
    SECOND APPROVAL: Approve for 5 months with a quantity limit of #4mL per 28 days (enter a start date of 1 week after the end date of the first approval).

    If no, continue to #13.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

13. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has an eosinophilic phenotype COPD
Therapy is prescribed by or in consultation with a pulmonologist
Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere)
Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

If yes, **approve all formulations of the 300mg/2mL strength for 4 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:
You have ONE of the following:
Moderate to severe atopic dermatitis (AD: a type of skin condition)
Moderate to severe asthma (a type of lung condition)
Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
Eosinophilic esophagitis (EoE: a type of immune system disorder)
Prurigo nodularis (PN: a type of skin condition)
Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe atopic dermatitis, approval also requires:
- You are 6 months of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
- You meet ONE of the following:
  - You were previously stable on another biologic (such as Rinvoq [upadacitinib]) and are switching to Dupixent
  - You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
  - You have atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

If you have moderate to severe asthma, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
- You meet ONE of the following:
  - You have an eosinophilic phenotype asthma (a type of inflammatory asthma) and meet all of the following:
    - You have a pre-treatment blood eosinophil level (a type of lab test) of 150 to 1500 cells/mcL
    - You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
  - You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

Dupixent will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)

You meet ONE of the following:

- You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
- You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
- You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
  - Daytime asthma symptoms more than twice per week
  - Any night waking due to asthma
  - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
  - Any activity limitation due to asthma

If you have chronic rhinosinusitis with nasal polyps, approval also requires:

- You are 12 years of age or older
- Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
- You have inadequately controlled disease
- You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
- Dupixent will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids [a type of medication used in the nose])
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

If you have eosinophilic esophagitis, approval also requires:
- You are 1 year of age or older
- You weigh at least 15 kilograms (33 pounds)
- Therapy is prescribed by or in consultation with a gastroenterologist (a type of doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) dietary therapy
- You have tried or have a contraindication to (harmful for you to use) a proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

If you have prurigo nodularis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
- You have multiple pruriginous lesions (wounds)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

If you have chronic obstructive pulmonary disease, approval also requires:

- You are 18 years of age or older
- You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
- Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUPILUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient has shown improvement while on Dupixent
   Dupixent will NOT be used concurrently with another systemic biologic (e.g., Adbry [tralokinumab-ldrm]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   200mg/1.14mL: #2.28mL per 28 days.
   300mg/2mL: #4mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype (ICD-10 J82.83) **AND** meet the following criterion?
   Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma (ICD-10 J45.909) **AND** meet the following criterion?
   Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of oral corticosteroid-dependent asthma

   If yes, continue to #4.
   If no, continue to #6.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

4. Will the patient continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   Reduction in asthma exacerbations from baseline
   Decreased utilization of rescue medications (e.g., albuterol)
   Increase in percent predicted FEV1 from pretreatment baseline
   Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   100mg/0.67mL: #1.34mL per 28 days.
   200mg/1.14mL: #2.28mL per 28 days.
   300mg/2mL: #4mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve all formulations of the 300mg/2mL strength for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, continue to #7.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
   The patient has shown improvement while on Dupixent (e.g., symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less)
   Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EoE

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   200mg/1.14mL: #2.28mL per 28 days.
   300mg/2mL: #8mL per 28 days.

   If no, continue to #8.

8. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   The patient has had prurigo nodularis improvement (reduction) of pruritus or pruriginous lesions
   Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nemluvio [nemolizumab-ilto]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

   If yes, **approve all formulations of the 300mg/2mL strength for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
   The patient has an eosinophilic phenotype COPD
   Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere)
   Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

10. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
    The patient has a reduction in COPD exacerbations from baseline
    The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.)
    The patient has an increase in FEV1 of at least 5 percent from pretreatment baseline

    If yes, **approve all formulations of the 300mg/2mL strength for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

    If no, do not approve.

    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:
    You have ONE of the following:
    - Moderate to severe atopic dermatitis (AD: a type of skin condition)
    - Moderate to severe asthma (a type of lung condition)
    - Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
    - Eosinophilic esophagitis (EoE: a type of immune system disorder)
    - Prurigo nodularis (PN: a type of skin condition)
    - Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)

    If you have moderate to severe atopic dermatitis, renewal also requires:
    - You have shown improvement while on Dupixent
    - You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe asthma, renewal also requires:

- You meet ONE of the following:
  - You have an eosinophilic phenotype asthma (a type of inflammatory asthma), AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
  - You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
- You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)
- You have shown a clinical response as evidenced by ONE of the following:
  - You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
  - You have decreased your use of rescue medications (such as albuterol)
  - You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Dupixent)
  - You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

If you have chronic rhinosinusitis with nasal polyps, renewal also requires:

- You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

If you have eosinophilic esophagitis, renewal also requires:
- You have shown improvement while on Dupixent (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less [a type of test that evaluates disease status])
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

If you have prurigo nodularis, renewal also requires:
- You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

If you have chronic obstructive pulmonary disease, renewal also requires:
- You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
- Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
- You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD
- You have shown a clinical response as evidenced by ONE of the following:
  - You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
  - You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)
  - You have had an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Dupixent)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUPILUMAB

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Dupixent.

REFERENCES

Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2024.

Created: 01/17
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

DURVALUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DURVALUMAB	IMFINZI	44230		GPI-10 (2135822900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have resectable (node positive or tumors are at least 4 cm) cancer and meet **ALL** of the following criteria?
   Imfinzi will be used in combination with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery and prior use in combination with platinum-containing chemotherapy
   The patient has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have unresectable Stage III cancer **AND** meet the following criterion?
   The patient's disease has NOT progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have metastatic cancer and meet **ALL** of the following criteria?
   The patient does NOT have sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #6.
   If no, continue to #8.

6. Does the patient have limited-stage (LS) cancer **AND** meet the following criterion?
   The patient's disease has not progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have extensive-stage (ES) cancer **AND** meet the following criterion?
   Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Does the patient have a diagnosis of locally advanced or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Imfinzi will be used in combination with gemcitabine and cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (uHCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of primary advanced or recurrent endometrial cancer (ICD-10 C54.1) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient's cancer is mismatch repair deficient (dMMR)
    Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **DURVALUMAB (Imfinzi)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    - Resectable (can be removed by surgery) (node positive [has spread to the lymph nodes] or tumors are at least 4 cm) non-small cell lung cancer (a type of lung cancer)
    - Unresectable Stage III non-small cell lung cancer (a type of lung cancer that cannot be completely removed by surgery)
    - Metastatic non-small cell lung cancer (a type of lung cancer that has spread to other parts of the body)
    - Small cell lung cancer (SCLS: a type of lung cancer)
    - Locally advanced or metastatic biliary tract cancer (a type of biliary tract cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
    - Unresectable hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery)
    - Primary advanced or recurrent endometrial cancer (a type of uterus cancer that has spread or has returned after treatment)

    If you have resectable non-small cell lung cancer, approval also requires:
    - You are 18 years of age or older
    - Imfinzi will be used in combination with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) after surgery and previous use in combination with platinum-containing chemotherapy
    - You have no known epidermal growth factor receptor (EGFR: a type of protein) mutations or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

If you have unresectable Stage III non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your disease has NOT progressed (worsened) after using concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You do NOT have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene)
- Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

If you have small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have limited-stage cancer (LS: cancer that is contained in a single area on one side of the chest) AND your disease has not progressed following concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy
  - You have extensive-stage cancer (ES: cancer that has spread widely throughout the lungs or other parts of the body) and Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin (cCRT: concurrent chemoradiotherapy)

If you have locally advanced or metastatic biliary tract cancer, approval also requires:
- You are 18 years of age or older
- Imfinzi will be used in combination with gemcitabine and cisplatin

If you have unresectable hepatocellular carcinoma, approval also requires:
- You are 18 years of age or older
- Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

If you have primary advanced or recurrent endometrial cancer, approval also requires:
- You are 18 years of age or older
- Your cancer is mismatch repair deficient (dMMR: a type of gene mutation [abnormal change])
- Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DURVALUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imfinzi.

REFERENCES

Imfinzi [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; December 2024.

Created: 08/17
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

DUVELISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUVELISIB	COPIKTRA	45269		GPI-10 (2153803000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received at least two prior therapies for CLL or SLL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Relapsed or refractory chronic lymphocytic leukemia (CLL: a type of blood cancer that has returned after treatment or did not fully respond to treatment)
   - Small lymphocytic lymphoma (SLL: a type of blood cancer)

   You are 18 years of age or older
   You have received at least two prior therapies for chronic lymphocytic leukemia or small lymphocytic lymphoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Copiktra.

REFERENCES
Copiktra [Prescribing Information]. Las Vegas, NV: Secura Bio, Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/18

ECULIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECULIZUMAB	SOLIRIS	34618		GPI-10 (8580505000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a hematologist
   The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) or has a contraindication to Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
   Soliris will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #240mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #180mL per 28 days (please enter a start date of 1 day after the end date of the first approval).

   If no, continue to #3.

3. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a neurologist
   The patient has a positive serologic test for the anti-acetylcholine receptor (AChR) antibody
   The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #360mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #240mL per 28 days (please enter a start date of 1 day after the end date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist
   The patient is positive for anti-aquaporin-4 (AQP4) antibodies
   The patient had a trial of or contraindication to Ultomiris (ravulizumab-cwvz)
   Soliris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have at least **ONE** of the following core clinical characteristics?
   Optic neuritis
   Acute myelitis
   Area postrema syndrome
   Acute brainstem syndrome
   Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #360mL per 28 days.
   SECOND APPROVAL: Approve for 11 months with a quantity limit of #240mL per 28 days (please enter a start date of 1 day after the end date of the first approval).

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   Soliris (eculizumab) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)
   (Initial denial text continued on next page)

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
- You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
- You will NOT use Soliris concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

If you have generalized myasthenia gravis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive serologic (a type of blood) test for the anti-acetylcholine receptor (AChR) antibody (a type of blood test that shows you have myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have neuromyelitis optica spectrum disorder, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
- You have tried or have a contraindication to (harmful for you to use) Ultomiris (ravaulizumab-cwvz)
- You will NOT use Soliris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])
- You have at least ONE of the following core clinical characteristics:
  - Optic neuritis (a type of brain disorder)
  - Acute myelitis (a type of brain disorder)
  - Area postrema syndrome (a type of brain disorder)
  - Acute brainstem syndrome (a type of brain disorder)
  - Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECULIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   Soliris will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) **AND** meet the following criterion?
   The patient experienced a clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   The patient experienced a reduction in relapse frequency compared to baseline
   Soliris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ECULIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
- You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline
- You will NOT use Soliris concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

If you have generalized myasthenia gravis, renewal also requires:
- You have experienced a clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

If you have neuromyelitis optica spectrum disorder, renewal also requires:
- You have experienced a reduction in relapse frequency compared to baseline
- You will NOT use Soliris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Soliris.

REFERENCES

Soliris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2025.

Created: 08/13
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

EDARAVONE ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EDARAVONE	RADICAVA ORS		52318	GPI-14 (74509030001820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
   - The duration of patient's disease (from onset of symptoms) is 3 years or less
   - The patient has a forced vital capacity (FVC) greater than 70%
   - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
   - The patient has tried riluzole OR is currently taking riluzole

   If yes, **enter two approvals by GPID or GPI-14 for a total of 6 months as follows:**
   - **<u>FIRST APPROVAL</u>: Approve for 30 days with a quantity limit of #70mL per 28 days.**
   - **<u>SECOND APPROVAL</u>: Approve for 5 months with a quantity limit of #50mL per 28 days (Enter a start date of 2 days before the end of the first approval).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
   C. You have had ALS (from onset of symptoms) for 3 years or less
   D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of greater than 70 percent
   E. You have tried riluzole OR are currently taking riluzole
   (Initial denial text continued on next page)

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EDARAVONE ORAL

INITIAL CRITERIA (CONTINUED)

F. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved baseline functional ability OR the patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #50mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE ORAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava ORS.

REFERENCES

- Radicava ORS [Prescribing Information].]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

EFINACONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFINACONAZOLE	JUBLIA	41184		GPI-10 (9015403700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenail(s) and meets the following criteria?
   - The patient previously tried or has a contraindication to oral terbinafine OR oral itraconazole AND ciclopirox topical solution
   - The patient has at least **ONE** of the following conditions:
     - The patient has diabetes, peripheral vascular disease (PVD), or immunosuppression
     - The patient has pain surrounding the nail or soft tissue involvement

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #4mL (1 bottle) per 30 days.**
   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #8mL (2 bottles) per 30 days.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFINACONAZOLE (Jublia)** requires the following rule(s) be met for approval:
   You have onychomycosis of the toenail(s) (toenail fungus)
   A. You have previously tried the following unless contraindicated (a medical reason why you cannot use): ciclopirox topical solution AND either oral terbinafine OR oral itraconazole
   B. You have at least ONE of the following conditions:
      1. Diabetes, peripheral vascular disease (narrowed blood vessels reduce blood flow to the limbs), or immunosuppression (weakened immune system)
      2. Pain surrounding the nail or soft tissue involvement

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EFINACONAZOLE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jublia.

REFERENCES

- Jublia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 06/14
Client Approval: 04/20
P&T Approval: 01/17

ELAPEGADEMASE-LVLR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAPEGADEMASE-LVLR	REVCOVI	45340		GPI-10 (3090203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) (ICD-10 D81.31) as manifested by **ONE** of the following criteria?
   The patient has a confirmatory genetic test
   The patient has suggestive laboratory findings (e.g., elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) AND hallmark signs/symptoms (e.g., recurrent infections, failure to thrive, persistent diarrhea)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is therapy prescribed by or in consultation with an immunologist, hematologist-oncologist, or physician specializing in inherited metabolic disorders?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient has failed or is NOT a candidate for hematopoietic cell transplantation (HCT)
   Revcovi will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system) as shown by ONE of the following:
- You have a confirmatory genetic test
- You have suggestive laboratory findings (such as elevated deoxyadenosine nucleotide levels, lymphopenia [low levels of a type of white blood cell]) AND you have hallmark signs/symptoms (such as recurrent infections, failure to thrive, persistent diarrhea)

Therapy is prescribed by or in consultation with an immunologist (a type of immune system doctor), hematologist-oncologist (a type of blood-cancer doctor), or physician specializing in inherited metabolic disorders

You meet ONE of the following:
- You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow)
- Revcovi will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAPEGADEMASE-LVLR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) (ICD-10 D81.31) and meet **ALL** of the following criteria?
   The patient has a trough plasma adenosine deaminase (ADA) activity of at least 30 mmol/hr/L AND trough deoxyadenosine nucleotide (dAXP) levels less than 0.02 mmol/L
   The patient has improvement in or maintenance of immune function from baseline (e.g., decrease in number and severity of infections)
   The patient has NOT received a successful hematopoietic cell transplantation (HCT) or gene therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:
   You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system)
   You have a trough plasma adenosine deaminase (ADA) activity of at least 30 mmol/hr/L AND trough deoxyadenosine nucleotide (dAXP) levels less than 0.02 mmol/L
   You have shown improvement in or maintenance of immune function from baseline (such as a decrease in the number and severity of infections)
   You have NOT received successful hematopoietic cell transplantation (HCT: blood cell transplant from bone marrow) or gene therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES

Revcovi [Prescribing Information]. Cary, NJ: Chiesi USA, Inc.; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/19
Client Approval: 06/24
P&T Approval: 01/19

EFLAPEGRASTIM-XNST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFLAPEGRASTIM-XNST	ROLVEDON	48301		GPI-10 (8240151880)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLAPEGRASTIM-XNST (Rolvedon)** requires the following rule(s) be met for approval:
   You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   You are 18 years of age or older
   You have a non-myeloid malignancy (cancer not affecting bone marrow)
   Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rolvedon.

REFERENCES
Rolvedon [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; June 2023.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

EFLORNITHINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFLORNITHINE HCL	IWILFIN	21417		GPI-10 (2175722030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma (HRNB) **AND** meet the following criterion?
   The patient has demonstrated a partial response to prior therapy, including anti-GD2 immunotherapy (e.g., Unituxin [dinutuximab])

   If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLORNITHINE (Iwilfin)** requires the following rule(s) be met for approval:
   You have high-risk neuroblastoma (HRNB: a type of rare cancer)
   You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior therapy, including anti-GD2 immunotherapy (such as Unituxin [dinutuximab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iwilfin.

REFERENCES
Iwilfin [Prescribing Information]. Louisville, KY: US WorldMeds, LLC.; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 01/24

ELACESTRANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELACESTRANT HYDROCHLORIDE	ORSERDU	48658		GPI-10 (2140372010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor 1 gene (ESR1) mutation(s)
   - The patient has disease progression following endocrine therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths, with the following quantity limits:**
   345 mg: #1 per day.
   86 mg: #3 per day.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
   B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor 1 (ESR1: a gene) mutation(s)
   C. You have disease progression following endocrine therapy (disease has worsened after using a type of hormone therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELACESTRANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orserdu.

REFERENCES

- Orserdu [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/23
Client Approval: 05/23
P&T Approval: 04/23

ELAFIBRANOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAFIBRANOR	IQIRVO	49672		GPI-10 (5278002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   The patient has an elevated alkaline phosphatase (ALP) level
   The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
   The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   The patient does not have decompensated cirrhosis (Child-Pugh B or C) OR a prior decompensation event
   The patient does NOT have compensated cirrhosis with evidence of portal hypertension
   Iqirvo will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   Iqirvo will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   Iqirvo will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAFIBRANOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for approval:
- You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
  - You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
  - You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
  - You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
- You do not have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) OR a prior decompensation event (liver stops working properly)
- You do NOT have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) with evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
- You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])
- You meet ONE of the following:
  - Iqirvo will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
  - Iqirvo will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAFIBRANOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   The patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo
   Iqirvo will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for renewal:
   You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo
   You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iqirvo.

REFERENCES

Iqirvo [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/16/24
Created: 06/24
Client Approval: 09/24
P&T Approval: 04/24

ELAGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX SODIUM	ORILISSA	45108		GPI-10 (3009003010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient previously received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200mg twice daily
   - A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) or histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have moderate hepatic impairment (Child-Pugh Class B)?

   If yes, **approve 150 mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #4.

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ELAGOLIX

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet ONE of the following?
   - The patient has normal liver function
   - The patient has mild hepatic impairment (Child-Pugh Class A)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **150mg: #1 per day.**
   - **200mg: #2 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   D. Your diagnosis of endometriosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   E. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   F. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
   G. Requests will not be approved if you previously received ONE of the following:
      1. A 6-month course of Orilissa 200mg twice daily
      2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAGOLIX

RENEWAL CRITERIA

1. Has the patient previously received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200mg twice daily
   - A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient has had improvement of pain related to endometriosis while on therapy
   - The patient has normal liver function OR mild hepatic impairment (Child-Pugh Class A)
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, **approve 150mg for 18 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
   B. You have improvement of pain related to endometriosis while on therapy
   C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
   D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   E. Requests will not be approved if you previously received ONE of the following:
      1. A 6-month course of Orilissa 200mg twice daily
      2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

   (Renewal denial text continued on next page)

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ELAGOLIX

RENEWAL CRITERIA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orilissa.

REFERENCES

- Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 08/18
Client Approval: 09/23
P&T Approval: 04/22

ELBASVIR/GRAZOPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELBASVIR/ GRAZOPREVIR	ZEPATIER	43030		GPI-10 (1235990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older OR weighs at least 30 kg (66 lbs)
   The patient has genotype 1 or 4 infection

   If yes, continue to #2.
   If no, continue to #11.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   Zepatier will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., phenytoin, carbamazepine, rifampin, efavirenz [e.g., Atripla, Sustiva], atazanavir [e.g., Evotaz, Reyataz], darunavir [e.g., Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [e.g., Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John's wort)
   Zepatier will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naïve **AND** meets the following criterion?
   The patient had an intolerance or contraindication to ONE of the following preferred agents:
   Epclusa, Harvoni

   If yes, continue to #5.
   If no, continue to #7.

5. Does the patient meet **ONE** of the following criteria?
   The patient has genotype 1a infection AND does not have baseline NS5A polymorphisms
   The patient has genotype 1b infection
   The patient has genotype 4 infection
   The patient is post-kidney transplant AND does not have baseline NS5A RAS polymorphisms

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Does the patient meet **ALL** of the following criteria?
   The patient has genotype 1a infection
   The patient has baseline NS5A polymorphisms
   Zepatier will be used with ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #11.

7. Is the patient treatment-experienced **AND** meets the following criterion?
   The patient had an intolerance or contraindication to ONE of the following preferred agents:
   Epclusa, Harvoni

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have genotype 1 infection and meet **ONE** of the following criteria?
   The patient has genotype 1a infection, without baseline NS5A polymorphisms, AND failed prior treatment with peginterferon/ribavirin
   The patient has genotype 1b infection AND failed prior treatment with peginterferon/ribavirin
   The patient failed prior treatment with a peginterferon/ribavirin/protease inhibitor triple regimen AND Zepatier will be used with ribavirin

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #9.

9. Does the patient meet **ONE** of the following criteria?
   The patient has genotype 1a infection with baseline NS5A polymorphisms, failed prior treatment with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   The patient has genotype 4 infection, failed prior treatment with peginterferon/ribavirin, AND Zepatier will be used with ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #10.

10. Is the patient post-kidney transplant and meets **ALL** of the following criteria?
    The patient failed prior treatment with a non-direct acting antiviral agent (e.g., interferon)
    The patient does not have baseline NS5A RAS polymorphisms

    If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
    If no, continue to #11.

11. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

- You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
- You are 12 years of age or older OR weigh at least 30 kilograms (66 pounds)
- You have genotype 1 or 4 hepatitis C infection (types of hepatitis C virus)
- You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
- You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
- You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
- You will NOT use Zepatier concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as phenytoin, carbamazepine, rifampin, efavirenz [such as Atripla, Sustiva], atazanavir [such as Evotaz, Reyataz], darunavir [such as Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [such as Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John's wort)
- You will NOT use Zepatier concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
- You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Harvoni

If you are treatment-naive (no prior treatment), approval also requires ONE of the following:

- You have genotype 1a infection AND you do not have baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein)
- You have genotype 1b infection
- You have genotype 4 infection
- You received a kidney transplant (replaced your kidney) AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)
- You have genotype 1a infection, with baseline NS5A polymorphisms, AND Zepatier will be used with ribavirin

(Denial text continued on next page)

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:

- You have genotype 1a infection, without baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein), AND were previously treated with peginterferon/ribavirin
- You have genotype 1b infection AND were previously treated with peginterferon/ribavirin
- You have genotype 1 infection, were previously treated with a peginterferon/ribavirin/protease inhibitor triple regimen, AND Zepatier will be used with ribavirin
- You have genotype 1a infection with baseline NS5A polymorphisms, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
- You have genotype 4 infection, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
- You received a kidney transplant (replaced your kidney), were previously treated with a non-direct acting antiviral (such as interferon), AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)

Zepatier will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELBASVIR/GRAZOPREVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepatier.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 29, 2023.

Zepatier [Prescribing Information]. Rahway, NJ: Merck; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/22/24
Created: 02/16
Client Approval: 06/24
P&T Approval: 04/24

ELAGOLIX/ESTRADIOL/NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX AND ESTRADIOL AND NORETHINDRONE	ORIAHNN	46577		GPI-10 (2499350340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** of following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or given in consultation with an OB/GYN

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) requires the patient had improvement of heavy menstrual bleeding.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You are 18 years of age or older
   C. You are a premenopausal woman
   D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
   E. You have not received a total of 24 months cumulative treatment with Oriahnn
   (Initial denial text continued on next page)

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You had improvement of heavy menstrual bleeding on therapy
   C. You have not received a total of 24 months cumulative treatment with Oriahnn

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

ELAGOLIX/ESTRADIOL/NORETHINDRONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oriahnn.

REFERENCES

- Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 08/20
Client Approval: 11/20
P&T Approval: 07/20

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA	46112		GPI-10 (4530990340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   The patient has at least ONE F508del mutation or a responsive mutation in the CFTR gene

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   80-40-60mg granule packets: #2 per day.
   100-50-75mg granule packets: #2 per day.
   50-25-37.5mg tablets: #3 per day.
   100-50-75mg tablets: #3 per day.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:
   You have cystic fibrosis (CF: a type of lung disorder)
   You are 2 years of age or older
   Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   You have at least ONE F508del mutation (abnormal change) or a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Trikafta)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   The patient has experienced an improvement in clinical status
   Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by GPID or GPI-14 for all of the following:**
   80-40-60mg granule packets: #2 per day.
   100-50-75mg granule packets: #2 per day.
   50-25-37.5mg tablets: #3 per day.
   100-50-75mg tablets: #3 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:
   You have cystic fibrosis (CF: a type of lung disorder)
   You have experienced an improvement in your clinical status
   You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trikafta.

REFERENCES

Trikafta [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; August 2023.

Created: 02/20
Effective: 01/28/25 Client Approval: 01/25 P&T Approval: 01/25

ELTROMBOPAG - ALVAIZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG CHOLINE	ALVAIZ	49330		GPI-10 (8240503005)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   The patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy
   Alvaiz will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) or a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])
   The patient had a trial of or contraindication to Promacta (eltrombopag)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has a platelet count of less than 30 x 10^9/L
   The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy
   The patient had a trial of or contraindication to Promacta (eltrombopag)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   9mg: #1 per day.
   18mg: #1 per day.
   36mg: #2 per day.
   54mg: #1 per day.

   If no, continue to #4.

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ELTROMBOPAG - ALVAIZ

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had an insufficient response to immunosuppressive therapy
   The patient had a trial of or contraindication to Promacta (eltrombopag)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   18mg: #1 per day.
   36mg: #2 per day.
   54mg: #2 per day.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   - Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   - Severe aplastic anemia (a type of blood disorder)

   If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:
   - You are 6 years of age or older
   - You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
   - You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])
   - You have tried or have a contraindication to (harmful for you to use) Promacta (eltrombopag)
   - You meet ONE of the following:
     - You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
     - You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   (Initial denial text continued on next page)

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ELTROMBOPAG - ALVAIZ

INITIAL CRITERIA (CONTINUED)

If you have thrombocytopenia due to chronic hepatitis C, approval also requires:
- You are 18 years of age or older
- Your thrombocytopenia does not allow you to start interferon-based therapy (a type of drug for hepatitis) or limits your ability to maintain interferon-based therapy
- You have tried or have a contraindication to (harmful for you to use) Promacta (eltrombopag)

If you have severe aplastic anemia, approval also requires:
- You are 18 years of age or older
- You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)
- You have tried or have a contraindication to (harmful for you to use) Promacta (eltrombopag)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - ALVAIZ

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   Alvaiz will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) or a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rules be met for renewal:
   You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Alvaiz) OR a decrease in bleeding events
   You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - ALVAIZ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alvaiz.

REFERENCES

Alvaiz [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 02/24
Client Approval: 09/24
P&T Approval: 04/24

ELTROMBOPAG - PROMACTA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA	35989		GPI-10 (8240503010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy
   Promacta will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has a platelet count of less than 30 x 10^9/L
   The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 2 months by GPID or GPI-14 for all of the following strengths and formulations:**
   12.5mg tablet: #1 per day.
   25mg tablet: #1 per day.
   50mg tablet: #1 per day.
   75mg tablet: #1 per day.
   12.5mg packets: #1 per day.
   25mg packets: #3 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
   The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   12.5mg tablet: #1 per day.
   25mg tablet: #1 per day.
   50mg tablet: #2 per day.
   75mg tablet: #1 per day.
   12.5mg packets: #1 per day.
   25mg packets: #4 per day.

   If no, continue to #4.

4. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   12.5mg tablet: #3 per day.
   25mg tablet: #1 per day.
   50mg tablet: #2 per day.
   75mg tablet: #2 per day.
   12.5mg packets: #3 per day.
   25mg packets: #6 per day.

   If no, continue to #5.

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9) **AND** meet the following criterion?
   The patient had an insufficient response to immunosuppressive therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   12.5mg tablet: #1 per day.
   25mg tablet: #1 per day.
   50mg tablet: #2 per day.
   75mg tablet: #2 per day.
   12.5mg packets: #1 per day.
   25mg packets: #6 per day.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Persistent or chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
   - Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   - Severe aplastic anemia (a type of blood disorder)

   If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:
   - You are 1 year of age or older
   - You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, or you did not have a good enough response to a splenectomy (spleen removal)
   - You will NOT use Promacta concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])
   - You meet ONE of the following:
     - You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
     - You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   (Initial denial text continued on next page)

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

If you have thrombocytopenia due to chronic hepatitis C, approval also requires:
Your thrombocytopenia does not allow you to start interferon-based therapy (a type of drug for hepatitis) or limits your ability to maintain interferon-based therapy
If you have severe aplastic anemia, approval also requires:
You meet ONE of the following:
You are 2 years of age or older and Promacta will be used in combination (together) with standard immunosuppressive therapy (treatment that lowers the activity of the body's immune system) as first-line treatment (used for initial treatment)
You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - PROMACTA

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   Promacta will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   12.5mg tablet: #1 per day.
   25mg tablet: #1 per day.
   50mg tablet: #1 per day.
   75mg tablet: #1 per day.
   12.5mg packets: #1 per day.
   25mg packets: #3 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rules be met for renewal:
   You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Promacta) OR a decrease in bleeding events
   You will NOT use Promacta concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - PROMACTA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Promacta.

REFERENCES

Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 01/09
Client Approval: 08/24
P&T Approval: 04/24

EMICIZUMAB-KXWH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMICIZUMAB-KXWH	HEMLIBRA	44640		GPI-10 (8510503020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist
   Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   Hemlibra will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hympavzi [marstacimab-hncq])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a patient WITH factor VIII inhibitors **AND** the patient meets the following criterion?
   The patient has a history of a high titer of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for a patient WITHOUT factor VIII inhibitors?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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EMICIZUMAB-KXWH

INITIAL CRITERIA (CONTINUED)

5. Does the patient have mild hemophilia A, defined as 5 percent - 40 percent factor VIII activity compared to normal, and meet **ONE** of the following criteria?
   The patient has experienced severe, traumatic, or spontaneous bleeding episode(s) (may occur in joint or muscle)
   The patient has experienced a life-threatening bleed (e.g., intracranial hemorrhage [ICH])
   The patient has venous access difficulties impeding regular clotting factor infusions

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:
   You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])
   If you have hemophilia A with factor VIII inhibitors (a type of protein), approval also requires:
      You have a history of a high titer (concentration) of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter
   If you have hemophilia A without factor VIII inhibitors (a type of protein), approval also requires ONE of the following:
      You have moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal
      You have mild hemophilia A, defined as 5 percent - 40 percent factor VIII activity compared to normal, and meet ONE of the following:
         You have experienced severe, traumatic, or spontaneous (sudden) bleeding episode(s) (may occur in joint or muscle)
         You have experienced a life-threatening bleed (such as intracranial hemorrhage [ICH: a type of bleeding in the head])
         It is difficult to access your veins which prevents or delays you in receiving regular clotting factor infusions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EMICIZUMAB-KXWH

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   The patient has shown a clinical benefit compared to baseline
   Hemlibra will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hympavzi [marstacimab-hncq])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:
   You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   You have shown a clinical benefit compared to baseline (before starting Hemlibra)
   You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hemlibra.

REFERENCES

Hemlibra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/25/24
Created: 02/18
Client Approval: 11/24
P&T Approval: 10/24

ENASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENASIDENIB	IDHIFA	44450		GPI-10 (2153503020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:

   A. You have relapsed or refractory acute myeloid leukemia (a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
   B. You are 18 years of age or older
   C. You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Idhifa.

REFERENCES

- Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/17
Client Approval: 04/20
P&T Approval: 10/17

ENCORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		GPI-10 (2153204000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
   Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
   The patient has a BRAF V600E mutation, as detected by an FDA-approved test

   If yes, continue to #3.
   If no, continue to #5.

3. Will Braftovi be used in combination with Erbitux (cetuximab) and mFOLFOX6 (fluorouracil, leucovorin and oxaliplatin)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

4. Will Braftovi be used in combination with Erbitux (cetuximab) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received prior therapy (e.g., irinotecan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENCORAFENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
- Metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

If you have unresectable or metastatic melanoma, approval also requires:
- You have a BRAF V600E or V600K mutation (abnormal change in types of genes), as detected by a Food and Drug Administration (FDA)-approved test
- Braftovi will be used in combination with Mektovi (binimetinib)

If you have metastatic colorectal cancer, approval also requires:
- You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- You meet ONE of the following:
  - Braftovi will be used in combination with Erbitux (cetuximab) and mFOLFOX6 (fluorouracil, leucovorin and oxaliplatin)
  - Braftovi will be used in combination with Erbitux (cetuximab), you are 18 years of age or older, and you have previously received treatment (such as irinotecan)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- Braftovi will be used in combination with Mektovi (binimetinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Braftovi.

REFERENCES

Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; December 2024.

Created: 08/18
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/25

ENSIFENTRINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENSIFENTRINE	OHTUVAYRE	49726		GPI-10 (4443002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Ohtuvayre will be used as maintenance treatment
   Therapy is prescribed by or in consultation with a pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a blood eosinophil level of 100 cells/microliter or greater?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUE ON NEXT PAGE

ENSIFENTRINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for approval:
You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
You are 18 years of age or older
Ohtuvayre will be used as maintenance treatment (taken on a regular basis)
Therapy is prescribed by or in consultation with a pulmonologist (a type of lung/breathing doctor)
You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
- LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
- LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUE ON NEXT PAGE

ENSIFENTRINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a blood eosinophil level of 100 cells/microliter or greater?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   The patient has a reduction in COPD exacerbations from baseline
   The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.)
   The patient has an increase in FEV1 by at least 5 percent from pretreatment baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

CONTINUE ON NEXT PAGE

ENSIFENTRINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for renewal:
You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
- LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
- LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater

You have shown a clinical response as evidenced by ONE of the following:
- You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Ohtuvayre)
- You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum (mucus) production, etc.)
- You have an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Ohtuvayre)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ohtuvayre.

REFERENCES

Ohtuvayre [Prescribing Information]. Raleigh, NC: Verona Pharma, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 07/24
Client Approval: 07/24
P&T Approval: 04/24

ENTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		GPI-10 (2153382000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has *ROS1*-positive tumors, as detected by an FDA-approved test

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of solid tumors and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, as detected by an FDA-approved test
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - The patient has progressed following treatment or there are no satisfactory alternative treatments

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Rozlytrek (100mg or 200mg) capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **100mg: #5 per day.**
   - **200mg: #3 per day.**

   If no, continue to #4.

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ENTRECTINIB

GUIDELINES FOR USE (CONTINUED)

4. Is the request for Rozlytrek 50mg pellets and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to Rozlytrek capsules made into an oral suspension
   - The patient has difficulty or is unable to swallow capsules

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **50mg: #12 per day.**
   - **100mg: #5 per day.**
   - **200mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Solid tumors (an abnormal mass)
   B. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. You are 18 years of age or older
      2. You have ROS1-positive (abnormal change in a type of gene) tumors, as detected by a Food and Drug Administration (FDA)-approved test
   C. **If you have solid tumors, approval also requires:**
      1. You are 1 month of age or older
      2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (you have an abnormal change in a type of gene that does not have any known resistance), as detected by a Food and Drug Administration (FDA)-approved test
      3. Your tumor is metastatic (has spread to other parts of the body) or surgical resection (removal) is likely to result in severe morbidity (disease)
      4. You have progressed (gotten worse) after treatment or there are no satisfactory alternative treatments
   D. **If the request is for Rozlytrek 50mg pellets, approval also requires:**
      1. You have tried or have a contraindication to (harmful for you to use) Rozlytrek capsules that are used to make an oral suspension
      2. You have difficulty or are not able to swallow capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENTRECTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

- Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 11/19
Client Approval: 11/23
P&T Approval: 01/24

ENZALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENZALUTAMIDE	XTANDI	39580		GPI-10 (2140243000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   Metastatic castration-resistant prostate cancer (mCRPC)
   Metastatic castration-sensitive prostate cancer (mCSPC)

   If yes, continue to #4.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC) **AND** meet the following criterion?
   The patient is at high risk for metastasis (i.e., prostate specific antigen [PSA] doubling time over 9 months or less)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ENZALUTAMIDE

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient has received a bilateral orchiectomy
   The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   Xtandi will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   40 mg: #4 per day.
   80 mg: #2 per day.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
   - Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
   - Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   - Non-metastatic castration-sensitive prostate cancer (nmCSPC: prostate cancer that has not spread to other parts of the body and responds to hormone therapy)

   If you have metastatic castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer, approval also requires that you meet ONE of the following:
   - You have received a bilateral orchiectomy (surgical removal of both testicles)
   - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   - Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

   (Initial denial text continued on next page)

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ENZALUTAMIDE

INITIAL CRITERIA (CONTINUED)

If you have non-metastatic castration-resistant prostate cancer, approval also requires:
- You have high-risk prostate cancer (rapidly increasing prostate specific antigen levels)
- You meet ONE of the following:
  - You have received a bilateral orchiectomy (surgical removal of both testicles)
  - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  - Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

If you have non-metastatic castration-sensitive prostate cancer, approval also requires:
- You are at high risk for metastasis (your prostate specific antigen level has doubled over 9 months or less)
- You meet ONE of the following:
  - You have received a bilateral orchiectomy (surgical removal of both testicles)
  - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  - Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENZALUTAMIDE

RENEWAL CRITERIA

NOTE: For the diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC), please refer to the Initial Criteria section.

1. Does the patient have **ONE** of the following diagnoses?
   Metastatic castration-resistant prostate cancer (mCRPC)
   Metastatic castration-sensitive prostate cancer (mCSPC)
   Non-metastatic castration-resistant prostate cancer (nmCRPC)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has received a bilateral orchiectomy
   The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   Xtandi will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   40 mg: #4 per day.
   80 mg: #2 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
   - Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
   - Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

   (Renewal denial text continued on next page)

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ENZALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have received a bilateral orchiectomy (surgical removal of both testicles)
- You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
- Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Xtandi.

REFERENCES
Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 09/12
Client Approval: 02/24
P&T Approval: 01/24

EPLONTERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPLONTERSEN SODIUM	WAINUA	49355		GPI-10 (6270102510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.8mL per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPLONTERSEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for approval:

- You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
- You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
- You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])
- Your diagnosis is confirmed by ONE of the following:
  - Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (*transthyretin*) protein
  - DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPLONTERSEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   The patient has not progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for renewal:
   You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   You have not progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPLONTERSEN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wainua.

REFERENCES

Wainua [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/24
Client Approval: 05/24
P&T Approval: 04/24

EPOETIN ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOETIN ALFA	EPOGEN, PROCRIT	04553		GPI-10 (8240102000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #2.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #3.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #4.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 10g/dL
   The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #5.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

5. Is the patient undergoing elective, noncardiac, nonvascular surgery and meet **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 13g/dL

   If yes, **approve for 1 month by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rules be met for approval:
   You have ONE of the following:
   - Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   - Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   - Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
   - Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   - You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

   (Initial denial text continued on next page)

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

If you have anemia due to chronic kidney disease, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
Your hemoglobin level (a type of blood test) is less than 10g/dL

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
Your hemoglobin level is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
Your hemoglobin level is less than 10g/dL

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
Your hemoglobin level is less than 10g/dL

If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
Your hemoglobin level is less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meet **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL if not on dialysis
   The patient's hemoglobin level is less than 11g/dL if on dialysis
   The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #3.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL
   The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy **AND** meet the following criterion?
   The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #5.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   Procrit 2,000U/mL: #12mL per 28 days.
   Procrit 3,000U/mL: #12mL per 28 days.
   Procrit 4,000U/mL: #12mL per 28 days.
   Procrit 10,000U/mL: #12mL per 28 days.
   Procrit 20,000U/mL: #12mL per 28 days.
   Procrit 40,000U/mL: #4mL per 28 days.
   Procrit 20,000U/2mL: #12mL per 28 days.
   Epogen 2,000U/mL: #12mL per 28 days.
   Epogen 3,000U/mL: #12mL per 28 days.
   Epogen 4,000U/mL: #12mL per 28 days.
   Epogen 10,000U/mL: #12mL per 28 days.
   Epogen 20,000U/mL: #12mL per 28 days.
   Epogen 20,000U/2mL: #12mL per 28 days.

   If no, continue to #6.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
The patient's hemoglobin level is between 10g/dL and 12g/dL

If yes, **approve for 6 months by GPID or GPI-14 for the requested agent as follows**:
Procrit 2,000U/mL: #12mL per 28 days.
Procrit 3,000U/mL: #12mL per 28 days.
Procrit 4,000U/mL: #12mL per 28 days.
Procrit 10,000U/mL: #12mL per 28 days.
Procrit 20,000U/mL: #12mL per 28 days.
Procrit 40,000U/mL: #4mL per 28 days.
Procrit 20,000U/2mL: #12mL per 28 days.
Epogen 2,000U/mL: #12mL per 28 days.
Epogen 3,000U/mL: #12mL per 28 days.
Epogen 4,000U/mL: #12mL per 28 days.
Epogen 10,000U/mL: #12mL per 28 days.
Epogen 20,000U/mL: #12mL per 28 days.
Epogen 20,000U/2mL: #12mL per 28 days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
- Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
- Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
- Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:
- Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level is less than 11g/dL if you are on dialysis
- Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions
- Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:
- Your hemoglobin level is less than 10g/dL
- Your hemoglobin level has approached or exceeds 12g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Procrit, Epogen.

REFERENCES
Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; July 2018.
Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/24
Created: 02/11
Client Approval: 05/24
P&T Approval: 10/23

EPOETIN ALFA-EPBX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOETIN ALFA-EPBX	RETACRIT	44931		GPI-10 (8240102004)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ONE** of the following criteria?
   The patient's hemoglobin level is less than 11g/dL
   The patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #3.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL
   The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #5.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

5. Is the patient undergoing elective, noncardiac, nonvascular surgery **AND** meet the following criterion?
   The patient's hemoglobin level is less than 13g/dL

   If yes, **approve for 1 month by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Anemia (a type of blood condition) due to chronic kidney disease (CKD: a long-term kidney disease)
   - Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   - Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
   - Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   - You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

   If you have anemia due to chronic kidney disease, approval also requires:
   - Your hemoglobin level (a type of blood test) is less than 10g/dL

   If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:
   - Your hemoglobin level is less than 11g/dL
   - Your hemoglobin level has decreased at least 2g/dL below your baseline level

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
Your hemoglobin level is less than 10g/dL

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
Your hemoglobin level is less than 10g/dL

If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
Your hemoglobin level is less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL if not on dialysis
   The patient's hemoglobin level is less than 11g/dL if on dialysis
   The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #3.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and the patient meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL
   The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) **AND** meet the following criterion?
   The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #5.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, continue to #6.

6. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
   The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   2,000U/mL: #12mL per 28 days.
   3,000U/mL: #12mL per 28 days.
   4,000U/mL: #12mL per 28 days.
   10,000U/mL: #12mL per 28 days.
   20,000U/mL: #12mL per 28 days.
   40,000U/mL: #4mL per 28 days.
   20,000U/2mL: #12mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Anemia (a type of blood condition) due to chronic kidney disease (CKD: a long-term kidney disease)
- Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
- Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
- Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:
- Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level is less than 11g/dL if you are on dialysis
- Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions
- Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:
- Your hemoglobin level is less than 10g/dL
- Your hemoglobin level has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
- Your hemoglobin level is between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA-EPBX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retacrit.

REFERENCES

Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

ERDAFITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERDAFITINIB	BALVERSA	45687		GPI-10 (2153222500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible FGFR3 genetic alteration as detected by an FDA-approved companion diagnostic test
   - The patient has disease progression on or after at least one line of prior systemic therapy (e.g., cisplatin, Keytruda [pembrolizumab])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   3mg: #3 per day.
   4mg: #2 per day.
   5mg: #1 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:
   You have locally advanced or metastatic urothelial carcinoma (a type of bladder cancer that has spread to nearby tissue or other parts of the body)
   You are 18 years of age or older
   You have a susceptible (can be treated with the drug) fibroblast growth factor receptor 3 (FGFR3: a type of protein) genetic alteration (mutation) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
   You have disease progression (condition has worsened) on or after at least one line of prior systemic therapy (treatment that targets the entire body, such as cisplatin, Keytruda [pembrolizumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERDAFITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

- Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 04/19
Client Approval: 01/24
P&T Approval: 04/24

ERENUMAB-AOOE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERENUMAB-AOOE	AIMOVIG	44923		GPI-10 (6770202010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Aimovig is prescribed for the preventive treatment of migraines
   Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Aimovig is prescribed for the preventive treatment of migraines
   Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ERENUMAB-AOOE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:
You have migraines (a type of headache)
If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Aimovig is prescribed for the preventive treatment of migraines
- You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
- You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Aimovig is prescribed for the preventive treatment of migraines
- You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
- You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only National Drug Code (NDC) 00023-1145-01 or NDC 00023-3921-02 are allowable]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RENEWAL CRITERIA

1. Is Aimovig being prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy
   The patient has experienced a reduction in migraine severity with Aimovig therapy
   The patient has experienced a reduction in migraine duration with Aimovig therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:
   Aimovig is being prescribed for the preventive treatment of migraines
   You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   You meet ONE of the following:
      You have experienced less migraines or headache attacks by at least 2 days per month with Aimovig therapy
      You have experienced a lessening in migraine severity with Aimovig therapy
      You have experienced a lessening in migraine duration with Aimovig therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Aimovig.

REFERENCE
Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERGOTAMINE-CAFFEINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERGOTAMINE TARTRATE/CAFFEINE	MIGERGOT	01868		GPI-10 (6799100210)	ROUTE ≠ ORAL

GUIDELINES FOR USE

1. Is Migergot being used to abort or prevent vascular headaches (e.g., migraine, migraine variants, so-called 'histaminic cephalalgia') and the patient meets **ALL** of the following criteria?
   - The patient cannot swallow ergotamine/caffeine tablets
   - The patient had a trial of or contraindication to generic ergotamine/caffeine tablets AND two triptans (e.g., sumatriptan, rizatriptan)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #24 per 30 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERGOTAMINE-CAFFEINE (Migergot)** requires the following rule(s) be met for approval:
   A. Migergot is being used to abort (stop) or prevent vascular headaches (such as migraines, migraine variants, so-called 'histaminic cephalalgia' [types of headaches])
   B. You cannot swallow ergotamine/caffeine tablets
   C. You had a trial of or contraindication (harmful for) to generic ergotamine/caffeine tablets AND two triptans (such as sumatriptan, rizatriptan)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Migergot.

REFERENCES

- Migergot [Prescribing Information]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc., August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:04/01/23
Created: 11/22
Client Approval: 02/23
P&T Approval: 10/22

ERLOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERLOTINIB HCL	TARCEVA, ERLOTINIB HCL	26745		GPI-10 (2136002510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - Tarceva (erlotinib) will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   25mg: #2 per day.
   100mg: #2 per day.
   150mg: #3 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with gemcitabine
   - The medication will be used as a first line treatment

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   25mg: #2 per day.
   100mg: #2 per day.
   150mg: #3 per day.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
      2. Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

(Denial text continued on next page)

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ERLOTINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test
   2. You will NOT be using Tarceva (erlotinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarceva.

REFERENCES

- Tarceva [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/10
Client Approval: 05/22
P&T Approval: 04/22

ESKETAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESKETAMINE HCL	SPRAVATO	41003		GPI-10 (5811002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a psychiatrist
   The patient has non-psychotic, unipolar depression
   The patient does NOT have active substance abuse
   (**NOTE:** Treatment resistant depression is defined as a treatment failure after trial of two or more antidepressant medications of adequate dose and duration.)

   If yes, **approve for a total of 3 months by HICL or GPI-10 as follows:**
   INDUCTION DOSE: Approve for 30 days with a quantity limit of #1 per day.
   MAINTENANCE DOSE: Approve for 2 months with a quantity limit of #12 per 28 days (Enter a start date of 2 days before the end of the induction dose approval).

   If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Spravato will be used in combination with an oral antidepressant (e.g., Zoloft [sertraline], Cymbalta [duloxetine])
   The patient has acute suicidal ideation or behavior
   Therapy is prescribed by or in consultation with a psychiatrist
   The patient has non-psychotic, unipolar depression
   The patient does NOT have active substance abuse

   If yes, **approve for 4 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ESKETAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
- Major depressive disorder (MDD: a type of mental illness)

If you have treatment-resistant depression, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
- You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
- You do NOT have active substance (drug) abuse

If you have major depressive disorder, approval also requires:
- You are 18 years of age or older
- Spravato will be used in combination with an oral antidepressant (such as Zoloft [sertraline], Cymbalta [duloxetine])
- You have acute (short-term) suicidal ideation or behavior (thoughts of killing yourself)
- Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
- You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
- You do NOT have active substance (drug) abuse

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ESKETAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) **AND** meet the following criterion?
   The patient has demonstrated clinical benefit (improvement in depression) compared to baseline
   (**NOTE:** Treatment resistant depression is defined as a treatment failure after trial of two or more antidepressant medications of adequate dose and duration.)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) **AND** meet the following criterion?
   The patient has demonstrated clinical benefit (improvement in depression) compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
   - Major depressive disorder (MDD: a type of mental illness)

   You have demonstrated clinical benefit (improvement in depression) compared to baseline (before treatment)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spravato.

REFERENCES

Spravato [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2025.

Created: 05/19
Effective: 02/17/25 Client Approval: 01/25 P&T Approval: 04/25

ETANERCEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETANERCEPT	ENBREL	18830		GPI-10 (6629003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #3.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., naproxen, ibuprofen, meloxicam)

   If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #5.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 4 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Enbrel
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 3 months with the following quantity limits:
   25mg: #16 vials OR #8mL per 28 days.
   50mg: #8mL per 28 days.
   SECOND APPROVAL: Approve for 3 months with the following quantity limits:
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as naproxen, ibuprofen, meloxicam)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:

- You are 4 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Enbrel
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #3.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, continue to #5.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   25mg: #8 vials OR #4mL per 28 days.
   50mg: #4mL per 28 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Ankylosing spondylitis (AS: a type of joint condition)
   - Moderate to severe plaque psoriasis (PsO: a type of skin condition)

   If you have moderate to severe rheumatoid arthritis, renewal also requires:
   - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

   (Renewal denial text continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enbrel.

REFERENCES

Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; September 2024.

Created: 02/03
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

ETEPLIRSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETEPLIRSEN	EXONDYS-51	43770		GPI-10 (7460003500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   The patient has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping therapy
   Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of DMD at a DMD treatment center
   The patient is ambulatory
   The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETEPLIRSEN (Exondys 51)** requires the following rule(s) be met for approval:
   You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   You have a confirmed mutation (abnormal change in a type of gene) in the DMD gene that will respond to exon 51 skipping therapy (a type of therapy to treat DMD)
   Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of DMD at a DMD treatment center
   You are ambulatory (able to walk)
   You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETEPLIRSEN

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETEPLIRSEN (Exondys 51)** requires ONE of the following rule(s) be met for renewal:
   You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exondys 51.

REFERENCES

Exondys 51 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; December 2024.

Created: 01/16
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 10/20

ETHACRYNIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETHACRYNIC ACID	EDECRIN, ETHACRYNIC ACID	03659		GPI-10 (3720002000)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Edema associated with congestive heart failure, cirrhosis of the liver, or renal disease (including nephrotic syndrome)
   - Ascites due to malignancy, idiopathic edema, or lymphedema

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a trial of or contraindication to **TWO** generic loop diuretics (e.g., furosemide, bumetanide, torsemide)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETHACRYNIC ACID (Edecrin)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), cirrhosis (liver damage), or renal disease (including nephrotic syndrome [a type of kidney disorder])
      2. Ascites (accumulation of fluid in the abdominal cavity) due to malignancy (cancer), idiopathic (unknown cause) edema, or lymphedema (swelling in an arm or leg due to build-up of lymph fluid)
   B. You had a trial of or contraindication (harmful for) to TWO generic loop diuretics (such as furosemide, bumetanide, torsemide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETHACRYNIC ACID

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Edecrin.

REFERENCES

- Edecrin [Prescribing Information]. Greenville, NC: Bausch Health Companies, Inc., August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

ETRASIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETRASIMOD ARGININE	VELSIPITY	49267		GPI-10 (5250452510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for approval:
   You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
   (Initial denial text continued on the next page)

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ETRASIMOD

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETRASIMOD

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for renewal:
   You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
   You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETRASIMOD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Velsipity.

REFERENCES

Velsipity [Prescribing Information]. New York, NY: Pfizer, Inc.; June 2024.

Created: 10/23
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

EVEROLIMUS-AFINITOR DISPERZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR DISPERZ, EVEROLIMUS		34589 34590 34592	GPI-14 (21532530007310 21532530007320 21532530007340)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Afinitor Disperz will be used as adjunctive treatment

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS (Afinitor Disperz)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
      2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures

   B. **If you have tuberous sclerosis complex (TSC)-subependymal giant cell astrocytoma (SEGA), approval also requires:**
      1. You are 1 year of age or older
      2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

   C. **If you have tuberous sclerosis complex (TSC)-associated partial-onset seizures, approval also requires:**
      1. You are 2 years of age or older
      2. Afinitor Disperz will be used as adjunctive (add-on) treatment

   (Denial text continued on next page)

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EVEROLIMUS-AFINITOR DISPERZ

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor Disperz.

REFERENCES

- Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 03/23
Client Approval: 03/23
P&T Approval: 04/18

EVEROLIMUS-AFINITOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR, TORPENZ, EVEROLIMUS		20784 20844 28783 31396	GPI-14 (21532530000330 21532530000310 21532530000320 21532530000325)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced hormone receptor (HR)-positive, HER2-negative breast cancer and meet **ALL** of the following criteria?
   The patient is a postmenopausal woman
   The requested medication will be used in combination with exemestane
   The patient has failed or has a contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   2.5mg: #1 per day.
   5mg: #1 per day.
   7.5mg: #2 per day.
   10mg: #2 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has neuroendocrine tumors of pancreatic origin (PNET)
   The patient has well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   2.5mg: #1 per day.
   5mg: #1 per day.
   7.5mg: #2 per day.
   10mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   2.5mg: #1 per day.
   5mg: #1 per day.
   7.5mg: #2 per day.
   10mg: #2 per day.

   If no, continue to #5.

5. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated renal angiomyolipoma and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient does NOT require immediate surgery

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   2.5mg: #1 per day.
   5mg: #1 per day.
   7.5mg: #2 per day.
   10mg: #2 per day.

   If no, continue to #6.

6. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EVEROLIMUS (Afinitor, Torpenz)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Advanced hormone receptor-positive (HR: a type of protein), human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer
- Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
- Advanced renal cell carcinoma (RCC: type of kidney cancer)
- Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
- Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)

If you have advanced hormone receptor-positive, HER2-negative breast cancer, approval also requires:
- You are a postmenopausal woman
- The requested medication will be used in combination with Aromasin (exemestane)
- You have failed or have a contraindication to (harmful for you to use) treatment with Femara (letrozole) or Arimidex (anastrozole)

If you have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
  - You have well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI: relating to the digestive system) or lung origin

If you have advanced renal cell carcinoma, approval also requires:
- You are 18 years of age or older

If you have tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, approval also requires:
- You are 18 years of age or older
- You do NOT require immediate surgery

(Denial text continued on next page)

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

If you have tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA), approval also requires:
You are 1 year of age or older
Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely removed with surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor/Torpenz.

REFERENCES

Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.
Torpenz [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 05/11
Client Approval: 07/24
P&T Approval: 04/18

FAM-TRASTUZUMAB DERUXTECAN-NXKI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU	46262		GPI-10 (2135507055)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic breast cancer (ICD-10 C79.81; Group C50)?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient's cancer HER2-positive (IHC 3+ or ISH positive) and the patient meets **ONE** of the following criteria?
   The patient has received a prior anti-HER2-based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the metastatic setting
   The patient has received a prior anti-HER2-based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the neoadjuvant or adjuvant setting AND has developed disease recurrence during or within 6 months of completing therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer HR-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), **AND** the patient meets the following criterion?
   The patient's disease has progressed on one or more endocrine therapies (e.g., letrozole, anastrozole, tamoxifen) in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient's cancer HER2-low (IHC 1+ or IHC 2+/ISH-) and the patient meets **ONE** of the following criteria?
   The patient has received a prior chemotherapy in the metastatic setting
   The patient has developed disease recurrence during or within 6 months of completing adjuvant chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have unresectable or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's tumors have activating HER2 (ERBB2) mutations
   The patient has received a prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer is HER2-positive (IHC 3+ or IHC 2+/ISH positive)
   The patient has received a prior trastuzumab-based regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of unresectable or metastatic solid tumors and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer is HER2-positive (IHC 3+)
   The patient has received prior systemic treatment and has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FAM-TRASTUZUMAB DERUXTECAN-NXKI (Enhertu)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic breast cancer (a type of breast cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that cannot be removed by surgery or has spread to other parts of the body)
- Locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
- Unresectable or metastatic solid tumors (a type of abnormal mass that cannot be removed by surgery or has spread to other parts of the body)

If you have unresectable or metastatic breast cancer, approval also requires ONE of the following:
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), and you meet ONE of the following:
  - You have received a prior anti-HER2-based regimen (type of medication such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the metastatic setting (cancer has spread to other parts of the body)
  - You have received a prior anti-HER2-based regimen (such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emastine]) in the neoadjuvant (given before main treatment) or adjuvant (additional treatment) setting AND the disease has returned during or within 6 months of completing therapy
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), AND your disease has progressed (worsened) while on one or more endocrine therapies (such as letrozole, anastrozole, tamoxifen) in the metastatic setting (cancer has spread to other parts of the body)
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-), and you meet ONE of the following:
  - You have received a prior chemotherapy (a type of cancer treatment) in the metastatic setting (cancer has spread to other parts of the body)
  - You have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (additional) chemotherapy

(Denial text continued on next page)

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

If you have unresectable or metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your tumors have activating HER2 (ERBB2) mutations (abnormal change in a type of gene)
- You have received a prior systemic therapy (treatment that targets the entire body)

If you have locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
- You are 18 years of age or older
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH positive)
- You have received a prior trastuzumab-based (type of medication) regimen

If you have unresectable or metastatic solid tumors, approval also requires:
- You are 18 years of age or older
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+)
- You have received previous systemic treatment (therapy that targets the entire body) and have no other satisfactory treatment options

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enhertu.

REFERENCES

Enhertu [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2025.

Created: 02/20
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/25

FECAL MICROBIOTA CAPSULE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIO SPORE, LIVE-BRPK	VOWST	48888		GPI-10 (5252202010)	

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vowst?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin], fidaxomicin [Dificid]) for recurrent CDI (defined as at least 3 CDI episodes)?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #12 per 3 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile*
   - The patient has not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #12 per 3 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FECAL MICROBIOTA CAPSULE (Vowst)** requires the following rule(s) be met for approval:

A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
B. You are 18 years of age or older
C. **If you have NOT previously received Vowst, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin], fidaxomicin [Dificid]) treatment for recurrent CDI (defined as at least 3 CDI episodes)
D. **If you have been previously treated with Vowst, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vowst.

REFERENCES

- Vowst [Prescribing Information]. Cambridge, MA: Seres Therapeutics, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 05/23
Client Approval: 05/23
P&T Approval: 04/23

FECAL MICROBIOTA SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIOTA, LIVE-JSLM	REBYOTA	48488		GPI-10 (5252201030)	

GUIDELINES FOR USE

1 Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) **AND** the patient meets the following criterion?
- The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

1 Has the patient previously received Rebyota?

If yes, continue to #4.
If no, continue to #3.

2 Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin]) for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior?

If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150 mL.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3 Does the patient meet **ALL** of the following criteria?
- The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of first dose of Rebyota AND a positive stool test for C. difficile
- The patient has not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150 mL.**
If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:
A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
B. You are 18 years of age or older
(Denial text continued on next page)

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FECAL MICROBIOTA SUSPENSION

GUIDELINES FOR USE (CONTINUED)

C. **If you have NOT previously received Rebyota, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin]) treatment for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior

D. **If you have been previously treated with Rebyota, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Rebyota AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebyota.

REFERENCES

- Rebyota [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23
Created: 02/23
Client Approval: 05/23
P&T Approval: 01/23

FEDRATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FEDRATINIB DIHYDROCHLORIDE	INREBIC	45953		GPI-10 (2153752020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Jakafi (ruxolitinib)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You previously had a trial of or contraindication (medical reason why you cannot use) to Jakafi (ruxolitinib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of 35% or greater from baseline
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of 35% or greater from baseline
      2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inrebic.

REFERENCES

- Inrebic [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/19
Client Approval: 11/21
P&T Approval: 10/21

FENFLURAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENFLURAMINE HCL	FINTEPLA	02116		GPI-10 (7260002810)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to TWO of the following: valproic acid derivative, clobazam, topiramate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to valproic acid or derivatives
   - The patient had a trial of or contraindication to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)
   B. **If you have Dravet syndrome, approval also requires:**
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
      3. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivative, clobazam, topiramate

   (Initial denial text continued on next page)

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FENFLURAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you have Lennox-Gastaut syndrome, approval also requires:**
1. You are 2 years of age or older
2. Therapy is prescribed by or given in consultation with a neurologist (a type of brain doctor)
3. You had a trial of or contraindication (harmful for) to valproic acid or derivatives
4. You had a trial of or contraindication (harmful for) to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of Lennox-Gastaut syndrome (LGS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient has shown continued clinical benefit (e.g., reduction of seizures, reduced length of seizures, seizure control maintained)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENFLURAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fintepla.

REFERENCES

- Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 07/20
Client Approval: 05/22
P&T Approval: 04/22

FENTANYL NASAL SPRAY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	LAZANDA		27648 29146 41539	GPI-14 (65100025102050) (65100025102060) (65100025102057)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried, or does the patient have a contraindication to at least 1 immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried, or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL NASAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried, or does the patient have a contraindication to Abstral, or Fentora?

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #15 per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL NASAL SPRAY (Lazanda)** requires the following rule(s) to be met for approval:
   A. You have a diagnosis of cancer-related pain
   B. You are currently taking a maintenance dose of a controlled-release pain medication (such as MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
   E. You had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazanda.

REFERENCES

- Lazanda [Prescribing Information]. Northbrook, IL: West Therapeutic Development, LLC; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/11
Client Approval: 04/20
P&T Approval: 11/14

FENTANYL SUBLINGUAL SPRAY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL SUBLINGUAL SPRAY	SUBSYS		31187 31188 31189 31192 31193 31596 31597	GPI-12 (651000250009)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

FENTANYL SUBLINGUAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to Abstral or Fentora?

   If yes, **approve for 6 months by GPID or GPI-12 with a quantity limit of #120 per month.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL SUBLINGUAL SPRAY (Subsys)** requires the following rule(s) be met for approval:
   A. You have cancer-related pain
   B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
   E. You had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Subsys.

REFERENCES

- Subsys [Prescribing Information]. Chandler, AZ: Insys Therapeutics; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/12
Client Approval: 04/20
P&T Approval: 11/14

FENTANYL TRANSDERMAL PATCH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL	DURAGESIC, FENTANYL		24635 19200 37952 19201 37947 19202 37948 19203	GPI-12 (651000250086)	

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or “PRN” basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Is the request for every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   FOR EVERY 72 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #10 patches per 30 days.
   FOR 100mcg/hr: up to #20 patches per 30 days.

   If no, continue to #4.

4. Is the request for every 48 hours dosing?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE (CONTINUED)

5. Has the patient tried every 72 hours dosing?

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
FOR EVERY 48 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #15 patches per 30 days.
FOR 100mcg/hr: up to #30 patches per 30 days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:
You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
The requested medication is not prescribed on an 'as needed' basis
Requests for every 48 hours dosing requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Duragesic.

REFERENCES
Fentanyl Patch [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 02/03
Client Approval: 09/24
P&T Approval: 07/19

FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	ACTIQ, ABSTRAL, FENTORA	01747		GPI-10 (6510002510)	FDB & Medi-Span: ROUTE = BUCCAL, SUBLINGUAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**
   If no, continue to #6.

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FENTANYL TRANSMUCOSAL AGENTS

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq, Fentora, Abstral)** requires the following rule(s) be met for approval:
   A. You have cancer-related pain
   B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actiq, Fentora, and Abstral.

REFERENCES

- Actiq [Prescribing Information]. North Wales, PA: Cephalon, Inc.; October 2019.
- Fentora [Prescribing Information]. North Wales, PA: Cephalon, Inc.; October 2019.
- Abstral [Prescribing Information]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/03
Client Approval: 04/20
P&T Approval: 11/14

FILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM	NEUPOGEN	06070		GPI-10 (8240152000)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM (Neupogen)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Neupogen for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Neupogen to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neupogen.

REFERENCES

- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 08/21
Client Approval: 05/23
P&T Approval: 04/23

FILGRASTIM-AAFI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AAFI	NIVESTYM	45154		GPI-10 (8240152010)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is therapy prescribed by or in consultation with a hematologist or oncologist?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-AAFI

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-AAFI (Nivestym)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Nivestym for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles or due to unknown cause)
   6. You will be using Nivestym to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FILGRASTIM-AAFI

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nivestym and Neupogen.

REFERENCES

- Nivestym [Prescribing Information]. Lake Forest, IL: Pfizer; April 2021.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

FILGRASTIM-AYOW

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AYOW	RELEUKO	47848		GPI-10 (8240152015)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a nonmyeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-AYOW

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a nonmyeloid malignancy (a type of cancer) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a nonmyeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Releuko for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Releuko to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

FILGRASTIM-AYOW

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Releuko and Neupogen.

REFERENCES

- Releuko [Prescribing Information]. Piscataway, NJ: Kashiv BioSciences, LLC; October 2022.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/22
Client Approval: 05/23
P&T Approval: 04/23

FILGRASTIM-SNDZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-SNDZ	ZARXIO	41814		GPI-10 (8240152060)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-SNDZ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-SNDZ (Zarxio)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Zarxio for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Zarxio to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FILGRASTIM-SNDZ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zarxio and Neupogen.

REFERENCES

- Zarxio [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

FILGRASTIM-TXID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-TXID	NYPOZI	49813		GPI-10 (8240152075)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10**.
   If no, continue to #3.

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meet **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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FILGRASTIM-TXID

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet ALL of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FILGRASTIM-TXID (Nypozi)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have non-myeloid malignancy (cancer not affecting the bone marrow)
   - You have undergone or are undergoing induction or consolidation chemotherapy (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
   - You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have non-myeloid malignancy (cancer not affecting the bone marrow)
   - You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)

   (Denial text continued on the next page)

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FILGRASTIM-TXID

GUIDELINES FOR USE (CONTINUED)

You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown causes)
You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]: an illness that happens after whole body radiation)
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nypozi.

REFERENCES

Nypozi [Prescribing Information]. San Diego, CA: Tanvex BioPharma USA, Inc.; June 2024.

Created: 11/24
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

FINASTERIDE-TADALAFIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINASTERIDE/TADALAFIL	ENTADFI	47719		GPI-10 (5685990230)	

GUIDELINES FOR USE

1. Has the patient received a 26-week course of Entadfi?

   If yes, do no approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a male patient with a diagnosis of benign prostatic hyperplasia (BPH) who meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO alpha blockers (e.g., terazosin, doxazosin, tamsulosin)
   - The patient had a trial of or contraindication to ONE 5-alpha-reductase inhibitor (e.g., finasteride, dutasteride)
   - The patient had a trial of or contraindication to tadalafil 2.5 mg or tadalafil 5 mg

   If yes, **approve for 26 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FINASTERIDE-TADALAFIL (Entadfi)** requires the following rule(s) be met for approval:
   A. You are male and have benign prostatic hyperplasia (BPH: a type of prostate condition)
   B. You are 18 years of age or older
   C. You had a trial of or contraindication (harmful for) to TWO alpha blockers (such as terazosin, doxazosin, tamsulosin)
   D. You had a trial of or contraindication (harmful for) to ONE 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
   E. You had a trial of or contraindication (harmful for) to tadalafil 2.5 mg or tadalafil 5 mg

   Requests will not be approved if you have received a 26-week course of Entadfi.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINASTERIDE-TADALAFIL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entadfi.

REFERENCES

- Entadfi [Prescribing Information]. Miami, FL: Veru, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 08/22
Client Approval: 08/22
P&T Approval: 04/22

FINERENONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINERENONE	KERENDIA	47487		GPI-10 (3035403000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) (ICD-10 Group E11.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has a history of and will continue on, or has a contraindication to, an angiotensin converting enzyme inhibitor (ACE-I; e.g., benazepril, lisinopril) or an angiotensin receptor blocker (ARB; e.g., losartan, valsartan)
   The patient had a trial of or contraindication to a sodium-glucose co-transporter -2 inhibitor (SGLT2i; e.g., Farxiga [dapagliflozin], Invokana [canagliflozin], Jardiance [empagliflozin])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINERENONE (Kerendia)** requires the following rule(s) be met for approval:
   You have chronic kidney disease (CKD: long-term kidney disease) associated with type 2 diabetes (T2D: a disorder with high blood sugar)
   You are 18 years of age or older
   You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), an angiotensin converting enzyme inhibitor (ACE-I, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB, such as losartan, valsartan)
   You have tried or have a contraindication to (harmful for you to use) a sodium-glucose co-transporter 2 inhibitor (SGLT2i, such as Farxiga [dapagliflozin], Invokana [canagliflozin], Jardiance [empagliflozin])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINERENONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) (ICD-10 Group E11.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINERENONE (Kerendia)** requires the following rule(s) be met for renewal:
   You have chronic kidney disease (CKD: long-term kidney disease) associated with type 2 diabetes (T2D: a disorder with high blood sugar)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerendia.

REFERENCES

Kerendia [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2022.

Created: 07/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

FINGOLIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD	GILENYA, FINGOLIMOD	37180		GPI-10 (6240702510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   The patient is 10 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Gilenya?
   A recent (within the past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker
   A baseline QTc interval of 500 msec or above
   Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:
   You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)

(Denial text continued on next page)

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FINGOLIMOD

GUIDELINES FOR USE (CONTINUED)

You are 10 years of age or older
You do NOT have ANY of the following contraindications to (harmful for you to use) Gilenya:
- A recent (within the past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke (a type of brain damage), transient ischemic attack (a type of stroke), decompensated heart failure (a type of heart condition) requiring hospitalization, or Class III/IV heart failure (a type of heart condition)
- A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
- A baseline QTc interval of 500 msec or above (a measure of the speed of electrical conduction in the heart)
- Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilenya.

REFERENCES

Gilenya [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/24
Created: 11/10
Client Approval: 05/24
P&T Approval: 07/18

FINGOLIMOD LAURYL SULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD LAURYL SULFATE	TASCENSO ODT	48165		GPI-10 (6240702520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient had a trial of fingolimod capsules
   - The patient is unable to swallow fingolimod capsules
   - The patient had a trial of or contraindication to ONE agent indicated for the treatment of MS

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Tascenso ODT?
   - A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
   - A baseline QTc interval of 500 msec or greater
   - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

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FINGOLIMOD LAURYL SULFATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (a type of nerve disorder), to include clinically isolated syndrome (a type of nerve disorder that occurs once), relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive disease (advanced disease)
B. You are 10 years of age or older
C. You had a trial of fingolimod capsules
D. You are unable to swallow fingolimod capsules
E. You had a trial of or contraindication (harmful for) to one other agent indicated for the treatment of multiple sclerosis
F. You do not have any of the following contraindications (harmful for) to Tascenso ODT:
    1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
    2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker
    3. A baseline QTc interval of 500 msec or greater (a measure of the speed of electrical conduction in the heart)
    4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINGOLIMOD LAURYL SULFATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tascenso ODT.

REFERENCES

- Tascenso ODT [Prescribing Information]. San Jose, CA: Handa Neuroscience, LLC; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/16/23
Created: 11/22
Client Approval: 12/22
P&T Approval: 10/22

FLIBANSERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLIBANSERIN	ADDYI	42447		GPI-10 (6217503000)	FDB: ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Addyi (flibanserin) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Have **ALL** of the following criteria been met?
   - The patient is a premenopausal female
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is not currently using Vyleesi (bremelanotide)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FLIBANSERIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FLIBANSERIN (Addyi)** requires the following rule(s) be met for approval:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty

B. You are a premenopausal female

C. You are 18 years of age or older

D. You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)

E. You are not currently using Vyleesi (bremelanotide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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FLIBANSERIN

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is not currently using Vyleesi
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 tablet per day.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:
   A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
      3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
   B. You are a premenopausal female
   C. You are 18 years of age or older
   D. You are not currently using Vyleesi (bremelanotide)
   E. You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FLIBANSERIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Addyi.

REFERENCES

- Addyi [Prescribing Information]. Raleigh, NC: Sprout Pharmaceuticals, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 09/15
Client Approval: 04/20
P&T Approval: 07/19

FLUOROURACIL CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLUOROURACIL 0.5%	CARAC, FLUOROURACIL		12514	GPI-14 (90372030003705)	
FLUOROURACIL 1%	FLUOROPLEX		30780	GPI-14 (90372030003710)	

**** Please use the criteria for the specific drug requested ****

GUIDELINE FOR USE

CARAC

1. Does the patient have a diagnosis of actinic or solar keratosis (AK) of the face and anterior scalp **AND** meet the following criterion?
   The patient had a trial of TWO generic topical agents indicated for AK (e.g., fluorouracil 5%, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FLUOROURACIL CREAM (Carac)** requires the following rule(s) be met for approval:
   You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the face and anterior (front) scalp
   You have tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil 5%, imiquimod, diclofenac 3%)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FLUOROURACIL CREAM

GUIDELINE FOR USE (CONTINUED)

FLUOROPLEX

1. Does the patient have a diagnosis of actinic or solar keratosis (AK) **AND** meet the following criterion?
   The patient had a trial of TWO generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FLUOROURACIL CREAM (Fluoroplex)** requires the following rule(s) be met for approval:
   You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure)
   You have tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carac or Fluoroplex.

REFERENCES

Carac [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.; May 2022.
Fluoroplex [Prescribing Information]. Exton, PA: Almirall, LLC.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/17/24
Created: 08/18
Client Approval: 05/24
P&T Approval: 04/21

FOSCARBIDOPA-FOSLEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSCARBIDOPA/ FOSLEVODOPA	VYALEV	49183		GPI-10 (7320990213)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
   Vyalev is being used for the treatment of motor fluctuations associated with Parkinson's disease
   Therapy is prescribed by or in consultation with a neurologist
   The patient's disease is responsive to treatment with levodopa
   The patient is currently being treated with at least 400mg of levodopa per day
   The patient has motor symptoms that are currently uncontrolled (defined as an average 'off' time of at least 2.5 hours per day over 3 consecutive days, with a minimum of 2 hours each day)

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient is unable to swallow extended-release tablets or administer extended-release capsules via a feeding tube
   The patient has failed to adhere to an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen via a feeding tube

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #20mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FOSCARBIDOPA-FOSLEVODOPA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
Vyalev will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
Your disease is responsive to treatment with levodopa
You are currently being treated with at least 400mg of levodopa per day
Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 2.5 hours per day over 3 consecutive days, with a minimum of 2 hours each day)
You meet ONE of the following:
- You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
- You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FOSCARBIDOPA-FOSLEVODOPA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?
   The patient has experienced improvement in motor symptoms while on Vyalev

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #20mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for renewal:
   You have advanced Parkinson's disease (PD: a type of movement disorder)
   You have experienced improvement in motor symptoms with the use of Vyalev

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyalev.

REFERENCES

Vyalev [Prescribing Information]. North Chicago, IL: AbbVie Inc.; October 2024.

Created: 10/24
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/25

FOSDENOPTERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSDENOPTERIN HYDROBROMIDE	NULIBRY	47158		GPI-10 (3090643020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of molybdenum cofactor deficiency (MoCD) Type A?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSDENOPTERIN (Nulibry)** requires the following rule(s) be met for approval:
   A. You have molybdenum cofactor deficiency (MoCD) Type A (rare condition characterized by brain dysfunction)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nulibry.

REFERENCES

- Nulibry [Prescribing Information]. Boston, MA: Origin Biosciences, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 05/21
Client Approval: 05/21
P&T Approval: 04/21

FOSTAMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTAMATINIB DISODIUM	TAVALISSE	44895		GPI-10 (8575604010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy
   Tavalisse will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has a platelet count of less than 30 x 10^9/L
   The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FOSTAMATINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:
You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
You will NOT use Tavalisse concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])
You meet ONE of the following:
You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   Tavalisse will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:
   You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
   You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Tavalisse) OR a decrease in bleeding events
   You will NOT use Tavalisse concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavalisse.

REFERENCES

Tavalisse [Prescribing Information]. South San Francisco, CA: Rigel Pharmaceuticals, Inc; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 08/18
Client Approval: 08/24
P&T Approval: 04/24

FOSTEMSAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTEMSAVIR	RUKOBIA	46684		GPI-10 (1210233040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with other antiretroviral(s)
   - The patient is treatment experienced
   - The patient has multidrug-resistant HIV-1 infection
   - The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
   B. You are 18 years of age or older
   C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
   D. You are treatment experienced (previously treated)
   E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
   F. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FOSTEMSAVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rukobia.

REFERENCES

- Rukobia [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:08/01/20
Created: 07/20
Client Approval: 07/20
P&T Approval:07/20

FREMANEZUMAB-VFRM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FREMANEZUMAB-VFRM	AJOVY	45236		GPI-10 (6770203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP (calcitonin gene-related peptide) inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Group G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP (calcitonin gene-related peptide) inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FREMANEZUMAB-VFRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have migraines (a type of headache)
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (at least 15 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

RENEWAL CRITERIA

1. Is Ajovy being prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   - Ajovy will NOT be used concurrently with other CGRP (calcitonin gene-related peptide) inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
   - The patient has experienced a reduction in migraine severity with Ajovy therapy
   - The patient has experienced a reduction in migraine duration with Ajovy therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:
   A. Ajovy is prescribed for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   C. You meet ONE of the following:
      1. You have experienced a decrease in migraine or headache frequency of at least 2 days per month with Ajovy therapy
      2. You have experienced a decrease in migraine severity with Ajovy therapy
      3. You have experienced a decrease in migraine duration (length of time) with Ajovy therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ajovy.

REFERENCES

- Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 09/18
Client Approval: 05/24
P&T Approval: 04/24

FUTIBATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FUTIBATINIB	LYTGOBI	48369		GPI-10 (2153222800)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable, locally advanced or metastatic iCCA
   - The patient has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to the initiation of Lytgobi and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FUTIBATINIB (Lytgobi)** requires the following rule(s) be met for approval:
   A. You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. You have been previously treated for unresectable, locally advanced or metastatic iCCA
   D. You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements
   E. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting Lytgobi and at the recommended scheduled times

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FUTIBATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lytgobi.

REFERENCES

- Lytgobi [Prescribing Information]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd., September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/14/22
Created: 11/22
Client Approval: 11/22
P&T Approval: 10/22

GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		GPI-10 (6770203530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Emgality is prescribed for the preventive treatment of migraines
   Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   The patient had a trial of ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for a total of 6 months by entering TWO approvals as follows:**
   FIRST APPROVAL: approve for 1 month by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.
   SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).

   If no, continue to #2.

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Emgality is prescribed for the preventive treatment of migraines
   Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   The patient had a trial of ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

   If yes, **approve for a total of 6 months by entering TWO approvals as follows:**
   FIRST APPROVAL: approve for 1 month by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.
   SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).

   If no, continue to #3.

3. Is the request for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 3 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:
   You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)
   (Initial denial text continued on next page)

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Emgality is prescribed for the preventive treatment of migraines
- You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
- You have tried ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Emgality is prescribed for the preventive treatment of migraines
- You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
- You have tried ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

If you have episodic cluster headaches, approval also requires:
- You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA

1. Is Emgality prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
   The patient has experienced a reduction in migraine severity with Emgality therapy
   The patient has experienced a reduction in migraine duration with Emgality therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is Emgality prescribed for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   The patient had improvement in episodic cluster headache frequency as compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:
   Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
   (Renewal denial text continued on next page)

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA (CONTINUED)

If you have migraines, renewal also requires:
- You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
- You meet ONE of the following:
  - You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
  - You have experienced a reduction in migraine severity with Emgality therapy
  - You have experienced a reduction in migraine duration with Emgality therapy

If you have episodic cluster headaches, renewal also requires:
- You had improvement in episodic cluster headache frequency as compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing information and/or Drug Monograph for Emgality.

REFERENCES
Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 10/18
Client Approval: 03/24
P&T Approval: 01/22

GANAXOLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GANAXOLONE	ZTALMY	47912		GPI-10 (7260003300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of seizures and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #36 mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GANAXOLONE (Ztalmy)** requires the following rule(s) be met for approval:
   A. You have seizures
   B. You are 2 years of age or older
   C. Your seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD: a type of genetic disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ztalmy.

REFERENCES

- Ztalmy [Prescribing Information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

GEFITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEFITINIB	IRESSA, GEFITINIB	25178		GPI-10 (2136003000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - Iressa (gefitinib) will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEFITINIB (Iressa)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a gene) as detected by an FDA (Food and Drug Administration)-approved test
   C. You will NOT be using Iressa (gefitinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iressa.

REFERENCES

- Iressa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23
Created: 07/15
Client Approval: 05/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		GPI-10 (2153302020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: type of white blood cell cancer)
   B. You are 18 years of age or older
   C. You have FMS-like tyrosine kinase 3 (type of gene) mutation (change in the DNA gene) as detected by a Food and Drug Administration-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES

- Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/19
Client Approval: 03/21
P&T Approval: 01/19

GIVINOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GIVINOSTAT HYDROCHLORIDE	DUVYZAT	49667		GPI-10 (7460302520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   The patient's diagnosis of DMD is confirmed by genetic testing
   The patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for approval:
   You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   You are 6 years of age or older
   Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   Your diagnosis of DMD is confirmed by genetic testing
   You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GIVINOSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) **AND** meet the following criterion?
   The patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   The patient has shown improvement since starting Duvyzat, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per day.**
   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since starting Duvyzat, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for renewal:
   You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat
   If you are currently ambulatory (can walk), approval also requires:
   You have shown improvement since starting Duvyzat, as measured by a standard set of ambulatory or functional status measures (such as 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
   (Renewal denial text continued on next page)

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GIVINOSTAT

RENEWAL CRITERIA (CONTINUED)

If you are currently non-ambulatory (cannot walk), approval also requires:
You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since starting Duvyzat, as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Duvyzat.

REFERENCES
Duvyzat [Prescribing Information]. Concord, MA: ITF Therapeutics, LLC; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 06/24
Client Approval: 06/24
P&T Approval: 10/23

GLASDEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLASDEGIB MALEATE	DAURISMO	45502		GPI-10 (2137003030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed acute myeloid leukemia (AML) **AND** meet the following criterion?
   - The requested medication will be used in combination with low-dose cytarabine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient has comorbidities that prevent use of intensive induction chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   - **Daurismo 25mg: #2 per day.**
   - **Daurismo 100mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:
   A. You have newly-diagnosed acute myeloid leukemia (AML: type of white blood cell cancer)
   B. The requested medication will be used in combination with low-dose cytarabine
   C. You are 75 years of age or older, **OR** you have comorbidities (having more than one disease) that prevents the use of intensive induction chemotherapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLASDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

- Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 01/19
Client Approval: 04/20
P&T Approval: 01/19

GLATIRAMER ACETATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLATIRAMER ACETATE	COPAXONE, GLATOPA, GLATIRAMER ACETATE	12810		GPI-10 (6240003010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **20mg/mL: #1mL per day.**
   - **40mg/mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLATIRAMER ACETATE (Copaxone, Glatopa)** requires the following rule(s) be met for approval:
   1. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   2. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLATIRAMER ACETATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copaxone and Glatopa.

REFERENCES

1. Copaxone [Prescribing Information]. Overland Park, KS: Teva; January 2020.
2. Glatopa [Prescribing Information]. Princeton, NJ: Sandoz Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 02/14
Client Approval: 11/20
P&T Approval: 02/14

GLECAPREVIR/PIBRENTASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		GPI-10 (1235990235)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
   The patient is 3 years of age or older
   The patient has genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #17.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   Mavyret will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)
   Mavyret will be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

4. Is the patient treatment-naïve?

   If yes, continue to #5.
   If no, continue to #8.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   The patient has a genotype 1, 4, 5, or 6 infection AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni
   The patient has a genotype 2 or 3 infection AND had an intolerance or contraindication to the preferred agent: Epclusa

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have compensated cirrhosis (Child-Pugh A) or does not have cirrhosis?

   If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
   100mg-40mg tablet: #3 per day.
   50mg-20mg pellets: #5 per day.

   If no, continue to #7.

7. Is the patient post-liver or post-kidney transplant?

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   100mg-40mg tablet: #3 per day.
   50mg-20mg pellets: #5 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   The patient is less than 18 years of age
   The patient is interferon-experienced

   If yes, continue to #9.
   If no continue to #10.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   The patient has a genotype 1, 4, 5, or 6 infection AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni
   The patient has a genotype 2 or 3 infection AND had an intolerance or contraindication to the preferred agent: Epclusa

   If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
   100mg-40mg tablet: #3 per day.
   50mg-20mg pellets: #5 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   The patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   The patient has prior treatment experience with an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
   The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [grazoprevir/elbasvir])

   If yes, continue to #12.
   If no, continue to #11.

11. Is the patient treatment-experienced and meets **ONE** of the following criteria?
   The patient has failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
   The patient has previously failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
   The patient has previously failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
   The patient is less than 18 years of age, has genotype 3, AND is interferon-experienced

   If yes, continue to #12.
   If no, continue to #13.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

12. Does the patient meet **ONE** of the following criteria?
    The patient has a genotype 1, 4, 5, or 6 infection AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni
    The patient has a genotype 2 or 3 infection AND had an intolerance or contraindication to the preferred agent: Epclusa

    If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
    100mg-40mg tablet: #3 per day.
    50mg-20mg pellets: #5 per day.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    The patient has genotype 1, 2, 4, 5, or 6
    The patient does not have cirrhosis
    The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
    100mg-40mg tablet: #3 per day.
    50mg-20mg pellets: #5 per day.

    If no, continue to #14.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

14. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    The patient has genotype 1, 2, 4, 5, or 6
    The patient has compensated cirrhosis (Child-Pugh A)
    The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    100mg-40mg tablet: #3 per day.
    50mg-20mg pellets: #5 per day.

    If no, continue to #15.

15. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    The patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age
    The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    The patient has prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
    The patient has NO prior treatment experience with an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    100mg-40mg tablet: #3 per day.
    50mg-20mg pellets: #5 per day.

    If no, continue to #16.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

16. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    The patient has genotype 3
    The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
    100mg-40mg tablet: #3 per day.
    50mg-20mg pellets: #5 per day.

    If no, continue to #17.

17. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

- You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
- You are 3 years of age or older
- You have a genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)
- You have an HCV RNA level (a measure of the amount of hepatitis C virus in your blood) within the past 6 months
- You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
- You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
- You will NOT use Mavyret concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)
- You will NOT use Mavyret concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
- **If you are treatment naive (no prior treatment), approval also requires ALL of the following:**
  - You meet ONE of the following:
    - You do not have cirrhosis (liver damage or scarring)
    - You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
    - You received a liver transplant (replaced your liver)
    - You received a kidney transplant (replaced your kidney)
  - You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa or Harvoni, if you have a genotype 1, 4, 5, or 6 infection, OR you had an intolerance or contraindication to the preferred medication: Epclusa, if you have a genotype 2 or 3 infection

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

If you are treatment-experienced (failed prior treatment) and prior therapy did not contain an NS5A inhibitor, approval also requires ONE of the following:

- You have a genotype 1, 2, 4, 5, or 6 infection, and you have compensated cirrhosis (a condition where there is liver damage and scarring without major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) or you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
- You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]), and you do not have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
- You have a genotype 3 infection, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

(Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

If you are treatment-experienced (failed prior treatment), approval also requires ALL of the following:

- You meet ONE of the following:
  - You are less than 18 years of age AND had prior treatment with an interferon
  - You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir]), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
  - You have failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
  - You have failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
  - You have failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
  - You are less than 18 years of age, have genotype 3, AND you had prior treatment with an interferon
- You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa or Harvoni, if you have a genotype 1, 4, 5, or 6 infection, OR you had an intolerance or contraindication to the preferred medication Epclusa, if you have a genotype 2 or 3 infection

Mavyret will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLECAPREVIR/PIBRENTASVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavyret.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed October 2023.

Mavyret [Prescribing Information]. North Chicago, IL: Abbvie; October 2023.

Created: 09/17
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

GLP-1 AGONIST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EXENATIDE MICROSPHERES	BYDUREON BCISE	38451		GPI-10 (2717002000)	
EXENATIDE	BYETTA	32893			
TIRZEPATIDE	MOUNJARO	48014		GPI-10 (2717308000)	BRAND ≠ ZEPBOUND
SEMAGLUTIDE	OZEMPIC, RYBELSUS	44675		GPI-10 (2717007000)	BRAND ≠ WEGOVY
DULAGLUTIDE	TRULICITY	41421		GPI-10 (2717001500)	
LIRAGLUTIDE	VICTOZA, LIRAGLUTIDE	36436		GPI-10 (2717005000)	BRAND ≠ SAXENDA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes (ICD-10 group E08, E09, E11, E13) confirmed by **ONE** of the following?
   - Medical records
   - Chart notes

   If yes, **approve the requested agent for 12 months as follows:**
   - **Bydureon BCise: Approve by HICL or GPI-10 with a quantity limit of #3.4mL per 28 days.**
   - **Byetta: Approve by HICL or GPI-10 with a quantity limit of #0.08mL per day.**
   - **Mounjaro: Approve by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**
   - **Ozempic: Approve by GPID or GPI-14 with a quantity limit of #3mL per 28 days.**
   - **Rybelsus: Approve by GPID or GPI-14 with a quantity limit of #1 per day.**
   - **Trulicity: Approve by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   - **Victoza (liraglutide): Approve by GPID or GPI-14 with a quantity limit of #0.3mL per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLP-1 AGONIST (Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza [liraglutide])** requires the following rule(s) be met for approval:
   I. You have type 2 diabetes (a disorder with high blood sugar)
   J. Your diagnosis of type 2 diabetes is confirmed by medical records OR chart notes

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLP-1 AGONIST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, or Victoza.

REFERENCES

- Bydureon BCise [Prescribing Information]. Wilmington, DE: AstraZeneca Pharma.; May 2023.
- Byetta [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals, LP; December 2022.
- Mounjaro [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; July 2023.
- Ozempic [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; September 2023.
- Rybelsus [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; December 2022.
- Trulicity [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2022.
- Victoza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/24
Created: 11/22
Client Approval: 08/24
P&T Approval: 10/23

GLYCEROL PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI	39990		GPI-10 (3090803000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) and meet **ALL** of the following criteria?
   The patient's disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   The patient's UCD is confirmed by enzymatic, biochemical or genetic testing
   Ravicti will be used as adjunctive therapy along with dietary protein restriction
   The patient does NOT have N-acetylglutamate synthetase (NAGS) deficiency or acute hyperammonemia
   The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:
   You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
   Your disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
   Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
   You do NOT have a deficiency (low level) of N-acetylglutamate synthetase (NAGS: a type of enzyme) or acute hyperammonemia (sudden and short-term increase in ammonia levels to a critical level)
   You have tried or have a contraindication to (harmful for you to use) Buphenyl (sodium phenylbutyrate)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLYCEROL PHENYLBUTYRATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) **AND** meet the following criterion?
   The patient had a clinical benefit compared to baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:
   You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
   You had a clinical benefit compared to baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ravicti.

REFERENCES

Ravicti [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/13
Client Approval: 06/24
P&T Approval: 07/19

GLYCOPYRRONIUM TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCOPYRRONIUM TOSYLATE	QBREXZA	45086		GPI-10 (9097003020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis (ICD-10 L74.510) and meet **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient had a trial of a prescription strength aluminum chloride product (e.g., Drysol)
   - Qbrexza will NOT be used concurrently with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Sofdra [sofpironium bromide])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 packet per day.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:
   A. You have primary axillary hyperhidrosis (excessive underarm sweating)
   B. You are 9 years of age or older
   C. You have tried a prescription strength aluminum chloride product (such as Drysol)
   D. You will NOT use Qbrexza concurrently (at the same time) with other topical anticholinergics indicated for primary axillary hyperhidrosis (such as Sofdra [sofpironium bromide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrexza.

REFERENCES

- Qbrexza [Prescribing Information]. Scottsdale, AZ: Journey Medical Corporation; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 11/18
Client Approval: 07/24
P&T Approval: 07/20

GOLIMUMAB - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB	SIMPONI ARIA		34983	GPI-14 (66270040002015)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is concurrently using or has a contraindication to methotrexate
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 L40.5) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient meet **ONE** of the following criteria?
   The patient is 2 to 5 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents: Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #6.

6. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Simponi Aria concurrently with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You meet ONE of the following:
  - You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
  - You are 6 to 17 years of age AND have tried or have a contraindication to TWO of the following preferred medications: Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Enbrel (etanercept), Rinvoq (upadacitinib)
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

If you have polyarticular juvenile idiopathic arthritis, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLIMUMAB - IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient is concurrently using or has a contraindication to methotrexate
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #4.
   If no, continue to #5.

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient is 2 to 5 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents: Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #6.

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Ankylosing spondylitis (AS: a type of joint condition)
   - Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)

   If you have moderate to severe rheumatoid arthritis, renewal also requires:
   - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
   - You will NOT use Simponi Aria concurrently with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
- You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, renewal also requires:

You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

You meet ONE of the following:
- You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
- You are 6 to 17 years of age AND have tried or have a contraindication to TWO of the following preferred medications: Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Enbrel (etanercept), Rinvoq (upadacitinib)
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi Aria.

REFERENCES

Simponi Aria [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; July 2023.

Created: 11/13
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

GOLIMUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB	SIMPONI		22533 22536 34697 35001	GPI-14 (6627004000D540) (6627004000E540) (6627004000D520) (6627004000E520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is concurrently using or has a contraindication to methotrexate
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #5.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 100mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 mL per 28 days (please enter a start date of 3 days before the end date of the first approval).

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   (Initial denial text continued on next page)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLIMUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient is concurrently using or has a contraindication to methotrexate
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #5.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 100mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1 mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Renewal denial text continued on next page)

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi.

REFERENCES

Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; March 2023.

Created: 06/09
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

GOLODIRSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLODIRSEN	VYONDYS-53	46254		GPI-10 (7460004200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   The patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping therapy
   Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of DMD at a DMD treatment center
   The patient is ambulatory
   The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLODIRSEN (Vyondys 53)** requires the following rule(s) be met for approval:
   You have Duchenne muscular dystrophy (DMD: a type of inherited muscle disorder)
   You have a confirmed mutation (abnormal change in a type of gene) in the DMD gene that will respond to exon 53 skipping therapy (a type of therapy to treat DMD)
   Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of DMD at a DMD treatment center
   You are ambulatory (able to walk)
   You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLODIRSEN

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLODIRSEN (Vyondys 53)** requires ONE of the following rule(s) be met for renewal:
   You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyondys 53.

REFERENCES

Vyondys 53 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2024.

Created: 02/20
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 10/20

GUSELKUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GUSELKUMAB	TREMFYA	44418		GPI-10 (5250402500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Tremfya
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve all formulations of the 100mg/mL strength for a total of 6 months. Please enter TWO approvals by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 56 days (please enter a start date of 3 WEEKS AFTER the START date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 100mg/mL strength for a total of 6 months. Please enter TWO approvals by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 56 days (please enter a start date of 3 WEEKS AFTER the START date of the first approval).

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve the 200mg/20mL vial for 2 months with a quantity limit of #20mL per 28 days.
   SECOND APPROVAL: Approve all formulations of the requested strength for 4 months with the following quantity limits (please enter a start date of 3 WEEKS AFTER the END date of the first approval):
   100mg/mL: #1mL per 56 days.
   200mg/2mL: #2mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Tremfya
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

(Initial denial text continued on next page)

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GUSELKUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 100mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender or swollen joint count while on therapy
   Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 100mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   100mg/mL: #1mL per 56 days.
   200mg/2mL: #2mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GUSELKUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tremfya.

REFERENCES
Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; September 2024.

Created: 07/17
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/25

HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MORPHINE SULFATE	MORPHINE SULFATE		16063	GPI-14 (65100055102090)	
OXYCODONE HCL	OXYCODONE HCL		16281	GPI-14 (65100075101320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care or end-of-life care

   If yes, **approve the requested drug for a lifetime approval by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
   - The patient has trouble swallowing opioid tablets, capsules, or large volumes of liquid

   If yes, **approve the requested drug for 3 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (morphine sulfate, oxycodone hydrochloride)** requires the following rule(s) be met for approval:
   A. You have pain severe enough to require opioid analgesic and for which alternative treatments are inadequate
   (Denial text continued on next page)

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

GUIDELINES FOR USE (CONTINUED)

B. You meet ONE of the following:
   1. You are enrolled in hospice OR you are receiving palliative care or end-of-life care
   2. You meet ALL of the following:
      a. You have previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
      b. You have trouble swallowing opioid tablets, capsules, or large volumes of liquid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Morphine Sulfate or Oxycodone Hydrochloride oral solution.

REFERENCES

- Morphine Sulfate [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals Inc., April 2021
- Oxycodone Hydrochloride [Prescribing Information]. East Windsor, NJ: Aurobindo Pharma USA, Inc., February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 07/21
Client Approval: 08/21
P&T Approval: 04/21

HYDROCORTISONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCORTISONE	ALKINDI SPRINKLE		46547 46548 46549 46551	GPI-14 (22100025006810) (22100025006815) (22100025006820) (22100025006830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of adrenocortical insufficiency and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient is unable to take the tablet formulation of hydrocortisone (e.g., need for lower strength, difficulty swallowing)

   If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:
   A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
   B. You are less than 18 years of age
   C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alkindi Sprinkle.

REFERENCES
- Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 02/21
Commercial Effective: 04/01/21 Client Approval: 02/21 P&T Approval: 01/21

HYDROMORPHONE ER

Generic	Brand		HICL	GCN	Medi-Span	Exception/Other
HYDROMORPHONE HCL	EXALGO, HYDROMORPHONE ER			22056 28427 22098 33088	GPI-12 (651000351075)	EXTENDED RELEASE ONLY

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or "PRN" basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient require a dosage of 16mg or less?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent (8mg, 12mg, 16mg) for #1 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, continue to #4.

4. Was this dosage recommended by a pain specialist?

   If yes, **approve for 12 months by GPID or GPI-14 (32mg) for #2 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROMORPHONE ER

GUDIELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exalgo.

REFERENCES

- Exalgo [Prescribing Information]. Hazelwood, MO: Mallinckrodt; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/22
Created: 04/10
Client Approval: 02/22
P&T Approval: 07/19

HYDROXYUREA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROXYUREA	XROMI	03897		GPI-10 (8280303000)	BRAND = XROMI

GUIDELINES FOR USE

1. Does the patient have a diagnosis of sickle cell anemia (ICD-10 Group D57.0) and meet **ALL** of the following criteria?
   The patient is 6 months to 17 years of age
   The patient has recurrent moderate to severe painful crises
   The patient had a trial of, contraindication to, or is unable to swallow generic hydroxyurea capsules

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROXYUREA (Xromi)** requires the following rule(s) be met for approval:
   You have sickle cell anemia (a type of blood disorder)
   You are 6 months to 17 years of age
   You have recurrent moderate to severe painful crises (repeated episodes of extreme pain)
   You have tried, have a contraindication to (harmful for you to use), or are unable to swallow generic hydroxyurea capsules

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xromi.

REFERENCES
Xromi [Prescribing Information]. Franklin, TN: Rare Disease Therapeutics, Inc.; December 2024.

Created: 02/25
Effective: 03/10/25 Client Approval: 03/25 P&T Approval: 04/25

IBREXAFUNGERP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBREXAFUNGERP CITRATE	BREXAFEMME	47416		GPI-10 (1150704010)	

GUIDELINES FOR USE

1. Is the request for the treatment of vulvovaginal candidiasis (VVC) and the patient meets **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole AND an intravaginal azole (e.g., terconazole cream)

   If yes, **approve for 30 days by HICL or GPI-10 for one fill with a quantity limit of #4.**
   If no, continue to #2.

2. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) and the patient meets **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole (the patient had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
   - The patient is NOT currently on oteseconazole for RVVC

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient previously received Brexafemme?

   If yes, continue to #5.
   If no, continue to #4.

4. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills total with a quantity limit of #4 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IBREXAFUNGERP

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Brexafemme for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills total with a quantity limit of #4 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBREXAFUNGERP (Brexafemme)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of vulvovaginal candidiasis (VVC: vaginal yeast infection)
      2. Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC: repeated vaginal yeast infection)
   B. **If you are using Brexafemme for the treatment of vulvovaginal candidiasis, approval also requires:**
      1. You are a post-menarchal (you have started having your period) female
      2. You have tried or have a contraindication to (harmful for) oral fluconazole AND an intravaginal azole (type of drug that is inserted into the vagina and used to treat yeast infections such as terconazole cream)
   C. **If you are using Brexafemme for the reduction in the incidence of recurrent vulvovaginal candidiasis, approval also requires:**
      1. You are a post-menarchal (you have started having your period) female
      2. You have tried or have a contraindication to (harmful for) oral fluconazole (you had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
      3. You are NOT currently on oteseconazole for RVVC
      4. You meet ONE of the following:
         a. You have not previously received Brexafemme AND you had 3 or more episodes of RVVC in the past 12 months
         b. You have been previously treated with Brexafemme and meet ALL of the following:
            i. You have successfully completed a course of Brexafemme for prevention of RVVC
            ii. You are either being treated or have just completed treatment for a new recurrence of VVC

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBREXAFUNGERP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brexafemme.

REFERENCES

- Brexafemme [Prescribing Information]. Jersey City, NJ: Scynexis, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 07/21
Client Approval: 02/23
P&T Approval: 07/21

IBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBRUTINIB	IMBRUVICA	40745		GPI-10 (2153213300)	

GUIDELINES FOR USE

1. Is the request for Imbruvica (ibrutinib) 560 mg tablet?

   If yes, do not approve. (**NOTE:** This strength does not have an FDA-approved indication.)
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   70 mg capsule: #1 per day.
   140 mg capsule: #2 per day.
   140 mg tablet: #1 per day.
   280 mg tablet: #1 per day.
   420 mg tablet: #1 per day.
   70 mg/mL oral suspension: #7.2 mL per day.

   If no, continue to #3.

3. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) (ICD-10 C88.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   70 mg capsule: #1 per day.
   140 mg capsule: #2 per day.
   140 mg tablet: #1 per day.
   280 mg tablet: #1 per day.
   420 mg tablet: #1 per day.
   70 mg/mL oral suspension: #7.2 mL per day.

   If no, continue to #4.

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil)
   Imbruvica will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   70 mg capsule: #1 per day.
   140 mg capsule: #2 per day.
   140 mg tablet: #1 per day.
   280 mg tablet: #1 per day.
   420 mg tablet: #1 per day.
   70 mg/mL oral suspension: #7.2 mL per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   Small lymphocytic lymphoma (SLL: a type of blood cancer)
   Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   Chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)
   If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:
   You are 18 years of age or older
   If you have chronic graft-versus-host disease, approval also requires:
   You are 1 year of age or older
   You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   You will NOT use Imbruvica concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

   NOTE: Requests for Imbruvica (ibrutinib) 560 mg tablet will not be approved. This strength does not have a Food and Drug Administration (FDA)-approved indication.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBRUTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imbruvica.

REFERENCES

Imbruvica [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; December 2024.

Created: 01/14
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

ICATIBANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ICATIBANT ACETATE	FIRAZYR, SAJAZIR, ICATIBANT ACETATE	35962		GPI-10 (8582004010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   - The requested medication is being used for treatment of acute attacks of hereditary angioedema
   - The requested medication will NOT be used concurrently with other acute treatments for HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

   If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of 18mL (6 syringes) per fill.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy doctor or immune system doctor) or hematologist (blood doctor)
   D. Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of lab test)
   E. The requested medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
   F. The requested medication will NOT be used concurrently (at the same time) with other acute treatments for HAE attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ICATIBANT

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Firazyr and Sajazir.

REFERENCE

- Firazyr [Prescribing Information]. Lexington, MA: Shire Orphan Therapies; January 2024.
- Sajazir [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; February 2024.

Created: 09/11
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 04/22

IDELALISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IDELALISIB	ZYDELIG	41297		GPI-10 (2153804000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL) **AND** meet the following criterion?
   - Zydelig will be used in combination with rituximab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
   A. You have relapsed chronic lymphocytic leukemia (CLL: a type of blood cancer)
   B. Zydelig will be used in combination with rituximab

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Zydelig.

REFERENCES

- Zydelig [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/14
Client Approval: 02/22
P&T Approval: 11/14

ILOPROST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ILOPROST TROMETHAMINE	VENTAVIS	26287		GPI-10 (4017006000)	BRAND = VENTAVIS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ILOPROST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
- Mean pulmonary artery pressure (PAP) greater than 20 mmHg
- Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
- Pulmonary vascular resistance (PVR) greater than 2 Wood units

You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
- Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
- Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
- Oral cGMP stimulator (such as Adempas [riociguat])
- Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

ILOPROST

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Ventavis.

REFERENCES

Ventavis [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/25/24
Created: 01/08
Client Approval: 11/24
P&T Approval: 01/24

IMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMATINIB MESYLATE	GLEEVEC, IMKELDI, IMATINIB MESYLATE	22096		GPI-10 (2153183510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) and meet **ONE** of the following criteria?
   The patient has newly diagnosed Ph+ CML in chronic phase
   The patient has Ph+ CML in blast crisis (BC), accelerated phase (AP), or chronic phase (CP) after failure of interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   400mg: #2 per day.
   100mg: #6 per day.

   If no, continue to #21.

4. Does the patient have a diagnosis of relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #5.
   If no, continue to #6.

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

5. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   400mg: #1 per day.
   100mg: #6 per day.

   If no, continue to #21.

6. Does the patient have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   The requested medication will be used in combination with chemotherapy

   If yes, continue to #7.
   If no, continue to #8.

7. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   400mg: #1 per day.
   100mg: #6 per day.

   If no, continue to #21.

8. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease (MDS/MPD) (ICD-10 C94.6) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's disease is associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements

   If yes, continue to #9.
   If no, continue to #10.

9. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #21.

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM) (ICD-10 C96.21) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's disease is without the D816V c-Kit mutation or c-Kit mutational status unknown

    If yes, continue to #11.
    If no, continue to #12.

11. Is the request for Gleevec (imatinib) tablet?

    If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
    400mg: #1 per day.
    100mg: #3 per day.

    If no, continue to #21.

12. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and/or chronic eosinophilic leukemia (CEL) (ICD-10 C94.8) **AND** meet the following criterion?
The patient is 18 years of age or older

    If yes, continue to #13.
    If no, continue to #14.

13. Is the request for Gleevec (imatinib) tablet?

    If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
    400mg: #1 per day.
    100mg: #3 per day.

    If no, continue to #21.

14. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP) (ICD-10 C44.99) **AND** meet the following criterion?
The patient is 18 years of age or older

    If yes, continue to #15.
    If no, continue to #16.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

15. Is the request for Gleevec (imatinib) tablet?

    If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
    400mg: #2 per day.
    100mg: #6 per day.

    If no, continue to #21.

16. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) **AND** meet the following criterion?
    The patient's tumor is Kit (CD117) positive

    If yes, continue to #18.
    If no, continue to #17.

17. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The request is for adjuvant treatment following complete gross resection of Kit (CD117) positive GIST

    If yes, continue to #18.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

18. Is the request for Gleevec (imatinib) tablet?

    If yes, continue to #19.
    If no, continue to #21.

19. Is the request for a dosage of 400mg twice daily?

    If yes, continue to #20.
    If no, **approve Gleevec (imatinib) as follows:**
    Adjuvant GIST treatment: approve 400mg for 36 months by GPID or GPI-14 with a quantity limit of #1 per day.
    Unresectable and/or metastatic malignant GIST: approve 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

20. Has the patient tried Gleevec (imatinib) 400mg once daily **OR** does the patient have GIST tumor expressing a KIT exon 9 mutation?

    If yes, **approve Gleevec (imatinib) as follows:**
    Adjuvant GIST treatment: approve 400mg for 36 months by GPID or GPI-14 with a quantity limit of #2 per day.
    Unresectable and/or metastatic malignant GIST: approve 400mg for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

21. Is the request for Imkeldi 80mg/mL solution **AND** the patient meets the following criterion?
    The patient is unable to swallow generic imatinib tablets

    If yes, **approve Imkeldi by GPID or GPI-14 with a quantity limit of #280mL per 28 days as follows:**
    Adjuvant GIST treatment: approve for 36 months.
    All other indications: approve for 12 months.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMATINIB (Gleevec, Imkeldi)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML: a type of blood cancer)
- Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of blood cancer that has returned or did not respond to treatment)
- Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of blood cancer)
- Myelodysplastic/myeloproliferative disease (MDS/MPD: type of blood cancer)
- Aggressive systemic mastocytosis (ASM: a type of blood disorder)
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) (types of inflammatory cancer)
- Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP: type of rare skin tumor that cannot be completely removed by surgery, has returned, and/or has spread to other parts of the body)
- Unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST: type of digestive tumor that cannot be completely removed by surgery and/or has spread to other parts of the body)
- Gastrointestinal stromal tumor (GIST: type of digestive tumor)

If the request is for Imkeldi solution, approval also requires that you are unable to swallow generic imatinib tablets

If you have Philadelphia chromosome positive chronic myeloid leukemia, approval also requires:

You meet ONE of the following:

- You have newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML: type of blood cancer) in chronic phase
- You have Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy

You have NOT received previous treatment with another tyrosine kinase inhibitor, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:

You are 18 years of age or older

(Denial text continued on next page)

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:
The requested medication will be used in combination with chemotherapy (a type of cancer treatment)

If you have myelodysplastic/myeloproliferative disease, approval also requires:
You are 18 years of age or older
Your disease is associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements (a type of gene mutation)

If you have aggressive systemic mastocytosis, approval also requires:
You are 18 years of age or older
Your disease is without the D816V c-Kit mutation (abnormal change in a type of gene) or c-Kit mutational status is unknown

If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:
You are 18 years of age or older

If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:
You are 18 years of age or older

If you have unresectable and/or metastatic malignant gastrointestinal stromal tumor, approval also requires:
Your tumor is Kit (CD117: a type of protein) positive
For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a gastrointestinal stromal tumor (GIST) expressing a KIT exon 9 mutation (abnormal change in a type of gene)

If you have gastrointestinal stromal tumor, approval also requires:
You are 18 years of age or older
The request is for adjuvant (additional) treatment following complete gross resection of Kit (CD117: a type of protein) positive gastrointestinal stromal tumor (GIST)
For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 mutation (abnormal change in a type of gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleevec and Imkeldi.

REFERENCES

Gleevec [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.
Imkeldi [Prescribing Information] Cambridge, MA: Shorla Oncology Inc.; November 2024.

Created: 11/11
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 10/19

IMIQUIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMIQUIMOD	ZYCLARA		28216 31436 32958	GPI-14 (90773040003715) (90773040003710)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis (AK) of the full face or balding scalp and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is immunocompetent
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve the requested strength for 4 months by GPID or GPI-14 with the following quantity limits:**
   - **3.75% packet: #28 packets per 28 days.**
   - **2.5% or 3.75% pump: #7.5g per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of external genital or perianal warts and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to generic imiquimod 5% topical cream

   If yes, **approve the requested strength for 2 months by GPID or GPI-14 with the following quantity limits:**
   - **3.75% packet: #28 packets per 28 days.**
   - **2.5% or 3.75% pump: #7.5g per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMIQUIMOD (Zyclara)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Actinic keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the full face or balding scalp
      2. External genital or perianal (around the anus) warts

   (Denial text continued on next page)

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IMIQUIMOD

GUIDELINES FOR USE (CONTINUED)

B. **If you have actinic keratosis of the full face or balding scalp, approval also requires:**
   1. You are 18 years of age or older
   2. You are immunocompetent (healthy immune system)
   3. You had a trial of TWO generic topical agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

C. **If you have external genital or perianal warts, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication (harmful for) to generic imiquimod 5% topical cream

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zyclara.

REFERENCES

- Zyclara [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/12/23

Created: 08/97
Client Approval: 05/23

P&T Approval: 04/21

IMMUNE GLOBULIN - CUTAQUIG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG	45734		GPI-10 (1910002057)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - CUTAQUIG** requires the following rule(s) be met for approval:
   K. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cutaquig.

REFERENCES

- Cutaquig [Prescribing Information]. Paramus, NJ: Octapharma USA, Inc.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/19

IMMUNE GLOBULIN - CUVITRU

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU	41796		GPI-10 (1910002020)	MEDISPAN: BRAND = CUVITRU

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - CUVITRU** requires the following rule(s) be met for approval:
   A. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuvitru.

REFERENCES

- Cuvitru [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 04/16

IMMUNE GLOBULIN - HIZENTRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUN GLOB G(IGG)/PRO/IGA 0-50	HIZENTRA	04202 41798		GPI-10 (1910002020)	BRAND = HIZENTRA

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - HIZENTRA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Primary immunodeficiency disease (genetic disease where the immune system is weak)
      2. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Hizentra.

REFERENCES
Hizentra [Prescribing Information]. Kankakee, IL: CSL Behring LLC; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 04/18

IMMUNE GLOBULIN - HYQVIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA	41391		GPI-10 (1999000235)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81, ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3, Group D83)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - HYQVIA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Primary immunodeficiency disease (genetic disease where the immune system is weak)
      2. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyqvia.

REFERENCES
Hyqvia [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 10/14

IMMUNE GLOBULIN - IV/SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUN GLOB G(IGG)/GLY/IGA OV50	GAMMAGARD LIQUID	04202		GPI-10 (1910002030)	FDB: BRAND = GAMMAGARD LIQUID
IMMUNE GLOBUL G/GLY/IGA AVG 46	GAMMAKED, GAMUNEX-C	25631			

GUIDELINES FOR USE

1. Is the request for use as a subcutaneous (SQ) injection?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a diagnosis of primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)?

   If yes, **approve the requested agent for 12 months as follows:**
   Gammagard Liquid: Approve by NDC for FDB or GPI-10 for Medi-Span.
   Gammaked: Approve by HICL or GPI-10.
   Gamunex-C: Approve by HICL or GPI-10.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for use as an intravenous (IV) injection?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN - IV/SQ

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)
   Immune (idiopathic) thrombocytopenic purpura (ITP) (ICD-10 D69.3)
   Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)
   Multifocal motor neuropathy (MMN) (ICD-10 G61.82)
   Kawasaki syndrome (ICD-10 M30.3)
   B-cell chronic lymphocytic leukemia (CLL) with hypogammaglobulinemia
   Autoimmune hemolytic anemia (AIHA) (ICD-10 Group D59.1)
   Pure red cell aplasia (PRCA) (ICD-10 D61.01)
   Guillain-Barre syndrome (GBS) (ICD-10 G61.0)
   Myasthenia gravis (ICD-10 Group G70.0)
   Autoimmune Graves' ophthalmopathy (ICD-10 E05.00)
   Cytomegalovirus-induced pneumonitis (ICD-10 B25.0) related to a solid organ transplant
   Prevention of bacterial infection in an HIV-infected child
   Reduction of secondary infections in pediatric HIV infections
   Dermatomyositis or polymyositis (ICD-10 M36.0, Group M33)
   Autoimmune uveitis (birdshot retinochoroidopathy)
   Lambert-Eaton myasthenic syndrome (ICD-10 G70.80)
   IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
   Stiff-man syndrome (ICD-10 G25.82)
   Neonatal sepsis (ICD-10 Group P36)
   Rotaviral enterocolitis (ICD-10 A08.0)
   Toxic shock syndrome (ICD-10 A48.3)
   Enteroviral meningoencephalitis (ICD-10 A87.0, A85.0)
   Toxic epidermal necrolysis (ICD-10 L51.2) or Stevens-Johnson syndrome (ICD-10 L51.1, L51.3)
   Autoimmune mucocutaneous blistering disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for Gammagard Liquid?

   If yes, **approve for 12 months by NDC (FDB or Medi-Span).**
   If no, continue to #6.

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IMMUNE GLOBULIN - IV/SQ

GUIDELINES FOR USE (CONTINUED)

6. Is the request for Gammaked or Gammunex-C?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Has the patient had a trial of or contraindication to **TWO** of the following preferred agents: Gammaplex, Gammagard S-D, Gammagard Liquid, Octagam, Panzyga, Privigen?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - IV/SQ (Gammagard Liquid, Gammaked, Gammunex-C**) requires the following rule(s) be met for approval:
   For subcutaneous (SQ) injection, approval requires:
   You have primary immunodeficiency disease (genetic disease where the immune system is weak)
   For intravenous (IV) injection, approval requires:
   You have ONE of the following:
   Primary immunodeficiency disease (genetic disease where the immune system is weak)
   Immune (idiopathic) thrombocytopenic purpura (a type of blood disorder)
   Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
   Multifocal motor neuropathy (a nerve disorder with increasing muscle weakness)
   Kawasaki syndrome (inflammation in the walls of blood vessels in the body)
   B-cell chronic lymphocytic leukemia (blood and bone marrow cancer of immune cells) with hypogammaglobulinemia (low levels of immunoglobulins)
   Autoimmune hemolytic anemia (body destroys red blood cells more rapidly than it produces them)
   Pure red cell aplasia (bone marrow stops making red blood cells)
   Guillain-Barre syndrome (immune system attacks the nerves)
   Myasthenia gravis (a type of chronic autoimmune disorder)
   Autoimmune Graves' ophthalmopathy (a type of eye disease)
   (Denial text continued on next page)

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IMMUNE GLOBULIN - IV/SQ

GUIDELINES FOR USE (CONTINUED)

- Cytomegalovirus-induced pneumonitis (lung tissue inflammation caused by a virus) related to a solid organ transplant
- Prevention of bacterial infection in an HIV (human immunodeficiency virus: an immune system disease caused by a virus)- infected child
- Reduction of secondary infections in pediatric HIV infections
- Dermatomyositis (a type of muscle and skin disorder) or polymyositis (a type of inflammatory muscle disease)
- Autoimmune uveitis (birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
- Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
- IgM (immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (a type of nerve damage)
- Stiff-man syndrome (a nerve disorder with increasing muscle stiffness [rigidity] and repeated episodes of painful muscle spasms)
- Neonatal sepsis (blood infection in infants)
- Rotaviral enterocolitis (severe diarrhea among infants and young children)
- Toxic shock syndrome (a life-threatening complication of certain bacterial infections)
- Enteroviral meningoencephalitis (inflammation of the brain and surrounding tissues caused by a virus)
- Toxic epidermal necrolysis or Stevens-Johnson syndrome (types of serious bacterial skin infections)
- Autoimmune mucocutaneous blistering disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita

If the request is for Gammaked or Gammunex-C, approval also requires:

- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gammaplex, Gammagard S-D, Gammagard Liquid, Octagam, Panzyga, Privigen

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMMUNE GLOBULIN - IV/SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gammagard Liquid, Gammaked, and Gamunex-C.

REFERENCES

Gammagard Liquid [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.
Gammaked [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
Gamunex-C [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 04/24

IMMUNE GLOBULIN - XEMBIFY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBULIN, GAMMA(IGG)KLHW	XEMBIFY	45891		GPI-10 (1910002064)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - XEMBIFY** requires the following rule(s) be met for approval:
   A. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xembify.

REFERENCES

- Xembify [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 01/20

INAVOLISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INAVOLISIB	ITOVEBI	49923		GPI-10 (2153804500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 Groups C50, C79.81) and meet **ALL** of the following criteria?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   The patient's tumor has a PIK3CA mutation as detected by an FDA-approved test
   Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
   The patient has experienced disease recurrence on or after completing adjuvant endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   3mg: #2 per day.
   9mg: #1 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INAVOLISIB (Itovebi)** requires the following rule(s) be met for approval:
   You have locally advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
   Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
   Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
   You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INAVOLISIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Itovebi.

REFERENCES

Itovebi [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/11/24
Created: 11/24
Client Approval: 11/24
P&T Approval: 01/25

INCLISIRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INCLISIRAN SODIUM	LEQVIO	47350		GPI-10 (3935604040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hyperlipidemia (ICD-10 E78.2, E78.5; Groups E78.0, E78.4), including heterozygous familial hypercholesterolemia (HeFH) (ICD-10 E78.01), and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
   The patient has an LDL-cholesterol level of at least 70 mg/dL at the initiation of Leqvio therapy
   The patient had a trial of or contraindication to Zetia (ezetimibe)
   The patient had a trial of or contraindication to ONE of the following preferred agents: Praluent (alirocumab), Repatha (evolocumab)
   Leqvio will NOT be used concurrently with a PCSK9 inhibitor (e.g., Praluent [alirocumab], Repatha [evolocumab])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient is currently taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND has been taking it for a duration of at least 8 weeks
   The patient is currently taking a maximally tolerated dose of any statin AND has been taking it for a duration of at least 8 weeks, given that the patient did not tolerate a high-intensity statin

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Leqvio?

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 3 months with a quantity limit of #1.5mL per 90 days.
   SECOND APPROVAL: Approve for 9 months with a quantity limit of #1.5mL per 180 days. (Enter a start date after the end date of first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INCLISIRAN

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   The patient has complete statin intolerance (defined by severe and intolerable adverse effects) (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least TWO separate statins AND have improved with the discontinuation of each statin

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   FIRST APPROVAL: Approve for 3 months with a quantity limit of #1.5mL per 90 days.
   SECOND APPROVAL: Approve for 9 months with a quantity limit of #1.5mL per 180 days. (Enter a start date after the end date of first approval).

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INCLISIRAN (Leqvio)** requires the following rule(s) be met for approval:
   You have primary hyperlipidemia (high levels of fat in the blood), which includes heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol disorder)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), endocrinologist (a type of hormone doctor), or lipidologist (a type of cholesterol doctor)
   You have a low density lipoprotein cholesterol (LDL-C: bad cholesterol) level of at least 70 mg/dL at the start of Leqvio therapy
   You had tried or have a contraindication to (harmful for you to use) Zetia (ezetimibe)
   You had tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Praluent (alirocumab), Repatha (evolocumab)
   You will NOT use Leqvio concurrently (at the same time) with a PCSK9 inhibitor (such as Praluent [alirocumab], Repatha [evolocumab])
   (Initial denial text continued on the next page)

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INCLISIRAN

INITIAL CRITERIA (CONTINUED)

If you are statin tolerant, approval also requires:
- You will continue statin treatment in combination with Leqvio
- You meet ONE of the following:
  - You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for a duration of at least 8 weeks
  - You are currently taking a maximally tolerated dose of any statin AND have been taking it for a duration of at least 8 weeks, given that you did not tolerate a high-intensity statin

If you are statin intolerant, approval also requires ONE of the following:
- You have an absolute contraindication to (harmful for you to use) statin therapy (such as, active decompensated liver disease [symptoms related to liver damage], nursing (breastfeeding) female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
- You have complete statin intolerance (defined by severe and intolerable adverse effects) that have occurred with trials of at least TWO separate statins, AND the adverse effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INCLISIRAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary hyperlipidemia (ICD-10 E78.2, E78.5; Groups E78.0, E78.4), including heterozygous familial hypercholesterolemia (HeFH) (ICD-10 E78.01), **AND** meet the following criterion?
   Leqvio will NOT be used concurrently with a PCSK9 inhibitor (e.g., Praluent [alirocumab], Repatha [evolocumab])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   The patient has continued concurrent therapy with a maximally tolerated dose of ANY statin
   The patient has an absolute contraindication to statin therapy
   The patient has complete statin intolerance

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.5mL per 180 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INCLISIRAN (Leqvio)** requires the following rule(s) be met for renewal:
   You have primary hyperlipidemia (high levels of fat in the blood), which includes heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol disorder)
   You will NOT use Leqvio concurrently (at the same time) with a PCSK9 inhibitor (such as Praluent [alirocumab], Repatha [evolocumab])
   You meet ONE of the following:
   - You have continued to take a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with Leqvio
   - You have continued to take a maximally tolerated dose of ANY statin along with Leqvio
   - You have an absolute contraindication to (harmful for you to use) statin therapy
   - You have complete statin intolerance (severe and intolerable adverse effects)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INCLISIRAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leqvio.

REFERENCES

Leqvio [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp.; June 2024.

Created: 01/22
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 01/24

INFLIXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB	REMICADE, INFLIXIMAB	18747		GPI-10 (5250504000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
    The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    Psoriatic arthritis (PsA: a type of skin and joint condition)
    Ankylosing spondylitis (AS: a type of joint condition)
    Severe plaque psoriasis (PsO: a type of skin condition)
    Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have moderate to severe ulcerative colitis, approval also requires:
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFLIXIMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient is currently using or has a contraindication to methotrexate
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #7.
   If no, continue to #8.

7. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

9. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Ankylosing spondylitis (AS: a type of joint condition)
   Severe plaque psoriasis (PsO: a type of skin condition)
   Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   (Renewal denial text continued on next page)

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe ulcerative colitis, renewal also requires:

You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

You meet ONE of the following:

- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remicade.

REFERENCES

Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; October 2021.

Created: 02/03
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

INFLIXIMAB-ABDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-ABDA	RENFLEXIS	44432		GPI-10 (5250504010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
    The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    - Psoriatic arthritis (PsA: a type of skin and joint condition)
    - Ankylosing spondylitis (AS: a type of joint condition)
    - Severe plaque psoriasis (PsO: a type of skin condition)
    - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

    If you have moderate to severe rheumatoid arthritis, approval also requires:
    - You are 18 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
    - You are currently using or have a contraindication to (harmful for you to use) methotrexate
    - You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have ankylosing spondylitis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

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INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, approval also requires:

You are 18 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
You meet ONE of the following:
- You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
- You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

If you have moderate to severe Crohn's disease, approval also requires:

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have moderate to severe ulcerative colitis, approval also requires:

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)

You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient is currently using or has a contraindication to methotrexate
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #7.
   If no, continue to #8.

7. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

9. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Ankylosing spondylitis (AS: a type of joint condition)
   Severe plaque psoriasis (PsO: a type of skin condition)
   Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   (Renewal denial text continued on next page)

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe ulcerative colitis, renewal also requires:

- You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Renflexis and Remicade.

REFERENCES

Renflexis [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc; January 2023.
Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; October 2021.

Created: 07/17
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

INFLIXIMAB-AXXQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-AXXQ	AVSOLA	46242		GPI-10 (5250504013)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
    The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    - Psoriatic arthritis (PsA: a type of skin and joint condition)
    - Ankylosing spondylitis (AS: a type of joint condition)
    - Severe plaque psoriasis (PsO: a type of skin condition)
    - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

    If you have moderate to severe rheumatoid arthritis, approval also requires:
    - You are 18 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
    - You are currently using or have a contraindication to (harmful for you to use) methotrexate
    - You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

You meet ONE of the following:

You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)

You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, approval also requires:

You are 18 years of age or older

Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)

You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have ankylosing spondylitis, approval also requires:

You are 18 years of age or older

Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)

You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

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INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, approval also requires:

You are 18 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
You meet ONE of the following:
- You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
- You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

If you have moderate to severe Crohn's disease, approval also requires:

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

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INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have moderate to severe ulcerative colitis, approval also requires:

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)

You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient is currently using or has a contraindication to methotrexate
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #7.
   If no, continue to #8.

7. Does the patient meet ONE of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

9. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Ankylosing spondylitis (AS: a type of joint condition)
   Severe plaque psoriasis (PsO: a type of skin condition)
   Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   (Renewal denial text continued on next page)

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

(Renewal denial text continued on next page)

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe ulcerative colitis, renewal also requires:

- You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avsola and Remicade.

REFERENCES

Avsola [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; October 2021.

Created: 06/20
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

INFLIXIMAB-DYYB - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-DYYB	INFLECTRA		40977	GPI-14 (52505040202120)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a gastroenterologist
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
    The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by GPID or GPI-14.**
    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **INFLIXIMAB-DYYB - IV (Inflectra)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
    - Psoriatic arthritis (PsA: a type of skin and joint condition)
    - Ankylosing spondylitis (AS: a type of joint condition)
    - Severe plaque psoriasis (PsO: a type of skin condition)
    - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
    - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

    If you have moderate to severe rheumatoid arthritis, approval also requires:
    - You are 18 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
    - You are currently using or have a contraindication to (harmful for you to use) methotrexate
    - You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

If you have ankylosing spondylitis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, approval also requires:

You are 18 years of age or older

Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)

You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp

You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

You meet ONE of the following:

- You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
- You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

If you have moderate to severe Crohn's disease, approval also requires:

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)

You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have moderate to severe ulcerative colitis, approval also requires:

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)

You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
- You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient is currently using or has a contraindication to methotrexate
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #5.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #7.
   If no, continue to #8.

7. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

9. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Humira (adalimumab), adalimumab-adaz, or Simlandi
   The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **INFLIXIMAB-DYYB - IV (Inflectra)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Ankylosing spondylitis (AS: a type of joint condition)
   Severe plaque psoriasis (PsO: a type of skin condition)
   Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   (Renewal denial text continued on next page)

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe ulcerative colitis, renewal also requires:

- You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Humira (adalimumab), adalimumab-adaz, or Simlandi
  - You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inflectra and Remicade.

REFERENCES

Inflectra [Prescribing Information]. New York, NY: Pfizer Labs, Inc.; April 2023.
Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; October 2021.

Created: 05/16
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

INFLIXIMAB-DYYB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-DYYB	ZYMFENTRA		55099 55098	GPI-14 (5250504020F530, 5250504020F830)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Zymfentra will be used following treatment with an intravenous infliximab agent (e.g., Remicade, Renflexis, Avsola)
   Therapy is prescribed by or in consultation with a gastroenterologist
   Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #2.

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Zymfentra will be used following treatment with an intravenous infliximab agent (e.g., Remicade, Renflexis, Avsola)
   Therapy is prescribed by or in consultation with a gastroenterologist
   Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Zymfentra will be used following treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:

- You are 18 years of age or older
- Zymfentra will be used following treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFLIXIMAB-DYYB - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zymfentra.

REFERENCES

Zymfentra [Prescribing Information]. Jersey City, New Jersey: Celltrion USA, Inc.; July 2024.

Created: 02/24
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

INGENOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INGENOL MEBUTATE	PICATO	38449		GPI-10 (9037803520)	

GUIDELINES FOR USE

Do not approve requests for Picato gel.

(NOTE: Picato discontinued due to safety concerns and increased risk of cancer.)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Picato.

Manufacturer provided FDA with notification of discontinuation in the manufacture of Picato. Discontinuation may be likely due to safety concerns; Picato is no longer authorized in the EU after concluding that Picato increases the risk of cancer.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 05/12
Client Approval: 08/21
P&T Approval: 04/21

INHALED INSULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		GPI-10 (2710401000)	BRAND= AFREZZA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet **ONE** of the following criteria?
   The patient has chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease)
   The patient has active lung cancer
   The patient is currently in diabetic ketoacidosis
   The patient smokes or has quit smoking within the past 6 months

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of type 1 diabetes mellitus (ICD-10 Group E10) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a baseline spirometry performed to measure FEV1
   The patient is concurrently using a long-acting insulin (e.g., Toujeo, Tresiba, Semglee)
   The patient had a trial of ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.
   90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.
   30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.

   If no, continue to #3.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a baseline spirometry performed to measure FEV1
   The patient had a trial of ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
   The prescriber has indicated that the patient is physically unable to or unwilling to administer injectable insulin

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.
   90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.
   30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Type 1 diabetes mellitus (a disorder with high blood sugar)
      Type 2 diabetes mellitus (a disorder with high blood sugar)
   If you have type 1 diabetes mellitus, approval also requires:
      You are 18 years of age or older
      You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
      Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)
      You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
   (Initial denial text continued on next page)

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

If you have type 2 diabetes mellitus, approval also requires:

- You are 18 years of age or older
- You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
- You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
- Your prescriber has indicated that you are physically unable to or unwilling to use injectable insulin

NOTE: Afrezza will NOT be approved if you have any of the following conditions: chronic lung disease (type of long-term lung disease), active lung cancer, currently in diabetic ketoacidosis (condition where body breaks down fat too fast), you are currently smoking or you quit smoking within the past 6 months.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INHALED INSULIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes mellitus (ICD-10 Group E10) **AND** is currently on a long-acting insulin (e.g., Toujeo, Tresiba, Semglee)?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Was follow-up spirometry to measure FEV1 performed after 6 months of treatment and then annually thereafter?

   If yes, continue to #4.
   If no, **approve for 1 month by GPID or GPI-14 (to allow for follow-up spirometry evaluation) with the following quantity limits:**
   90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
   90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.
   90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.
   30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
   60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

4. Has the patient's FEV1 declined by 20% or more from baseline?

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.
90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.
90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.
30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.
60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Type 1 diabetes mellitus (a disorder with high blood sugar)
- Type 2 diabetes mellitus (a disorder with high blood sugar)

If you have type 1 diabetes, renewal also requires:
- You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
- Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)
- Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)

If you have type 2 diabetes, renewal also requires:
- You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
- Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

REFERENCES

Afrezza [Prescribing Information]. Danbury, CT: Mannkind Corporation; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/24
Created: 02/15
Client Approval: 08/24
P&T Approval: 07/17

INOTERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		GPI-10 (6270104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   Tegsedi will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
   The patient had a trial of or contraindication to the preferred agent: Amvuttra (vutrisiran)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INOTERSEN

INTIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:
You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Amvuttra
Your diagnosis is confirmed by ONE of the following:
- Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (*transthyretin*) protein
- DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INOTERSEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   The patient has NOT progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   Tegsedi will NOT be used concurrently with other hATTR-PN agents (e.g. Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:
   You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tegsedi.

REFERENCES

Tegsedi [Prescribing Information]. Waltham, MA: Sobi, Inc.; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/18
Client Approval: 05/24
P&T Approval: 04/24

INSULIN PUMPS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUBCUTANEOUS INSULIN PUMP	T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, TANDEM MOBI SYSTEM, MINIMED 670G, MINIMED 770G, MINIMED 780G, MINIMED 630G, ILET INSULIN PUMP	35487		GPI-10 (9720103000)	FDB & Medi-Span: BRAND = MINIMED 670G, MINIMED 770G, MINIMED 780G, MINIMED 630G, T:SLIM X2%, T:SLIM X2 CONTROL-IQ%, T:SLIM X2 WITH BASAL-IQ%, TANDEM MOBI%, ILET INSULIN PUMP

GUIDELINES FOR USE

1. Is the claim rejecting for the following POS message: "***Coverage of this product should be provided through medical benefit, available manufacturer programs, or patient assistance programs'"*?**

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient meet **ALL** of the following criteria?
   The insulin pump is prescribed by or in consultation with an endocrinologist
   The patient has completed a comprehensive diabetes education program within the preceding 24 months
   The patient follows a maintenance program of at least 3 injections of insulin per day and requires frequent self-adjustments of insulin dose for the past 6 months
   The patient requires glucose self-testing of at least 4 times per day on average in the preceding 2 months
   The patient has NOT received an insulin pump within the last 4 years (Exception: pump is malfunctioning, not repairable, and not under warranty)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria while on a multiple daily insulin injection regimen?
   The patient's glycosylated hemoglobin level (HbA1c) is greater than 7%
   The patient has a history of recurring hypoglycemia
   The patient has wide fluctuations in blood glucose before mealtime
   The patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL
   The patient has a history of severe glycemic excursions (i.e., sudden spikes in blood sugar levels)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for T: Slim X2 OR T: Slim X2 with Basal-IQ **AND** the patient meets the following criterion?
   The patient is 6 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #5.

5. Is the request for the T: Slim X2 with Control-IQ **AND** the patient meets the following criterion?
   The patient is 6 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #6.

6. Is the request for Tandem Mobi System and the patient meets **ALL** of the following criteria?
   The patient has a diagnosis of type 1 diabetes mellitus
   The patient is 6 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #7.

7. Is the request for MiniMed 670G and the patient meets **ALL** of the following criteria?
   The patient has a diagnosis of type 1 diabetes mellitus
   The patient is 7 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #8.

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

8. Is the request for MiniMed 770G and the patient meets **ALL** of the following criteria?
   The patient has a diagnosis of type 1 diabetes mellitus
   The patient is 2 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #9.

9. Is the request for MiniMed 780G and the patient meets **ALL** of the following criteria?
   The patient has a diagnosis of type 1 diabetes mellitus
   The patient is 7 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #10.

10. Is the request for MiniMed 630G and the patient meets **ALL** of the following criteria?
    The patient has a diagnosis of type 1 diabetes mellitus
    The patient is 14 years of age or older

    If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
    If no, continue to #11.

11. Is the request for iLet Bionic Pancreas insulin pump and the patient meets **ALL** of the following criteria?
    The patient has a diagnosis of type 1 diabetes mellitus
    The patient is 6 years of age or older

    If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **INSULIN PUMPS** requires the following rule(s) be met for approval:
    The requested insulin pump is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
    You have completed a comprehensive diabetes education program within the previous 24 months
    You follow a maintenance program of at least 3 injections of insulin per day and require frequent self-adjustments of your insulin dose for the past 6 months
    (Denial text continued on next page)

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

You require glucose self-testing of at least 4 times per day on average in the previous 2 months
You have NOT received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
You are on a multiple daily insulin injection regimen and meet ONE of the following:
- You have a glycosylated hemoglobin level (HbA1c: a type of lab test) greater than 7 percent
- You have a history of recurring hypoglycemia (low blood sugar)
- You have wide fluctuations in blood sugar before mealtime
- You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/Dl
- You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

If you are requesting the T: Slim X2 OR T: Slim X2 with Basal-IQ, approval also requires:
You are 6 years of age or older

If you are requesting the T: Slim X2 with Control-IQ, approval also requires:
You are 6 years of age or older

If you are requesting the Tandem Mobi System, approval also requires:
You have type 1 diabetes mellitus (a disorder with high blood sugar)
You are 6 years of age or older

If you are requesting the MiniMed 670G, approval also requires:
You have type 1 diabetes mellitus (a disorder with high blood sugar)
You are 7 years of age or older

If you are requesting the MiniMed 770G, approval also requires:
You have type 1 diabetes mellitus (a disorder with high blood sugar)
You are 2 years of age or older

If you are requesting the MiniMed 780G, approval also requires:
You have type 1 diabetes mellitus (a disorder with high blood sugar)
You are 7 years of age or older

If you are requesting the MiniMed 630G, approval also requires:
You have type 1 diabetes mellitus (a disorder with high blood sugar)
You are 14 years of age or older

If you are requesting the iLet Bionic Pancreas insulin pump, approval also requires:
You have type 1 diabetes mellitus (a disorder with high blood sugar)
You are 6 years of age or older

This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

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INSULIN PUMPS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related insulin pumps.

REFERENCES

T:Slim X2 Insulin Pump. Tandem Diabetes Care. Important Safety Information. Available at: https://www.tandemdiabetes.com/products/t-slim-x2-insulin-pump
Tandem Mobi Insulin Pump. Tandem Diabetes Care. Important Safety Information. Available at: https://www.tandemdiabetes.com/legal/important-safety-information/tandem-mobi
MiniMed 670G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-670g
MiniMed 770G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-770g
MiniMed 780G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-780g
MiniMed 630G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-630g
iLet Bionic Pancreas. Beta Bionics. Important Safety Information. Available at: Safety Information - Beta Bionics

Created: 08/20
Effective: 02/17/25 Client Approval: 01/25 P&T Approval: 07/24

INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON ALFA-2B,RECOMB.	INTRON A	04528		GPI-10 (2170006020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Hairy cell leukemia
   - Condylomata acuminata
   - AIDS-related Kaposi's sarcoma
   - Chronic hepatitis B
   - Non-Hodgkin's lymphoma
   - Malignant melanoma
   - Chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis)
   - Follicular lymphoma
   - Angioblastoma
   - Carcinoid tumor
   - Chronic myeloid leukemia
   - Laryngeal papillomatosis
   - Multiple myeloma
   - Neoplasm of conjunctiva-neoplasm of cornea
   - Ovarian cancer
   - Polycythemia vera
   - Renal cell carcinoma
   - Skin cancer
   - Thrombocytosis
   - Vulvar vestibulitis

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, continue to #2.

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)
   - The patient has a detectable pretreatment HCV RNA level/viral load of 50 IU/mL or higher
   - The requested medication will be used with ribavirin or the patient has a contraindication to ribavirin
   - The patient had a trial of or contraindication to peginterferon alfa-2a or peginterferon alfa-2b

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Chronic hepatitis C (type of liver inflammation)
      2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
      3. Condylomata acuminate (genital warts)
      4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
      5. Chronic hepatitis B (type of liver inflammation)
      6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
      7. Malignant melanoma (serious type of skin cancer)
      8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
      9. Follicular lymphoma (type of lymphatic system cancer)
      10. Angioblastoma (certain blood-vessel tumors of the brain)
      11. Carcinoid (cancer) tumor
      12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
      13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)

   (Initial denial text continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

14. Multiple myeloma (plasma cell cancer)
15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
16. Ovarian cancer
17. Polycythemia vera (cancer where bone marrow makes too many red blood cells)
18. Renal cell carcinoma (type of kidney cancer)
19. Skin cancer, thrombocytosis (your body makes too many platelets)
20. Thrombocytosis (high level of platelets (cells that helps blood clot and stop bleeding) in your blood)
21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

B. **If you have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of 50 IU/mL or higher
   3. The requested medication will be used with ribavirin or you have a contraindication (harmful for)
   4. You had a trial of or contraindication (harmful for) to peginterferon alfa-2a or peginterferon alfa-2b

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic hepatitis C **AND** meet the following criterion? Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)

   If yes, continue to #2.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

2. Has the patient already received 24 weeks or more of interferon during this treatment?

   If yes, continue to #3.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

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INTERFERON ALFA-2B

RENEWAL CRITERIA (CONTINUED)

3. Is the patient's HCV RNA undetectable (less than 50 IU/mL) at 24 weeks?

If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:

A. The request is for continuation of current therapy or renewal with Intron A therapy
B. **If you have chronic hepatitis C (type of liver inflammation), renewal also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. If you already received 24 weeks or more of interferon treatment, your HCV (hepatitis C virus) RNA level (amount of virus in your blood) is undetectable (less than 50 IU/mL) at 24 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Intron A.

REFERENCES

- Intron A [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 02/14
Client Approval: 05/22
P&T Approval: 02/14

INTERFERON FOR MS - AVONEX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A	AVONEX, AVONEX PEN	11253		GPI-10 (6240306045)	MEDI-SPAN: BRAND = AVONEX, AVONEX PEN, AVONEX PREFILLED

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Avonex: #1 kit per 28 days or 2mL (#4 syringes) per 28 days.**
   - **Avonex Pen: #1 pen injector kit per 28 days or 2mL (#4 syringes) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - AVONEX** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Avonex.

REFERENCES
- Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

INTERFERON FOR MS - BETASERON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1B	BETASERON	08537		GPI-10 (6240306050)	BRAND = BETASERON

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for all NDCs or GPI-14 of Betaseron for #14 vials or kits per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - BETASERON** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Betaseron.

REFERENCES

- Betaseron [Prescribing Information]. Whippany, NJ: Bayer; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

INTERFERON FOR MS - EXTAVIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1B	EXTAVIA	08537		GPI-10 (6240306050)	BRAND = EXTAVIA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Avonex (interferon beta-1a), Copaxone/Glatiramer/Glatopa (glatiramer), fingolimod, Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a/albumin), Betaseron (interferon beta-1b), dimethyl fumarate, Mavenclad (cladribine), Mayzent (siponimod), Vumerity (diroximel fumarate), Aubagio (teriflunomide), Kesimpta (ofatumumab), Zeposia (ozanimod)
     (Please note: these MS agents may also require prior authorization)

   If yes, **approve for 12 months for all NDCs or GPI-14 of Extavia with a quantity limit of #14 vials or kits per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - EXTAVIA** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Avonex (interferon beta-1a), Copaxone/Glatiramer/Glatopa (glatiramer), fingolimod, Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a/albumin), Betaseron (interferon beta-1b), dimethyl fumarate, Mavenclad (cladribine), Mayzent (siponimod), Vumerity (diroximel fumarate), Aubagio (teriflunomide), Kesimpta (ofatumumab), Zeposia (ozanimod)
      (PLEASE NOTE: these medications may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - EXTAVIA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Extavia.

REFERENCES

- Extavia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/22
Client Approval: 05/24
P&T Approval: 01/20

INTERFERON FOR MS - PLEGRIDY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN	41331		GPI-10 (6240307530)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Plegridy injection starter pack: approve for 1 month with a quantity limit of 1mL (#2 prefilled pens or syringes).**
   - **SECOND APPROVAL: Plegridy Pen/Syringe: approve for 11 months (total approval duration of 12 months) with a quantity limit of 1mL (#2 125mcg prefilled pens or syringes) per 28 days. (Please enter start date of 3 weeks AFTER the START date of the first approval.).**

   SUBSEQUENT REQUESTS:
   - **Plegridy Pen/Syringe: approve for 12 months with a quantity limit of 1mL (#2 125mcg prefilled pens or syringes) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - PLEGRIDY** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - PLEGRIDY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Plegridy.

REFERENCES

- Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

INTERFERON FOR MS - REBIF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A/ALBUMIN	REBIF, REBIF REBIDOSE	23353		GPI-10 (6240306045)	FDB: BRAND = REBIF, REBIF REBIDOSE MED-SPAN: BRAND = REBIF REBIDOSE, REBIF REBIDOSE TITRATIONPACK, REBIF

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Rebif Titration Pack/Rebif Rebidose Titration Pack: approve for 1 month with a quantity limit of 4.2mL (#12 syringes) per 28 days.**
   - **SECOND APPROAL: Rebif/Rebif Rebidose: approve for 11 months (total approval duration of 12 months) with a quantity limit of 6mL (#12 syringes) per 28 days. (Please enter start date of 3 weeks AFTER the START date of the first approval.).**

   SUBSEQUENT REQUESTS:
   - **Rebif/Rebif Rebidose: approve for 12 months with a quantity limit of 6mL (#12 syringes) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - REBIF** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - REBIF

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebif.

REFERENCES

- Rebif [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

INTERFERON GAMMA-1B, RECOMB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE	06068		GPI-10 (2170006070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist, infectious disease specialist, or immunologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe malignant osteopetrosis (SMO) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an endocrinologist or hematologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Chronic granulomatous disease (CGD: a type of immune disorder)
      2. Severe malignant osteopetrosis (SMO: a type of bone condition)
   B. **If you have chronic granulomatous disease, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), infectious disease specialist (a doctor that specializes in treating infections), or immunologist (a type of immune system doctor)
   C. **If you have severe malignant osteopetrosis, approval also requires:**
      1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or hematologist (a type of blood doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON GAMMA-1B, RECOMB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO) and meet **ALL** of the following criteria?
   - The patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections)
   - The patient has NOT received hematopoietic cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:
   A. You have ONE of the following:
      1. Chronic granulomatous disease (CGD: a type of immune disorder)
      2. Severe malignant osteopetrosis (SMO: a type of bone condition)
   B. You have shown clinical benefit compared to baseline (such as reduction in frequency and severity of serious infections)
   C. You have NOT received hematopoietic cell transplantation (bone marrow transplant)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actimmune.

REFERENCES

- Actimmune [Prescribing Information] Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

Created: 09/05
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

IPTACOPAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IPTACOPAN HCL	FABHALTA	49336		GPI-10 (8580753520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a hematologist
   The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10 percent AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]) or Factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g)
   Therapy is prescribed by or in consultation with a nephrologist
   The patient's diagnosis is confirmed by a renal biopsy
   The patient has an eGFR of at least 20 mL/min/1.73m^2
   The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   The patient has tried an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR has a contraindication to an SGLT2 inhibitor
   Fabhalta will NOT be used concurrently with Filspari (sparsentan)

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IPTACOPAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- Your PNH diagnosis is confirmed by flow cytometry (a type of lab test) that shows ALL of the following:
  - You have a PNH granulocyte clone size of at least 10 percent
  - You have at least 2 different GPI-protein deficiencies (a certain type of protein is missing, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
- You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]), or Factor D inhibitor (such as Voydeya [danicopan])

If you have primary immunoglobulin A nephropathy, approval also requires:
- You are 18 years of age or older
- You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: a test that measures the amount of protein in urine] of at least 1.5 g/g)
- Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
- Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
- You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 20 mL/min/1.73m^2
- You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

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IPTACOPAN

INITIAL CRITERIA (CONTINUED)

You have tried a sodium-glucose cotransporter-2 inhibitor (SGLT2 inhibitor: a type of medication used to protect kidneys, such as Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR you have a contraindication to an SGLT2 inhibitor
You will NOT use Fabhalta concurrently (at the same time) with Filspari (sparsentan)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPTACOPAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]) or Factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   The patient has improved, or stable kidney function compared to baseline OR has a reduction in proteinuria
   Fabhalta will NOT be used concurrently with Filspari (sparsentan)

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   - Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)

   If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
   - You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before treatment)
   - You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), a C3 complement inhibitor (such as Empaveli [pegcetacoplan]) or Factor D inhibitor (such as Voydeya [danicopan])

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IPTACOPAN

RENEWAL CRITERIA (CONTINUED)

If you have primary immunoglobulin A nephropathy, renewal also requires:
You have improved, or stable kidney function compared to baseline (before starting Fabhalta) OR you have a reduction in proteinuria (lowered levels of protein in the urine)
You will NOT use Fabhalta concurrently (at the same time) with Filspari (sparsentan)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabhalta.

REFERENCES
Fabhalta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2024.

Created: 12/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

ISAVUCONAZONIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISAVUCONAZONIUM SULFATE	CRESEMBA		38095 54696	GPI-14 (11407030110125, 11407030110115)	

GUIDELINES FOR USE

1. Is this request for continuation of therapy after the patient was started on Cresemba in the hospital?

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with a quantity limit as follows:**
   74.5 mg: #150 per 30 days.
   186 mg: #60 per 30 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of invasive aspergillosis and meet **ALL** of the following criteria?
   The patient is 6 years of age or older and weighs at least 16 kg (35.2 lb)
   Therapy is prescribed by or in consultation with an infectious disease specialist
   The patient had a trial of or contraindication to voriconazole

   If yes, **approve the requested strength for 6 months total by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: Approve for 1 month with a quantity limit as follows:
   74.5 mg: #170 per 30 days for 1 fill.
   186 mg: #68 per 30 days for 1 fill.
   SECOND APPROVAL: Approve for 5 months with a quantity limit as follows (enter a start date of 3 days before the end date of the first approval):
   74.5 mg: #150 per 30 days.
   186 mg: #60 per 30 days.
   SUBSEQUENT REQUESTS:
   Approve the requested strength for 6 months with a quantity limit as follows:
   74.5 mg: #150 per 30 days.
   186 mg: #60 per 30 days.

   If no, continue to #3.

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of invasive mucormycosis and meet **ALL** of the following criteria?
   The patient is 6 years of age or older and weighs at least 16 kg (35.2 lb)
   Therapy is prescribed by or in consultation with an infectious disease specialist

   If yes, **approve the requested strength for 6 months total by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: Approve for 1 month with a quantity limit as follows:
   74.5 mg: #170 per 30 days for 1 fill.
   186 mg: #68 per 30 days for 1 fill.
   SECOND APPROVAL: Approve for 5 months with a quantity limit as follows (enter a start date of 3 days before the end date of the first approval):
   74.5 mg: #150 per 30 days.
   186 mg: #60 per 30 days.
   SUBSEQUENT REQUESTS:
   Approve the requested strength for 6 months with a quantity limit as follows:
   74.5 mg: #150 per 30 days.
   186 mg: #60 per 30 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISAVUCONAZONIUM (Cresemba)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   This is a request for continuation of therapy after you were started on Cresemba in the hospital
   You have invasive aspergillosis (a type of fungal infection)
   You have invasive mucormycosis (a type of fungal infection)
   If you have invasive aspergillosis, approval also requires:
   You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
   Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   You have tried or have a contraindication to (harmful for you to use) voriconazole
   (Denial text continued on next page)

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

If you have invasive mucormycosis, approval also requires:
You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cresemba.

REFERENCES

Cresemba [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/12/24
Created: 05/21
Client Approval: 08/24
P&T Approval: 01/24

ISTRADEFYLLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISTRADEFYLLINE	NOURIANZ	45994		GPI-10 (7340102500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (PD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing 'OFF' episodes
   - Nourianz will be used concurrently with levodopa/carbidopa
   - The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's agents from **TWO** different therapeutic classes: dopamine agonists (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (e.g., selegiline, rasagiline), or catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (times when medication wears off and you have movement problems)
   D. Nourianz will be used along with levodopa/carbidopa
   E. You had a previous trial of or contraindication to (medical reason why you cannot use) **TWO** Parkinson's agents from **TWO** different drug classes:
      1. Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
      2. Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
      3. Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ISTRADEFYLLINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nourianz.

REFERENCES

- Nourianz [Prescribing Information]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/19
Client Approval: 04/20
P&T Approval: 10/19

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ITRACONAZOLE	TOLSURA		45848	GPI-14 (11407035000113)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of **ONE** of the following types of fungal infections?
   - Blastomycosis, pulmonary and extrapulmonary
   - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
   - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of a generic itraconazole formulation
   - Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   <u>INITIAL REQUESTS</u>
   - **FIRST APPROVAL: approve for 1 fill with a quantity limit of #126 per 30 days.**
   - **SECOND APPROVAL: approve for 11 months with a quantity limit of #120 per 30 days.**

   <u>SUBSEQUENT REQUESTS</u>
   - **Approve for 12 months with a quantity limit of #120 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ITRACONAZOLE - TOLSURA

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ITRACONAZOLE (Tolsura)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following fungal infections:
   1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary (affecting the lungs) disease and disseminated, nonmeningeal (not affecting spinal cord and brain membranes) histoplasmosis
   3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with an infectious disease specialist

D. You had a previous trial of a generic itraconazole formulation

E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

REFERENCES

- Tolsura [Prescribing Information]. Greenville, NC: Mayne Pharma; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21

Created: 03/19
Client Approval: 05/21

P&T Approval: 04/21

IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVACAFTOR	KALYDECO	38461		GPI-10 (4530203000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient has a responsive mutation in the CFTR gene
   - The patient is NOT homozygous for the F508del mutation in the CFTR gene

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You are 1 month of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   E. You have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Kalydeco)
   F. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the CFTR gene

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalydeco.

REFERENCES

- Kalydeco [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; August 2023.

Created: 02/12
Effective: 01/28/25 Client Approval: 01/25 P&T Approval: 01/25

IVOSIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVOSIDENIB	TIBSOVO	45096		GPI-10 (2153494000)	

GUIDELINES FOR USE

1. Does the patient have a new diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - Tibsovo will be used in combination with azacitidine or as monotherapy
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older AND has comorbidities that prevent the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of relapsed or refractory myelodysplastic syndromes (MDS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #5.

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
   - The patient's cancer has been previously treated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
      2. Relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or has not responded to treatment)
      3. Relapsed or refractory myelodysplastic syndromes (MDS: a type of blood cancer that has returned or has not respond to treatment)
      4. Locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
   B. **If you have a new diagnosis of acute myeloid leukemia, approval also requires:**
      1. Tibsovo will be used in combination with azacitidine or as monotherapy (one drug treatment)
      2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test
      3. You meet ONE of the following:
         a. You are 75 years of age or older
         b. You are 18 years of age or older AND have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)
   C. **If you have relapsed or refractory acute myeloid leukemia, approval also requires:**
      1. You are 18 years of age or older
      2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have relapsed or refractory myelodysplastic syndromes, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

E. **If you have locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has an isocitrate dehydrogenase-1 (IDH1) mutation (type of enzyme mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Your cancer has been previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES

- Tibsovo [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23
Created: 11/18
Client Approval: 10/23
P&T Approval: 01/24

IXAZOMIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXAZOMIB CITRATE	NINLARO	42826		GPI-10 (2153604510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   - Ninlaro (ixazomib) will be used in combination with lenalidomide and dexamethasone
   - The patient has received at least one prior therapy for the treatment of multiple myeloma such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (plasma cell cancer)
   B. The requested medication will be used in combination with lenalidomide and dexamethasone
   C. You have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ninlaro.

REFERENCES
- Ninlaro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 12/15
Client Approval: 04/20
P&T Approval: 02/16

IXEKIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXEKIZUMAB	TALTZ SYRINGE, TALTZ AUTOINJECTOR	43193		GPI-10 (9025055400)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Taltz
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   For patients who are 6 years to 17 years of age, enter TWO approvals:
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month as follows:
   80mg/mL: #2mL per 28 days.
   40mg/0.5mL: #0.5mL per 28 days.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (enter a start date of 1 WEEK BEFORE the END date of the first approval):
   80mg/mL: #1mL per 28 days.
   40mg/0.5mL: #0.5mL per 28 days.
   20mg/0.25mL: #0.25mL per 28 days.
   For patients who are 18 years of age or older, enter THREE approvals:
   FIRST APPROVAL: Approve all formulations of the 80mg/mL strength for 1 month with a quantity limit of #3mL per 28 days.
   SECOND APPROVAL: Approve all formulations of the 80mg/mL strength for 2 months with a quantity limit of #2mL per 28 days (enter a start date of 1 WEEK BEFORE the END date of the first approval).
   THIRD APPROVAL: Approve all formulations of the 80mg/mL strength for 3 months with a quantity limit of #1mL per 28 days (enter a start date of 1 WEEK BEFORE the END date of the second approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve all formulations of the 80mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter THREE approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #3mL per 28 days.
   SECOND APPROVAL: Approve for 2 months with a quantity limit of #2mL per 28 days (enter a start date of 1 WEEK BEFORE the END date of the first approval).
   THIRD APPROVAL: Approve for 3 months with a quantity limit of #1mL per 28 days (enter a start date of 1 WEEK BEFORE the END date of the second approval).

   If no, **approve all formulations of the 80mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter TWO approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #2mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 28 days (enter a start date of 1 WEEK BEFORE the END date of the first approval).

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve all formulations of the 80mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter TWO approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #2mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 28 days (enter a start date of 1 WEEK BEFORE the END date of the first approval).

   If no, continue to #7.

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Cimzia [certolizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Taltz
   The patient has C-reactive protein (CRP) levels above the upper limit of normal
   The patient has sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve all formulations of the 80mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Taltz
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Taltz
  - You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IXEKIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 as follows:**
   80mg/mL: #1mL per 28 days.
   40mg/0.5mL: #0.5mL per 28 days.
   20mg/0.25mL: #0.25mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, continue to #3.

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, continue to #4.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Taltz will NOT be used concurrently with another systemic biologic (e.g., Cimzia [certolizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, renewal also requires:

- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Taltz.

REFERENCES

Taltz [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; August 2024.

Created: 04/16
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

LACOSAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACOSAMIDE	MOTPOLY XR		54119 54121 54122	GPI-14 (72600036007030, 72600036007020, 72600036007025)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   The patient weighs at least 50 kgs (110 lbs.)
   The patient had a trial of or contraindication to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine)
   The patient is unable to tolerate lacosamide immediate-release

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: Approve for 1 month for all strengths with the following quantity limits:
   100 mg: #4 per day.
   150 mg: #2 per day.
   200 mg: #2 per day.
   SECOND APPROVAL: Approve for 11 months for the requested strength with the following quantity limits (please enter a start date of 3 days before the end of the first approval):
   100 mg: #1 per day.
   150 mg: #2 per day.
   200 mg: #2 per day.
   SUBSEQUENT REQUESTS:
   Approve for 12 months for the requested strength with the following quantity limits:
   100 mg: #1 per day.
   150 mg: #2 per day.
   200 mg: #2 per day.

   If no, continue to #2.

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LACOSAMIDE

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of primary generalized tonic-clonic seizures (ICD-10 Group G40.3) and meet **ALL** of the following criteria?
   The patient weighs at least 50 kgs (110 lbs.)
   Motpoly XR will be used as adjunctive treatment
   The patient had a trial of or contraindication to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine)
   The patient is unable to tolerate lacosamide immediate-release

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: Approve for 1 month for all strengths with the following quantity limits:
   100 mg: #4 per day.
   150 mg: #2 per day.
   200 mg: #2 per day.
   SECOND APPROVAL: Approve for 11 months for the requested strength with the following quantity limits (please enter a start date of 3 days before the end of the first approval):
   100 mg: #1 per day.
   150 mg: #2 per day.
   200 mg: #2 per day.
   SUBSEQUENT REQUESTS:
   Approve for 12 months for the requested strength with the following quantity limits:
   100 mg: #1 per day.
   150 mg: #2 per day.
   200 mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LACOSAMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Partial-onset seizures (a type of seizure)
- Primary generalized tonic-clonic seizures (a type of seizure)

If you have primary-onset seizures, approval also requires:
- You weigh at least 50 kilograms (110 pounds)
- You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
- You are not able to tolerate lacosamide immediate-release

If you have primary generalized tonic-clonic seizures, approval also requires:
- You weigh at least 50 kilograms (110 pounds)
- Motpoly XR will be used as adjunctive (add-on) treatment
- You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
- You are not able to tolerate lacosamide immediate-release

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Motpoly XR.

REFERENCES

Motpoly XR [Prescribing Information]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; June 2024.

Created: 11/23
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 07/24

LACTIC ACID/CITRIC/POTASSIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACTIC ACID/CITRIC/POTASSIUM	PHEXXI	46568		GPI-10 (5532990340)	

Please refer to CONTRACEPTIVE ZERO COST SHARE OVERRIDE section below if the request is also for zero copay override.

GUIDELINES FOR USE

1. Is the request for prevention of pregnancy in a female patient with reproductive potential and the patient meets **ALL** of the following criteria?
   - The patient is NOT concurrently using vaginal ring products (e.g., Annovera, Nuvaring)
   - The patient had a previous trial of or contraindication to two contraceptive agents (e.g., intrauterine device [Mirena, Kyleena, Liletta, Skyla, ParaGard], hormonal implant/injection/patch/oral products [Nexplanon, Depo-Provera, Xulane, etc.])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 grams per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACTIC ACID/CITRIC/POTASSIUM (Phexxi)** requires the following rule(s) be met for approval:
   A. You are a female patient with reproductive potential using the requested medication for prevention of pregnancy
   B. You are not using vaginal ring products (such as Annovera or Nuvaring) together with Phexxi
   C. You had a previous trial of two contraceptive agents (such as an intrauterine device, hormonal implant, injection, patch, or oral products), unless there is a medical reason you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LACTIC ACID/CITRIC/POTASSIUM

GUIDELINES FOR USE (CONTINUED)

CONTRACEPTIVE ZERO COST SHARE OVERRIDE CRITERIA

6. Is the patient requesting a cost share exception for the requested contraceptive agent **AND** does the plan cover contraceptives at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

7. Do **ANY** of the following criteria apply?
   - The patient's plan has specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)
   - The request is for an agent with an excluded route of administration, such that the agent will be covered on the medical benefit

   If yes, guideline does not apply.
   If no, continue to #3.

8. Is the request for a generic agent?

   If yes, **approve for 12 months by HICL or GPI-10 at zero copay.**
   If no, continue to #4.

9. Is the request for **ONE** of the following?
   - A single-source brand (SSB) contraceptive agent that has no preferred generic agents or therapeutically equivalent products available
   - A multi-source brand (MSB) contraceptive agent

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LACTIC ACID/CITRIC/POTASSIUM

GUIDELINES FOR USE - CONTRACEPTIVE ZERO COST SHARE OVERRIDE CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    - Two preferred medications are medically inappropriate for the patient (alternatively, one if only one agent is available)
    - The patient has tried or has a documented medical contraindication to two preferred medications (alternatively, a trial of one if only one agent is available)
    - The prescriber provided documentation confirming that the requested drug is considered medically necessary (considerations may include severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service)

    If yes, **approve for 12 months by HICL or GPI-10 at zero copay.**
    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **CONTRACEPTIVE ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:
    A. The request is for ONE of the following:
        1. A generic contraceptive agent
        2. A single-source brand (SSB) contraceptive agent that has no preferred generic agents or therapeutically equivalent products available
        3. A multi-source brand (MSB) contraceptive agent
    B. **If the request is for a single-source brand or multi-source brand contraceptive medication, approval also requires ONE of the following:**
        1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
        2. You have tried or have a documented medical contraindication (harmful for) to two preferred medications (or one if only one agent is available)
        3. Your doctor has provided documentation confirming that the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

    Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LACTIC ACID/CITRIC/POTASSIUM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phexxi.

The Contraceptive Zero Cost Share Override criteria applies to plans where the pharmacy benefit allows for coverage of contraceptives at zero copay. The override criteria allow patient access to all FDA-approved contraceptive methods at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded contraceptives.

The MedImpact standard Zero Copay list currently offers coverage of all methods at zero cost share. The zero cost share list offers a variety of contraceptives. Covered methods (zero cost share) include 1) specified barrier contraceptives (condoms, diaphragms, cervical caps, and nonoxynol-9) 2) generic oral hormonal contraceptives under STC 0248, including generic emergency contraceptives and Ella 3) generic transdermal patch contraceptive (currently marketed by Mylan as Xulane) 4) Nuvaring vaginal ring 5) Intrauterine devices – levonorgestrel IUDs and copper IUDs 6) Depo-Provera injections, 7) Nexplanon implant devices, and 8) Intravaginal contraceptives. The majority of the contraceptives on the EHB Zero cost share list are generic agents, which promotes a cost-effective formulary.
The healthcare.gov website (https://www.healthcare.gov/coverage/birth-control-benefits/) currently recommends: All approved contraceptive methods prescribed by a woman's doctor are covered, including:

- Barrier methods (used during intercourse), like diaphragms and sponges
- Hormonal methods, like birth control pills and vaginal rings
- Implanted devices, like intrauterine devices (IUDs)
- Emergency contraception, like Plan B® and Ella®
- Sterilization procedures
- Patient education and counseling

REFERENCES

- Phexxi [Prescribing Information]. San Diego, CA: Evofem, Inc., February 2022.
- Birth control benefits; https://www.healthcare.gov/coverage/birth-control-benefits/
- FAQS About Affordable Care Act Implementation Part 51; https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/22
Created: 08/20
Client Approval: 08/22
P&T Approval: 04/22

LANADELUMAB-FLYO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LANADELUMAB-FLYO	TAKHZYRO	45177		GPI-10 (8584204020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Takhzyro will be used for prophylaxis against HAE attacks
   The patient's diagnosis of HAE is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q
   Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
   Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: The prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for approval:
   You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   You are 2 years of age or older
   Takhzyro will be used for the prevention of hereditary angioedema attacks
   Your diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (a type of blood test)
   Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for HAE (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANADELUMAB-FLYO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
   The patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline
   Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days. APPROVAL TEXT:** The prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for renewal:
   You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
   You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for HAE (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Takhzyro.

REFERENCES

Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; February 2023.

Created: 09/18
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 07/24

LAPATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAPATINIB DITOSYLATE	TYKERB, LAPATINIB	34541		GPI-10 (2153302610)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The requested medication will be used in combination with Xeloda (capecitabine)
   - The patient has received prior therapy with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The patient's tumor is hormone receptor-positive
   - The requested medication will be used in combination with Femara (letrozole)
   - The patient is a postmenopausal woman

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: gene/protein in breast cancer) positive
   C. **If you have advanced or metastatic breast cancer, approval also requires:**
      1. The requested medication will be used in combination with Xeloda (capecitabine)
      2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
   D. **If you have metastatic breast cancer, approval also requires:**
      1. Your tumor is hormone receptor-positive
      2. The requested medication will be used in combination with Femara (letrozole)
      3. You are a postmenopausal woman

   (Denial text continued on the next page)

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LAPATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tykerb.

REFERENCES

- Tykerb [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 04/10
Client Approval: 03/21
P&T Approval: 08/13

LAROTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAROTRECTINIB	VITRAKVI	45494		GPI-10 (2153383520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - There are no satisfactory alternative treatments, or the patient has progressed following treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vitrakvi oral capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

   If no, continue to #3.

3. Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
   - The request is for a pediatric patient
   - The patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
   - The patient has other medical need for the oral solution

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Vitrakvi 20mg/mL oral solution: #10mL per day.**

   If no, do not approve Vitrakvi oral suspension. **Please enter a proactive PA for Vitrakvi capsules and approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

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LAROTRECTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

- Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/19
Client Approval: 04/20
P&T Approval: 01/19

LASMIDITAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LASMIDITAN SUCCINATE	REYVOW	46082		GPI-10 (6740654060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months for the requested strength by GPID OR GPI-14 as follows:**
   - **50mg: #8 per 30 days.**
   - **100mg: #8 per 30 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
   A. The request is for acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LASMIDITAN

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - The patient has experienced clinical improvement defined as ability to function normally within 2 hours of dose, headache pain disappears within 2 hours of dose, OR therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **50mg: #8 per 30 days.**
   - **100mg: #8 per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
   A. The request is for acute (quick onset) treatment of migraines (a type of headache)
   B. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LASMIDITAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reyvow.

REFERENCES

- Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC, September 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/20

LAZERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAZERTINIB MESYLATE	LAZCLUZE	49822		GPI-10 (2136004830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw)
   The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   80mg: #2 per day.
   240mg: #1 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAZERTINIB (Lazcluze)** requires the following rule(s) be met for approval:
   You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
   You are 18 years of age or older
   Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw)
   Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LAZERTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazcluze.

REFERENCES

Lazcluze [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/09/24
Created: 08/24
Client Approval: 09/24
P&T Approval: 10/24

LEBRIKIZUMAB-LBKZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEBRIKIZUMAB-LBKZ	EBGLYSS	49658		GPI-10 (9027304010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient weighs at least 40 kg (88 lbs)
   Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   The patient had a trial of or contraindication to TWO of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   Ebglyss will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following?
   High potency topical corticosteroid (e.g., halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   Topical calcineurin inhibitor (e.g., Protopic [tacrolimus], Elidel [pimecrolimus])
   Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole])
   Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   Phototherapy

   If yes, **approve for a total of 6 months by HICL or GPI-10. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #8mL.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #4mL per 28 days (enter a start date of 3 days BEFORE the END date of the first approval).
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEBRIKIZUMAB-LBKZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for approval:
You have moderate to severe atopic dermatitis (AD: a type of skin condition)
You are 12 years of age or older
You weigh at least 40 kilograms (88 pounds)
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
You have tried or have a contraindication to (harmful for you to use) TWO of the following:
- High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
- Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
- Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole])
- Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
- Phototherapy (a type of light therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEBRIKIZUMAB-LBKZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient has shown improvement while on Ebglyss
   The patient had a trial of or contraindication to TWO of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   Ebglyss will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for renewal:
   You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   You have shown improvement while on Ebglyss
   You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ebglyss.

REFERENCES

Ebglyss [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2024.

Created: 09/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

L-GLUTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLUTAMINE (L-GLUTAMINE)	ENDARI, GLUTAMINE (L-GLUTAMINE)		13365	GPI-10 (8280102000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (SCD) (ICD-10 Group D57) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between 5 to 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #6 packets per day.**

   If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient had at least 2 sickle cell crises in the past year (a sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration)
   - The patient is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
   - The patient has a history of or has recurrent acute chest syndrome (ACS)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #6 packets per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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L-GLUTAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (a type of blood disorder)
B. You are 5 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. The patient had a trial of or contraindication to (harmful for you to use) hydroxyurea
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year (a sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered [injected into the vein] narcotic [a class of drugs used to treat pain] or parenterally administered ketorolac, the occurrence of chest syndrome, priapism [prolonged erection of penis], or splenic sequestration [sickle-shaped blood cells trapped in spleen])
    2. You are having sickle-cell associated symptoms (such as pain or anemia [a type of blood condition]) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) **AND** meet the following criterion?
   - The patient has maintained or experienced a reduction in acute complications of sickle cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS])

   If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #6 packets per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for renewal:
   A. You have sickle cell disease (a type of blood disorder)
   B. You have maintained or experienced a reduction in acute (short-term) complications of sickle cell disease (such as the number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever, low oxygen level])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Endari

REFERENCES

- Endari [Prescribing Information]. East Windsor, NJ: Novitium Pharma LLC; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/05/24
Created: 09/17
Client Approval: 07/24
P&T Approval: 01/20

LEDIPASVIR/SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEDIPASVIR/ SOFOSBUVIR	HARVONI, LEDIPASVIR/ SOFOSBUVIR	41457		GPI-10 (1235990240)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
   The patient is 3 years of age or older
   The patient has genotype 1, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #13.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   Harvoni will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. John's wort)
   Harvoni will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naïve and meets **ALL** of the following criteria?
   The patient has genotype 1 or 4 infection
   The patient does not have cirrhosis
   The patient has an HCV RNA level of less than 6 million IU/mL

   If yes, continue to #5.
   If no, continue to #6.

5. Is the request for Harvoni 45mg-200mg pellets **AND** the patient is unable to swallow tablets?

   If yes, **approve 45mg-200mg pellets for 8 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, **approve for 8 weeks by GPID or GPI-14 for the requested strength as follows:**
   90mg-400mg tablet: #1 per day.
   45mg-200mg tablet: #1 per day.
   33.75mg-150mg pellets: #1 per day.

6. Is the patient treatment-naïve and meets **ONE** of the following criteria?
   The patient does not have cirrhosis
   The patient has compensated cirrhosis (Child-Pugh A)
   The patient has decompensated cirrhosis (Child-Pugh B or C) AND Harvoni will be used with ribavirin
   The patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin
   The patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

   If yes, continue to #11.
   If no, continue to #7.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have genotype 1 infection and meet **ALL** of the following criteria?
   The patient is treatment-experienced (previously failed a peginterferon alfa-based regimen)
   The patient has compensated cirrhosis (Child-Pugh A)

   If yes, continue to #12.
   If no, continue to #8.

8. Is the patient treatment-experienced (previously failed a peginterferon alfa-based regimen) and meets **ONE** of the following criteria?
   The patient does not have cirrhosis
   The patient has genotype 4, 5, or 6 infection AND has compensated cirrhosis (Child-Pugh A)
   The patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin
   The patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

   If yes, continue to #11.
   If no, continue to #9.

9. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   The patient has decompensated cirrhosis (Child-Pugh B or C)
   Harvoni will be used with ribavirin

   If yes, continue to #11.
   If no, continue to #10.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
    The patient has a contraindication to ribavirin (ribavirin ineligible)
    The patient failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
    The patient is post-liver transplant, treatment-experienced, AND Harvoni will be used with ribavirin

    If yes, continue to #12.
    If no, continue to #13.

11. Is the request for Harvoni 45mg-200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg-200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    90mg-400mg tablet: #1 per day.
    45mg-200mg tablet: #1 per day.
    33.75mg-150mg pellets: #1 per day.

12. Is the request for 45mg-200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg-200mg pellets for 24 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
    90-400mg tablet: #1 per day.
    45-200mg tablet: #1 per day.
    33.75-150mg pellets: #1 per day.

13. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:
You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
You are 3 years of age or older
You have genotype 1, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
You will NOT use Harvoni concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. John's wort)
You will NOT use Harvoni concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
If the request is for Harvoni 45mg/200mg pellets, approval also requires:
You are unable to swallow tablets
If you are treatment-naïve (no prior treatment), approval also requires ONE of the following:
You do not have cirrhosis (liver damage and scarring)
You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, AND Harvoni will be used with ribavirin
You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin
(Denial text continued on next page)

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:

- You do not have cirrhosis (liver damage and scarring) AND were previously treated with a peginterferon alfa-based regimen
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) AND were previously treated with a peginterferon alfa-based regimen
- You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
- You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
- You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
- You have decompensated cirrhosis, failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
- You have received a liver transplant, have decompensated cirrhosis, AND Harvoni will be used with ribavirin

Harvoni will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEDIPASVIR/SOFOSBUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harvoni.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 28, 2023.

Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/22/24
Created: 11/14
Client Approval: 06/24
P&T Approval: 04/24

LEFAMULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEFAMULIN	XENLETA		46826	GPI-14 (16240040100320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEFAMULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:

A. You have community-acquired bacterial pneumonia (type of lung infection)
B. You are 18 years of age or older
C. The infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
D. You meet **ONE** of the following criteria:
    1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
    2. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with a) resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** b) susceptibility to Xenleta
    3. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of at least **TWO** standard of care agents (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) for community-acquired bacterial pneumonia, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

REFERENCES

- Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

LENACAPAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENACAPAVIR SODIUM	SUNLENCA	48555		GPI-10 (1210155520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-experienced
   - The patient's HIV-1 is multidrug resistant and has failed current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve for 12 months by GPID or GPI-14 for all dosage forms as follows:**
   - **300mg tablet: #5 per 6 months.**
   - **463.5mg/1.5mL vial: #3 mL per 6 months.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENACAPAVIR (Sunlenca)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1: a type of immune disorder)
   B. You are 18 years of age or older
   C. You are treatment-experienced
   D. You have a multidrug resistant (not responding to treatment) HIV-1 infection and have failed your current antiretroviral regimen (HIV treatment) due to resistance, intolerance (side effects), or safety considerations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LENACAPAVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunlenca.

REFERENCES

- Sunlenca [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 01/23
Client Approval: 05/23
P&T Approval: 01/22

LENALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENALIDOMIDE	REVLIMID, LENALIDOMIDE	33412		GPI-10 (9939405000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Will the requested medication be used as induction or consolidation treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #21 every 28 days.**
   If no, continue to #3.

3. Will the requested medication be used as maintenance treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of anemia due to a myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's myelodysplastic syndrome (MDS) is associated with a deletion 5q abnormality

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib)

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days.**
   If no, continue to #6.

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has previously been treated for follicular lymphoma (FL)
   The requested medication will be used in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, continue to #7.

7. Does the patient have a diagnosis of marginal zone lymphoma (MZL) (ICD-10 Group C83.0) and meet **ALL** the following criteria?
   The patient is 18 years of age or older
   The patient has previously been treated for marginal zone lymphoma (MZL)
   The requested medication will be used in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** the requested medication will be used in combination with another chemotherapy agent(s)?
   (**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with the requested medication. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Multiple myeloma (MM: a type of blood cancer)
- Anemia (a type of blood condition) due to a myelodysplastic syndrome (MDS: a type of blood cancer)
- Mantle cell lymphoma (MCL: a type of blood cell)
- Follicular lymphoma (FL: a type of blood cancer)
- Marginal zone lymphoma (MZL: a type of blood cancer)
- The requested medication will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have multiple myeloma, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as induction, consolidation, or maintenance treatment for multiple myeloma

If you have anemia due to a myelodysplastic syndrome, approval also requires:
- You are 18 years of age or older
- Your myelodysplastic syndrome is associated with a deletion 5q abnormality (a type of gene mutation)

If you have mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have relapsed or progressed (disease has returned or worsened) after two prior therapies, one of which included Velcade (bortezomib)

If you have follicular lymphoma, approval also requires:
- You are 18 years of age or older
- You have previously been treated for follicular lymphoma
- The requested medication will be used in combination with a rituximab product (a type of cancer drug)

If you have marginal zone lymphoma, approval also requires:
- You are 18 years of age or older
- You have previously been treated for marginal zone lymphoma
- The requested medication will be used in combination with a rituximab product (a type of cancer drug)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LENALIDOMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revlimid.

REFERENCES

Revlimid [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

Created: 08/12
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 07/19

LENIOLISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENIOLISIB PHOSPHATE	JOENJA	48803		GPI-10 (9939154060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENIOLISIB (Joenja)** requires the following rule(s) be met for approval:
   A. You have activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS: a type of mutation that impacts the immune system)
   B. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Joenja.

REFERENCES

- Joenja [Prescribing Information]. Leiden, The Netherlands: Pharming Technologies B.V.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 04/23
Client Approval: 05/23
P&T Approval: 04/23

LENVATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		GPI-10 (2133505420)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) (ICD-10 C73) and meet **ALL** of the following criteria? (**NOTE**: Differentiated thyroid cancer (DTC) can be classified as papillary (PTC), follicular (FTC), or Hurthle cell)
   The thyroid cancer is locally recurrent or metastatic
   The thyroid cancer is progressive
   The thyroid cancer is refractory to radioactive iodine therapy

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   10 mg daily dose: #1 per day.
   14 mg daily dose: #2 per day.
   20 mg daily dose: #2 per day.
   24 mg daily dose: #3 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #5.

3. Will Lenvima be used in combination with pembrolizumab (Keytruda)?

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   8 mg daily dose: #2 per day.
   10 mg daily dose: #1 per day.
   14 mg daily dose: #2 per day.
   20 mg daily dose: #2 per day.

   If no, continue to #4.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

4. Will Lenvima be used in combination with everolimus (Afinitor) **AND** the patient meets the following criterion?
   The patient has tried one anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   8 mg daily dose: #2 per day.
   10 mg daily dose: #1 per day.
   14 mg daily dose: #2 per day.
   18 mg daily dose: #3 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
   The patient's cancer is unresectable

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   4 mg every other day: #1 per 2 days.
   4 mg daily dose: #1 per day.
   8 mg daily dose: #2 per day.
   12 mg daily dose: #3 per day.

   If no, continue to #6.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of advanced endometrial carcinoma (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   Lenvima will be used in combination with pembrolizumab (Keytruda)
   The patient's cancer is mismatch repair proficient (pMMR) OR is not microsatellite instability-high (MSI-H), as determined by an FDA-approved test
   The patient has experienced disease progression following prior systemic therapy
   The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   8 mg daily dose: #2 per day.
   10 mg daily dose: #1 per day.
   14 mg daily dose: #2 per day.
   20 mg daily dose: #2 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:
   You have **ONE** of the following:
   - Differentiated thyroid cancer (DTC: a type of thyroid cancer)
   - Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   - Hepatocellular carcinoma (HCC: a type of liver cancer)
   - Advanced endometrial carcinoma (EC: a type of uterus cancer)

   If you have differentiated thyroid cancer, approval also requires:
   - Your thyroid cancer is locally recurrent (re-appears in the same spot) or metastatic (has spread to other parts of the body)
   - Your thyroid cancer is progressive (getting worse)
   - Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

   (Denial text continued on next page)

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

If you have advanced renal cell carcinoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Lenvima will be used in combination with pembrolizumab (Keytruda)
  - Lenvima will be used in combination with everolimus (Afinitor) AND you have tried one anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

If you have hepatocellular carcinoma, approval also requires:
- Your cancer is unresectable (cannot be removed by surgery)

If you have advanced endometrial carcinoma, approval also requires:
- Lenvima will be used in combination with pembrolizumab (Keytruda)
- Your cancer is mismatch repair proficient (pMMR: your tumor has normal expression of types of protein) OR is not microsatellite instability-high (MSI-H: a type of mutation), as determined by a Food and Drug Administration (FDA)-approved test
- You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
- You are not a candidate for curative (to cure) surgery or radiation

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES

Lenvima [Prescribing Information]. Nutley, NJ: Eisai, Inc.; January 2025.

Created: 2/15
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 04/25

LETERMOVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LETERMOVIR	PREVYMIS	44622		GPI-10 (1220004500)	

GUIDELINES FOR USE

1. Is the request for prophylaxis of cytomegalovirus (CMV) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT) recipient and the patient meets **ALL** of the following criteria?
   The patient is 6 months of age or older AND weighs at least 6 kg (13.2 lbs)
   The patient is a CMV-seropositive recipient [R+] of an allogeneic HSCT
   The patient will start or started Prevymis between Day 0 and Day 28 post-transplant (before or after engraftment)

   If yes, continue to #2.
   If no, continue to #4.

2. Will the patient receive Prevymis beyond 100 days post-transplant?

   If yes, continue to #3.
   If no, **approve for 100 days by GPID or GPI-14 for all strengths as follows:**
   240mg tablet: #1 per day.
   480mg tablet: #1 per day.
   240mg/12mL vial: #12mL per day.
   480mg/24mL vial: #24mL per day.
   20mg pellet: #4 per day.
   120mg pellet: #4 per day.

3. Is the patient at risk for late CMV infection and disease, **AND** will not receive Prevymis beyond 200 days post-transplant?

   If yes, **approve for 200 days by GPID or GPI-14 for all strengths as follows:**
   240mg tablet: #1 per day.
   480mg tablet: #1 per day.
   240mg/12mL vial: #12mL per day.
   480mg/24mL vial: #24mL per day.
   20mg pellet: #4 per day.
   120mg pellet: #4 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LETERMOVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the request for prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient and the patient meets **ALL** of the following criteria?
   The patient is 12 years of age or older AND weighs at least 40 kg (88 lbs)
   The patient is a kidney transplant recipient at high risk (i.e., donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
   The patient will start or started Prevymis between Day 0 and Day 7 post-transplant
   The patient will not receive Prevymis beyond 200 days post-transplant

   If yes, **approve for 200 days by GPID or GPI-14 for all strengths as follows:**
   240mg tablet: #1 per day.
   480mg tablet: #1 per day.
   240mg/12mL vial: #12mL per day.
   480mg/24mL vial: #24mL per day.
   120mg pellet: #4 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LETERMOVIR (Prevymis)** requires the following rule(s) be met for approval:
   The request is for ONE of the following:
   Prophylaxis (prevention) of cytomegalovirus (CMV: a type of virus) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT: cells transplanted from a matching donor) recipient
   Prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient
   If the request is for prophylaxis of cytomegalovirus infection and disease in an allogeneic hematopoietic stem cell transplant recipient, approval also requires:
   You are 6 months of age or older AND weigh at least 6 kilograms (13.2 pounds)
   You are a CMV-seropositive recipient [R+] of an allogeneic HSCT
   You will start or have started Prevymis between Day 0 and Day 28 post-transplant (before or after engraftment [a type of transplant])
   You meet ONE of the following:
   You are NOT at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 100 days post (after)-transplant
   You are at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 200 days post (after)-transplant
   (Denial text continued on next page)

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LETERMOVIR

GUIDELINES FOR USE (CONTINUED)

If the request is for prophylaxis of cytomegalovirus disease in a kidney transplant recipient, approval also requires:

You are 12 years of age or older AND weigh at least 40 kilograms (88 pounds)
You are a kidney transplant recipient at high risk (donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
You will start or have started Prevymis between Day 0 and Day 7 post (after)-transplant
You will not receive Prevymis beyond 200 days post-transplant

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prevymis.

REFERENCES

Prevymis [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; January 2025.

Created: 02/18
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 10/24

LEUPROLIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE		84597	GPI-14 (21405010106407)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64)?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 kits per 28 days.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #4.

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
      3. Central precocious puberty (CPP: early sexual development in girls and boys)
   B. **If you are female and have central precocious puberty, approval also requires:**
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
      3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      4. You are/were younger than 8 years of age when your condition started
      5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   (Initial denial text continued on next page)

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

C. **If you are male and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or advanced prostate cancer, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has NOT reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have NOT reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leuprolide.

REFERENCES

- Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 09/18
Client Approval: 06/24
P&T Approval: 04/22

LEUPROLIDE-ELIGARD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	ELIGARD		17377 18155 19219 24301	GPI-14 (21405010106415, (21405010156432, (21405010206435, (21405010256445)	

GUIDELINES FOR USE

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **7.5mg: #1 per month.**
   - **22.5mg: #1 per 3 months.**
   - **30mg: #1 per 4 months.**
   - **45mg: #1 per 6 months.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-ELIGARD** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE-ELIGARD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eligard.

REFERENCES

- Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 09/18
Client Approval: 01/23
P&T Approval: 04/22

LEVACETYLLEUCINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVACETYLLEUCINE	AQNEURSA	49883		GPI-10 (6200002300)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a neurologist or geneticist

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for approval:
   You have Niemann-Pick disease type C (NPC: a type of genetic condition)
   Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVACETYLLEUCINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
   The patient has experienced disease improvement or a reduction in disease progression

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for renewal:
   You have Niemann-Pick disease type C (NPC: a type of genetic condition)
   You have shown disease improvement or a reduction in disease progression

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aqneursa.

REFERENCES

Aqneursa [Prescribing Information]. Austin, TX: IntraBio Inc.; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 10/24
Client Approval: 10/24
P&T Approval: 07/24

LEVAMLODIPINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVAMLODIPINE MALEATE	CONJUPRI, LEVAMLODIPINE MALEATE	46284		GPI-10 (3400006728)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to TWO generic dihydropyridine calcium channel blockers (e.g., amlodipine, felodipine, nicardipine)
   - The patient had a trial of or contraindication to TWO other antihypertensive agents in another class (e.g., hydrochlorothiazide, lisinopril, losartan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 6 years of age or older
   C. You have tried or have a contraindication (harmful for) to TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine)
   D. You have tried or have a contraindication (harmful for) to TWO other antihypertensive agents in another class (such as hydrochlorothiazide, lisinopril, losartan)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Conjupri.

REFERENCES

- Conjupri [Prescribing Information]. Hong Kong: CSPC Ouyi Pharmaceutical Co., Ltd.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/22
Created: 10/20
Client Approval: 05/22
P&T Approval: 10/20

LEVETIRACETAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVETIRACETAM	SPRITAM		36266 31202 36046 36265	GPI-14 (7260004300G850 7260004300G820 7260004300G830 7260004300G840)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient is unable to swallow levetiracetam tablets
   - The patient had a trial of levetiracetam oral solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **250mg: #4 per day.**
   - **500mg: #4 per day.**
   - **750mg: #4 per day.**
   - **1000mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of myoclonic seizures in juvenile myoclonic epilepsy and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Spritam will be used as adjunctive therapy
   - The patient is unable to swallow levetiracetam tablets
   - The patient had a trial of levetiracetam oral solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **250mg: #4 per day**
   - **500mg: #4 per day**
   - **750mg: #4 per day**
   - **1000mg: #2 per day**

   If no, continue to #3.

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LEVETIRACETAM

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of primary generalized tonic-clonic seizures and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Spritam will be used as adjunctive therapy
   - The patient is unable to swallow levetiracetam tablets
   - The patient had a trial of levetiracetam oral solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **250mg: #4 per day.**
   - **500mg: #4 per day.**
   - **750mg: #4 per day.**
   - **1000mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVETIRACETAM (Spritam)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Partial-onset seizures (type of seizure)
      2. Myoclonic seizures in juvenile myoclonic epilepsy (type of seizure in childhood)
      3. Primary generalized tonic-clonic seizures (type of seizure)
   B. **If you have partial-onset seizures, approval also requires:**
      1. You are 4 years of age or older
      2. You are unable to swallow levetiracetam tablets
      3. You had a trial of levetiracetam oral solution
   C. **If you have myoclonic seizures in juvenile myoclonic epilepsy, approval also requires:**
      1. You are 12 years of age or older
      2. Spritam will be used as adjunctive (add-on) therapy
      3. You are unable to swallow levetiracetam tablets
      4. You had a trial of levetiracetam oral solution
   D. **If you have primary generalized tonic-clonic seizures, approval also requires:**
      1. You are 6 years of age or older
      2. Spritam will be used as adjunctive (add-on) therapy
      3. You are unable to swallow levetiracetam tablets
      4. You had a trial of levetiracetam oral solution

   (Denial text continued on next page)

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LEVETIRACETAM

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spritam.

REFERENCES

- Spritam [Prescribing Information]. Blue Ash, OH: Aprecia Pharmaceuticals LLC; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23

Created: 11/22
Client Approval: 02/23

P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVODOPA	INBRIJA	01897		GPI-10 (73200040000)	ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - Inbrija is being used for intermittent treatment of OFF episodes associated with Parkinson's disease
   - The patient is currently being treated with carbidopa/levodopa
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient is **NOT** currently taking more than 1600mg of levodopa per day
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's disease agents from **TWO** different classes of the following: dopamine agonist (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline), catechol-o-methyl transferase (COMT) inhibitors (e.g., entacapone, tolcapone), adenosine receptor antagonist A2A (e.g., istradefylline)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
   C. You are currently being treated with carbidopa/levodopa
   D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
   (Initial denial text continued on next page)

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LEVODOPA

INITIAL CRITERIA (CONTINUED)

E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVODOPA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inbrija.

REFERENCES

- Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
Client Approval: 04/20
P&T Approval: 10/19

LEVOKETOCONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOKETOCONAZOLE	RECORLEV	47743		GPI-10 (3002204000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's syndrome and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient is not a candidate for surgery or surgery has not been curative
   - The patient has tried or has a contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   INTIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for approval:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. You are not a candidate for surgery or surgery has not been curative
   E. You have tried or have a contraindication (harmful for) to oral ketoconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVOKETOCONAZOLE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's syndrome and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's syndrome (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Recorlev

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for renewal:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You continue to have improvement of Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Recorlev

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Recorlev.

REFERENCES

- Recorlev [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/22
Created: 01/22
Client Approval: 01/22
P&T Approval: 01/22

LEVOTHYROXINE-ERMEZA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	ERMEZA		52325	GPI-14 (28100010102024)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer **AND** meet the following criterion?
   - The requested medication will be used as an adjunct to surgery and radioiodine therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial and failure of Thyquidity
   - The patient had a trial and failure of generic levothyroxine tablets
   - The patient is unable to swallow levothyroxine tablets or capsules

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOTHYROXINE-ERMEZA** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer
   B. You had a trial and failure (drug did not work) of Thyquidity
   C. You had a trial and failure (drug did not work) of generic levothyroxine tablets
   D. You are unable to swallow levothyroxine tablets or capsules
   E. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
      1. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)

   (Denial text continued on next page)

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LEVOTHYROXINE-ERMEZA

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ermeza.

REFERENCES

- Ermeza [Prescribing Information]. Morgantown, WV: Mylan Specialty L.P.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 02/23
Client Approval: 02/23
P&T Approval: 01/23

LEVOTHYROXINE-TIROSINT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	TIROSINT, LEVOTHYROXINE	02849		GPI-10 (2810001010)	FORM = CAPSULE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E03.0, E03.1) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial and failure of generic levothyroxine tablets
   - There is a rationale for NOT using generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The requested medication is being used as an adjunct to surgery and radioiodine therapy
   - The patient had a trial and failure of generic levothyroxine tablets
   - There is a rationale for NOT using generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOTHYROXINE-TIROSINT** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer
   B. **If you have congenital or acquired hypothyroidism, approval also requires:**
      1. You are 6 years of age or older
      2. You have tried and failed (drug did not work) generic levothyroxine tablets
      3. There is a rationale (reason) for NOT using generic levothyroxine tablets

   (Denial text continued on next page)

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LEVOTHYROXINE-TIROSINT

GUIDELINES FOR USE (CONTINUED)

C. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. You are 6 years of age or older
   2. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   3. You have tried and failed (drug did not work) generic levothyroxine tablets
   4. There is a rationale (reason) for NOT using generic levothyroxine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint.

REFERENCES

- Tirosint [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 07/21
Client Approval: 06/24
P&T Approval: 10/21

LEVOTHYROXINE-TIROSINT-SOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	TIROSINT-SOL	02849		GPI-10 (2810001010)	BRAND = TIROSINT-SOL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E03.0, E03.1) and meet **ALL** of the following criteria?
   The patient had a trial and failure of Thyquidity
   The patient had a trial and failure of or contraindication to generic levothyroxine tablets
   There is a rationale for not using Thyquidity and generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   Tirosint-Sol is being used as an adjunct to surgery and radioiodine therapy
   The patient had a trial and failure of Thyquidity
   The patient had a trial and failure of or contraindication to generic levothyroxine tablets
   There is a rationale for not using Thyquidity and generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, do not approve.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

Our guideline named **LEVOTHYROXINE-TIROSINT-SOL** requires the following rule(s) be met for approval:

You have ONE of the following:
- Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
- Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

If you have congenital or acquired hypothyroidism, approval also requires:
- You have tried and failed (drug did not work) Thyquidity
- You have tried and failed (drug did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets
- There is a rationale (reason) for not using Thyquidity and generic levothyroxine tablets

(Denial text continued on the next page)

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LEVOTHYROXINE-TIROSINT-SOL

GUIDELINES FOR USE (CONTINUED)

If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:

Tirosint-Sol will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
You have tried and failed (drug did not work) Thyquidity
You have tried and failed (drug did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets
There is a rationale (reason) for not using Thyquidity and generic levothyroxine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint-Sol.

REFERENCES

Tirosint-Sol [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 07/21
Client Approval: 06/24
P&T Approval:10/21

LIRAGLUTIDE - SAXENDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIRAGLUTIDE	SAXENDA		37637	GPI-10 (6125205000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) and the patient meets **ALL** of the following criteria?
   There is evidence of active enrollment in an exercise and caloric reduction program, which may include physician attestation of patient use of an optional weight loss/behavioral modification program
   Saxenda will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   The patient has a body mass index (BMI) of at least 30 kg/m(2)
   The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, **approve for 29 weeks by GPID or GPI-10 with a quantity limit of #0.5mL per day.**
   If no, continue to #4.

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LIRAGLUTIDE - SAXENDA

INITIAL CRITERIA (CONTINUED)

4. Is the patient 12 to 17 years of age and meets **ALL** of the following criteria?
   The patient's body weight is greater than 60 kg
   The patient's initial BMI corresponds to 30 kg/m(2) or greater to that for adults (see table below)

BMI Cut-offs for Obesity in Patients 12 to 17 years that corresponds to 30 kg/m^2 in Adults

Age	Body Mass Index	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

If yes, **approve for 29 weeks by GPID or GPI-10 with a quantity limit of #0.5mL per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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LIRAGLUTIDE - SAXENDA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for approval:
The request is for weight loss OR weight loss management
You are 12 years of age or older
You have evidence of active enrollment in an exercise and caloric reduction program, which may include other optional weight loss/behavioral modification programs
You will NOT use Saxenda concurrently (at the same time) with a GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Ozempic [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
If you are 18 years of age or older, approval also requires ONE of the following:
You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
If you are 12 to 17 years of age, approval also requires:
You have a body weight greater than 60 kg
You have an initial BMI corresponding to 30 kg/m(2) for adults

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LIRAGLUTIDE - SAXENDA

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 18 years of age or older **AND** meets the following criterion?
   The patient has achieved or maintained at least a 5 percent weight loss of baseline body weight after 16 weeks of treatment

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #0.5mL per day.**
   If no, continue to #3.

3. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   The patient has achieved or maintained at least a 1 percent weight loss of baseline BMI after at least 12 weeks on the maximally tolerated dose

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #0.5mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for renewal:
   The request is for weight loss OR weight loss management
   You are 12 years of age or older
   If you are 18 years of age or older, approval also requires:
   You have achieved or maintained at least a 5 percent weight loss of baseline body weight after 16 weeks of treatment
   If you are 12 to 17 years of age, approval also requires:
   You have achieved or maintained at least a 1 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after at least 12 weeks of treatment on your maximally tolerated dose

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LIRAGLUTIDE - SAXENDA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saxenda.

REFERENCES

Saxenda [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 05/24
Client Approval: 08/24
P&T Approval: 07/24

LIXISENATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIXISENATIDE	ADLYXIN	40782		GPI-10 (2717005600)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist, cardiologist, nephrologist, family practice, internal medicine, or another healthcare provider who is specialized in diabetic management
   The patient had a trial of metformin (IR/ER), a sulfonylurea (e.g., glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above agents (e.g., glipizide-metformin, pioglitazone-metformin)
   The patient had a trial of a preferred GLP-1 agonist (e.g., Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
   Adlyxin will NOT be used together with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], alogliptin, saxagliptin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
   You have type 2 diabetes (a disorder with high blood sugar)
   You are 18 years of age or older
   Adlyxin is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   You have tried metformin (immediate-release/ extended-release), a sulfonylurea (such as glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above medications (such as glipizide-metformin, pioglitazone-metformin)
   You have tried a preferred GLP-1 agonist (such as Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
   Adlyxin will NOT be used together with a DPP-4 inhibitor (such as Januvia [sitagliptin], alogliptin, saxagliptin)
   (Initial denial text continued on the next page)

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LIXISENATIDE

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIXISENATIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an endocrinologist, cardiologist, nephrologist, family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   Adlyxin will NOT be used together with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], alogliptin, saxagliptin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
   You have type 2 diabetes (a disorder with high blood sugar)
   Adlyxin is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   Adlyxin will NOT be used together with a DPP-4 inhibitor (such as Januvia [sitagliptin], alogliptin, saxagliptin)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlyxin.

REFERENCES

Adlyxin [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC, September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/22
Client Approval: 10/23
P&T Approval: 10/23

LOFEXIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOFEXIDINE HCL	LUCEMYRA, LOFEXIDINE HCL	07803		GPI-10 (6280504510)	

GUIDELINES FOR USE

1. Is the requested medication being used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation (ICD-10 Group F11) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in a setting with close monitoring of treatment with Lucemyra (lofexidine) and has a treatment duration that does NOT exceed 18 days
   - Lucemyra will be administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and the implementation of psychosocial support to help prevent relapse

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #264 per 18 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:
   A. Lucemyra will be used to reduce opioid withdrawal symptoms to help abrupt opioid discontinuation
   B. You are 18 years of age or older
   C. You are in a setting with close monitoring of Lucemyra (lofexidine) treatment and will be treated with Lucemyra (lofexidine) for a maximum of 18 days
   D. Lucemyra will be used as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOFEXIDINE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Lucemyra.

REFERENCES

- Lucemyra [Prescribing Information]. Louisville, KY. US WorldMeds, LLC; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/18

LOMITAPIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMITAPIDE MESYLATE	JUXTAPID	39883		GPI-10 (3948005020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) and meet **ONE** of the following criteria?
   The patient has a Simon Broome diagnostic criteria (definite)
   The patient has a Dutch Lipid Network criteria with a score of at least 8
   The patient has a clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL and either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
   The patient has an LDL-cholesterol level of at least 70 mg/dL while on maximally tolerated drug treatment

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient is currently taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND has been taking it for a duration of at least 8 weeks
   Given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), the patient is currently taking a maximally tolerated dose of any statin AND has been taking it for a duration of at least 8 weeks

   If yes, continue to #4.
   If no, continue to #5.

4. Will the patient continue statin treatment as described above in combination with Juxtapid?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   The patient has complete statin intolerance (defined by severe and intolerable adverse effects) (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least TWO separate statins AND have improved with the discontinuation of each statin

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of Repatha (evolocumab)
   The patient lacks functioning LDL receptors

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   Juxtapid 5mg: #45 per 30 days.
   Juxtapid 10mg: #30 per 30 days.
   Juxtapid 20mg: #90 per 30 days.
   Juxtapid 30mg: #30 per 30 days.
   Juxtapid 40mg: #30 per 30 days.
   Juxtapid 60mg: #30 per 30 days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:
You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
Your diagnosis is determined by meeting ONE of the following:
- You have Simon Broome diagnostic criteria (definite) (a tool for diagnosing homozygous familial hypercholesterolemia)
- You have a Dutch Lipid Network (a tool for diagnosing homozygous familial hypercholesterolemia) criteria with a score of at least 8
- You have a clinical diagnosis based on a history of an untreated low density lipoprotein - cholesterol (LDL-C: bad cholesterol) level greater than 500 mg/dL AND you have either xanthoma (a type of skin condition) before 10 years of age or there is evidence of heterozygous familial hypercholesterolemia (HeFH: type of inherited high cholesterol) in both parents

Therapy is prescribed by or in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
You have a low density lipoprotein cholesterol (LDL-C: bad cholesterol) level of at least 70 mg/dL while on maximally tolerated statin (medication used for cholesterol) treatment
You have tried Repatha (evolocumab) OR you do not have a functional LDL (low density lipoprotein) receptors
If you are statin tolerant, approval also requires:
- You meet ONE of the following:
  - You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for a duration of at least 8 weeks
  - You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), but you are currently taking a maximally tolerated dose of any statin AND have been taking it for a duration of at least 8 weeks
- You will continue statin (medication used for cholesterol) treatment in combination with Juxtapid

(Denial text continued on next page)

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LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

If you are statin intolerant, approval also requires ONE of the following:

- You have an absolute contraindication to (harmful for you to use) statin therapy (medication used for cholesterol) (such as active decompensated liver disease [symptoms related to liver damage], nursing [breastfeeding] female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
- You have complete statin intolerance (defined by severe and intolerable adverse effects) that have occurred with trials of at least TWO separate statins, AND the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (breakdown of muscle tissue), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Juxtapid.

REFERENCES

Juxtapid [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 01/13
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/18

LOMUSTINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMUSTINE	GLEOSTINE	03900		GPI-10 (2110202000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Hodgkin's lymphoma?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary and metastatic brain tumors **AND** meet the following criterion?
   - The patient has previously received appropriate surgical and/or radiotherapeutic procedures

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will the patient be using this medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LOMUSTINE (Gleostine)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Hodgkin's lymphoma (type of immune system cancer)
      2. Primary and metastatic brain tumors (tumor that has spread to other parts of body)
   B. **If you have primary and metastatic brain tumors, approval also requires:**
      1. You have previously received appropriate surgical and/or radiotherapeutic procedures
      2. The requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOMUSTINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleostine.

REFERENCES

- Gleostine [Prescribing Information]. NextSource Biotechnology, LLC: Miami, FL; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 02/18
Client Approval: 11/22
P&T Approval: 01/18

LONAFARNIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAFARNIB	ZOKINVY	46991		GPI-10 (9946304500)	

GUIDELINES FOR USE

1. Is the patient 1 year of age or older **AND** meets the following criterion?
   - The patient has a body surface area (BSA) of 0.39m(2) or above

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of processing-deficient progeroid laminopathies with **ONE** of the following?
   - Heterozygous LMNA mutation with progerin-like protein accumulation
   - Homozygous or compound heterozygous ZMPSTE24 mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:
   A. You have Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies (rare genetic disorders that cause premature aging in children)
   B. You are 1 year of age or older
   C. You have a body surface area (BSA) of 0.39 meters squared or more
   D. **If you have processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:**
      1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
      2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

LONAFARNIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zokinvy.

REFERENCES

- Zokinvy [Prescribing Information]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval:02/21
P&T Approval: 01/21

LONAPEGSOMATROPIN-TCGD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		GPI-10 (3010000380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age AND weighs at least 11.5 kg (25.3 lbs)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per 7 days.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per 7 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 1 to 17 years of age and weigh at least 11.5 kilograms (25.3 pounds)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
E. You meet ONE of the following:
    1. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
    2. Your height velocity is less than the 25th percentile for your age
    3. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
F. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age AND weighs at least 11.5 kg (25.3 lbs)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per 7 days.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per 7 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 1 to 17 years of age and weigh at least 11.5 kilograms (25.3 pounds)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
E. You meet ONE of the following:
    1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
    2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
F. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skytrofa.

REFERENCES

- Skytrofa [Prescribing Information]. Princeton, NJ: Ascendis Pharma US, Inc.; May 2025.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/22

LORCASERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LORCASERIN HCL	BELVIQ, BELVIQ XR	40373		GPI-10 (6125655010)	

GUIDELINES FOR USE

Do not approve requests for Belviq or Belviq XR.

(**NOTE:** Safety concerns [increased risk of cancer] have prompted market withdrawal of Belviq and Belviq XR.)

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Belviq/Belviq XR.

FDA requested removal from the market as Belviq/Belviq XR displayed an increased risk of cancer in a safety trial. Manufacturer complied with FDA request and product has been discontinued.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 01/13
Client Approval: 08/21
P&T Approval: 04/21

LORLATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LORLATINIB	LORBRENA	45448		GPI-10 (2153055600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Lorbrena 25mg: #3 per day.**
   - **Lorbrena 100mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive, as detected by an Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LORLATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lorbrena.

REFERENCES

- Lorbrena [Prescribing Information]. New York, NY: Pfizer, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 03/19
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/21

LOTEPREDNOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOTEPREDNOL ETABONATE	EYSUVIS		48834	GPI-14 (86300035101825)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) **AND** meet the following criterion?
   The patient had a trial of or contraindication to one generic loteprednol ophthalmic (e.g., loteprednol 0.2%, loteprednol 0.5%) AND one non-loteprednol ophthalmic corticosteroid (e.g., fluorometholone, dexamethasone, prednisolone)

   If yes, **approve for 2 weeks by GPID or GPI-14 with a quantity limit of #8.3mL (1 bottle) per 14 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTEPREDNOL (Eysuvis)** requires the following rule(s) be met for approval:
   You have dry eye disease
   You have tried or have a contraindication to (harmful for you to use) one generic loteprednol ophthalmic (eye) medication (such as loteprednol 0.2%, loteprednol 0.5%) AND one non-loteprednol ophthalmic corticosteroid (such as fluorometholone, dexamethasone, prednisolone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Eysuvis.

REFERENCES
Eysuvis [Prescribing Information]. Fort Worth, TX: Alcon Laboratories, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/21

LOTILANER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOTILANER	XDEMVY	45544		GPI-10 (8610605000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Demodex blepharitis (ICD-10 Group H01.00) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 6 weeks by HICL or GPI-10 with a quantity limit of #10mL for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTILANER (Xdemvy)** requires the following rule(s) be met for approval:
   You have Demodex blepharitis (a type of inflammatory eye condition)
   You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xdemvy.

REFERENCES
Xdemvy [Prescribing Information]. Irvine, CA: Tarsus Pharmaceuticals, Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

LUMACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMACAFTOR/IVACAFTOR	ORKAMBI	42235		GPI-10 (4530990230)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient is homozygous for the F508del mutation in the CFTR gene

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **75-94mg granule packets: #2 per day.**
   - **100-125mg granule packets: #2 per day.**
   - **150-188mg granule packets: #2 per day.**
   - **100-125mg tablets: #4 per day.**
   - **200-125mg tablets: #4 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   E. You are homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the CFTR gene

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMACAFTOR-IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by GPID or GPI-14 for all of the following:**
   - **75-94mg granule packets: #2 per day.**
   - **100-125mg granule packets: #2 per day.**
   - **150-188mg granule packets: #2 per day.**
   - **100-125mg tablets: #4 per day.**
   - **200-125mg tablets: #4 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orkambi.

REFERENCES

- Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2024.

Created: 07/15
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 01/25

LUSUTROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUSUTROMBOPAG	MULPLETA	45127		GPI-10 (8240504500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, endocrinologist, or surgeon
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 8 to 14 days following initiation of Mulpleta (lusutrombopag) therapy
   - The patient has a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
   - The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., avatrombopag, romiplostim, eltrombopag)

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #7 tablets.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:
   A. You have thrombocytopenia (a type of blood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (a doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (a type of hormone doctor), or surgeon
   D. You have chronic liver disease
   E. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
   F. You have a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
   G. You are not receiving other thrombopoietin receptor agonist therapy, such as avatrombopag, romiplostim, eltrombopag

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUSUTROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mulpleta.

REFERENCES

- Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/18
Client Approval: 02/22
P&T Approval: 01/22

MACITENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN	OPSUMIT	40677		GPI-10 (4016005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) greater than 2 Wood units
   (Initial denial text continued on next page)

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MACITENTAN

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

MACITENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsumit.

REFERENCES

Opsumit [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/22
Client Approval: 06/24
P&T Approval: 01/24

MACITENTAN-TADALAFIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN/ TADALAFIL	OPSYNVI	47644		GPI-10 (4099550250)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has WHO Functional Class II-III symptoms
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You are 18 years of age or older
   (Initial denial text continued on the next page)

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MACITENTAN-TADALAFIL

INITIAL CRITERIA (CONTINUED)

You have WHO Functional Class II-III symptoms (a way to classify how limited physical activity)
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
- Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
- Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) less than or equal to 15 mmHg
- Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units

You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsynvi.

REFERENCES

Opsynvi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 04/24
Client Approval: 06/24
P&T Approval: 04/24

MARALIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARALIXIBAT CHLORIDE	LIVMARLI	47604		GPI-10 (5235005010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in ALGS cholestasis
   Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient is 3 months to 11 months of age
   The patient is 12 months of age or older AND had a trial of or contraindication to the preferred agent: Bylvay (odevixibat)

   If yes, **approve 9.5mg/mL for 6 months by GPID or GPI-14 with a quantity limit of #3mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   The patient is 12 months of age or older
   Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis
   Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])
   The patient had a trial of or contraindication to the preferred agent: Bylvay (odevixibat)

   If yes, **approve 19mg/mL for 6 months by GPID or GPI-14 with a quantity limit of #2mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MARALIXIBAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
- Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:
- Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
- You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])
- You meet ONE of the following:
  - You are 3 months to 11 months of age
  - You are 12 months of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Bylvay (odevixibat)

If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:
- You are 12 months of age or older
- Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
- You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Bylvay (odevixibat)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MARALIXIBAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve 9.5mg/mL for 12 months by GPID or GPI-14 with a quantity limit of #3mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   The patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein
   Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve 19mg/mL for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
- Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:
- You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
- You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

(Renewal denial text continued on next page)

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MARALIXIBAT

RENEWAL CRITERIA (CONTINUED)

If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:

You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)

You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)

You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livmarli.

REFERENCES

Livmarli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/12/24

Created: 10/21
Client Approval: 08/24

P&T Approval: 10/24

MARIBAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARIBAVIR	LIVTENCITY	47687		GPI-10 (1220005000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of post-transplant cytomegalovirus (CMV) infection (ICD-10 Group B25) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The infection is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARIBAVIR (Livtencity)** requires the following rule(s) be met for approval:
   A. You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
   B. You are 12 years of age or older
   C. Your infection is refractory (has not responded) to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livtencity.

REFERENCES

- Livtencity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 12/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/21

MARSTACIMAB-HNCQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARSTACIMAB-HNCQ	HYMPAVZI	49937		GPI-10 (8510505020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a hematologist
   The patient's hemophilia is without factor VIII inhibitors
   Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (congenital factor IX deficiency) (ICD-10 D67) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a hematologist
   The patient's hemophilia is without factor IX inhibitors
   Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MARSTACIMAB-HNCQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
- Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

If you have hemophilia A (congenital factor VIII deficiency), approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- Your hemophilia is without factor VIII inhibitors (a type of protein)
- Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

If you have hemophilia B (congenital factor IX deficiency), approval also requires
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- Your hemophilia is without factor IX inhibitors (a type of protein)
- Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MARSTACIMAB-HNCQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   The patient's hemophilia is without factor VIII inhibitors
   The patient has shown a clinical benefit compared to baseline
   Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (congenital factor IX deficiency) (ICD-10 D67) and meet **ALL** of the following criteria?
   The patient's hemophilia is without factor IX inhibitors
   The patient has shown a clinical benefit compared to baseline
   Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
- Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

If you have hemophilia A (congenital factor VIII deficiency), renewal also requires:
- Your hemophilia is without factor VIII inhibitors (a type of protein)
- You have shown a clinical benefit compared to baseline (before starting Hympavzi)
- You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

If you have hemophilia B (congenital factor IX deficiency), renewal also requires:
- Your hemophilia is without factor IX inhibitors (a type of protein)
- You have shown a clinical benefit compared to baseline (before starting Hympavzi)
- You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

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MARSTACIMAB-HNCQ

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hympavzi.

REFERENCES

Hympavzi [Prescribing Information]. New York, NY: Pfizer Inc.; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/25/24
Created: 11/24
Client Approval: 11/24
P&T Approval: 10/24

MAVACAMTEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MAVACAMTEN	CAMZYOS	47972		GPI-10 (4019005000)	

GUIDELINES FOR USE

NITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has New York Heart Association (NYHA) class II-III symptoms
   - The patient has a left ventricular outflow track (LVOT) gradient of 50 mmHg or higher
   - Therapy is prescribed by or in consultation with a cardiologist
   - The patient had a trial of or contraindication to beta-blockers (e.g., metoprolol, carvedilol) AND non-dihydropyridine calcium channel blockers (e.g., verapamil, diltiazem)

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for approval:
   A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
   B. You are 18 years of age or older
   C. You have New York Heart Association (NYHA) class II-III (classification system for heart failure) symptoms
   D. You have a left ventricular outflow track gradient (a predictor of heart failure and cardiovascular death) of 50 mmHg or higher
   E. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
   F. You had a trial of or contraindication (harmful for) to beta-blockers (such as metoprolol, carvedilol) AND non-dihydropyridine calcium channel blockers (such as verapamil, diltiazem)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MAVACAMTEN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) **AND** meet the following criterion?
   - The patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement)

   If yes, **approve for 12 months by HICL or GPI-10 with quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for renewal:
   A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
   B. You have experienced continued clinical benefit (such as reduction of symptoms, NYHA classification improvement)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Camzyos.

REFERENCES

- Camzyos [Prescribing Information]. Brisbane, CA: MyoKardia, Inc.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:06/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

MAVORIXAFOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MAVORIXAFOR	XOLREMDI	49557		GPI-10 (8250204600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome **AND** meet the following criterion?
   The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVORIXAFOR (Xolremdi)** requires the following rule(s) be met for approval:
   You have WHIM (warts, hypogammaglobulinemia [low levels of antibodies in the blood], infections, and myelokathexis [low white blood cell count]) syndrome (a rare genetic disorder of the immune system)
   You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolremdi.

REFERENCES

Xolremdi [Prescribing Information]. Boston, MA: X4 Pharmaceuticals, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/27/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

MEBENDAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEBENDAZOLE	EMVERM		43181	GPI-14 (15000010000505)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of *Enterobius vermicularis* (pinworm) infection (ICD-10 B80) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   The patient had a trial of or contraindication to pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #2**.
   If no, continue to #2.

2. Does the patient have a diagnosis of *Trichuris trichiura* (whipworm) (ICD-10 B79) or *Ascaris lumbricoides* (roundworm) (ICD-10 Group B77) infection and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   The patient had a trial of or contraindication to albendazole (Albenza)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6**.
   If no, continue to #3.

3. Does the patient have a diagnosis of *Ancylostoma duodenale* (hookworm) (ICD-10 B76.0) or *Necator americanus* (hookworm) (ICD-10 B76.1) infection and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   The patient had a trial of or contraindication to albendazole (Albenza) or pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MEBENDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MEBENDAZOLE (Emverm)** requires the following rule(s) be met for approval:
You have ONE of the following:
- *Enterobius vermicularis* (pinworm) infection
- *Trichuris trichiura* (whipworm) infection
- *Ascaris lumbricoides* (roundworm) infection
- *Ancylostoma duodenale* (hookworm) infection
- *Necator americanus* (hookworm) infection

If you have *Enterobius vermicularis* (pinworm) infection, approval also requires:
- You are 2 years of age or older
- You have tried or have a contraindication to (harmful for you to use) over-the-counter (OTC) pyrantel pamoate

If you have Trichuris trichiura (whipworm) or Ascaris lumbricoides (roundworm) infection, approval also requires:
- You are 2 years of age or older
- You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza)

If you have Ancylostoma duodenale (hookworm) or Necator americanus (hookworm) infection, approval also requires:
- You are 2 years of age or older
- You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza) OR over-the-counter (OTC) pyrantel pamoate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emverm.

REFERENCES

Emverm [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/16
Client Approval: 06/24
P&T Approval: 07/20

MECAMYLAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECAMYLAMINE HCL	VECAMYL		1471	GPI-10 (3660002010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderately severe to severe essential (or primary) hypertension or uncomplicated malignant hypertension?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried or does the patient have a contraindication to three of the following: angiotensin converting enzyme (ACE) inhibitor or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker?
   PAC NOTE: These drugs include: benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MECAMYLAMINE HYDROCHLORIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECAMYLAMINE HYDROCHLORIDE (Vecamyl)** requires the following rule(s) be met for approval:

A. The requested medication will be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension
B. You have had a trial of at least three of the following, unless there is a medical reason why you cannot (contraindication): angiotensin converting enzyme inhibitor (ACE-I) or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vecamyl.

REFERENCES

- Vecamyl [Prescribing Information]. Fort Collins, CO: Manchester Pharmaceuticals; July 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/13
Client Approval: 04/20
P&T Approval: 08/13

MECASERMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECASERMIN	INCRELEX	33207		GPI-10 (3016004500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Severe primary IGF-1 deficiency
   - Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) **AND** have neutralizing antibodies to GH

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years to less than 18 years of age
   - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist or a pediatric nephrologist
   - Height standard deviation score ≤ -3.0
   - Basal IGF-1 standard deviation score ≤ -3.0
   - Normal or elevated growth hormone (GH), [serum growth hormone level of ≥ 10ngm/mL to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)]
   - The patient's epiphyses (bone growth plates) open (as confirmed by radiograph of the wrist and hand)

   If yes, **approve by HICL or GPI-10 for 6 months up to a maximum dose of 9 vials per month.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
      2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone

   (Initial denial text continued on the next page)

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MECASERMIN

INITIAL CRITERIA (CONTINUED)

B. You are 2 years to less than 18 years of age
C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)
D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]
E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient shown a response in the first 6 months of IGF-1 therapy (i.e., increase in height, increase in height velocity)?

If yes, **approve by HICL or GPI-10 for 12 months up to a maximum dose of 9 vials per month.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:
A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECASERMIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Increlex.

REFERENCES

- Increlex [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/06
Client Approval: 03/20
P&T Approval: 04/20

MECHLORETHAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECHLORETHAMINE HCL	VALCHLOR	03892		GPI-10 (9037105020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids [Targretin, Tazorac], imiquimod, or local radiation therapy)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECHLORETHAMINE (Valchlor)** requires the following rule(s) be met for approval:
   A. You have stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (type of immune system cancer)
   B. You had prior skin-directed therapy such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Valchlor.

REFERENCES

- Valchlor [Prescribing Information]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 11/13
Client Approval: 03/23
P&T Approval: 11/13

MEPOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEPOLIZUMAB	NUCALA	42775		GPI-10 (4460405500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
   100mg: #1 per 28 days.
   40mg/0.4mL: #0.4mL per 28 days.

   If no, continue to #3.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   Daytime asthma symptoms more than twice per week
   Any night waking due to asthma
   Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   Any activity limitation due to asthma

   If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
   100mg: #1 per 28 days.
   40mg/0.4mL: #0.4mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   The patient has inadequately controlled disease
   The patient had a 56-day trial of ONE intranasal corticosteroid (e.g., mometasone nasal spray)
   Nucala will be used as add-on maintenance treatment
   Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve all formulations of the 100mg strength for 6 months by GPID or GPI-14 with a quantity limit of #1 per 28 days.**

   If no, continue to #5.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient has had HES for at least 6 months without an identifiable non-hematologic secondary cause
   Nucala will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HES

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   - Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
   - Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
   - Hypereosinophilic syndrome (HES: a type of blood disorder)

   (Initial denial text continued on next page)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have severe asthma with an eosinophilic phenotype, approval also requires:

- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) or allergy medicine
- You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
- Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
- You meet ONE of the following:
  - You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
  - You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
  - You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
    - Daytime asthma symptoms more than twice per week
    - Any night waking due to asthma
    - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
    - Any activity limitation due to asthma

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have chronic rhinosinusitis with nasal polyps, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
- You have inadequately controlled disease
- You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
- Nucala will be used as add-on maintenance treatment (taken on a regular basis)
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

If you have eosinophilic granulomatosis with polyangiitis, approval also requires:
- You are 18 years of age or older
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

If you have hypereosinophilic syndrome, approval also requires:
- You are 12 years of age or older
- You have had hypereosinophilic syndrome (HES) for at least 6 months without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MEPOLIZUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   Reduction in asthma exacerbations from baseline
   Decreased utilization of rescue medications (e.g., albuterol)
   Increase in percent predicted FEV1 from pretreatment baseline
   Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   100mg: #1 per 28 days.
   40mg/0.4mL: #0.4mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of CRSwNP

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #1 per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   The patient has shown a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid use
   Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   - Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
   - Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

   (Renewal denial text continued on next page)

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

If you have severe asthma with an eosinophilic phenotype, renewal also requires:
- You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
- You have shown a clinical response as evidenced by ONE of the following:
  - You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Nucala)
  - You have decreased your use of rescue medications (such as albuterol)
  - You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Nucala)
  - You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
- You have shown a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell, size of polyps)
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:
- You have shown a reduction in eosinophilic granulomatosis with polyangiitis (EGPA) symptoms compared to baseline (before starting Nucala), OR you have been able to decrease or eliminate (stop) corticosteroid use
- You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of EGPA

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MEPOLIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nucala.

REFERENCES

Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC.; March 2023.

Created: 11/15
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

METHOTREXATE - JYLAMVO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOTREXATE	JYLAMVO	03906		GPI-10 (2130005000)	BRAND = JYLAMVO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   Jylamvo will be used as part of a combination chemotherapy maintenance regimen
   The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mycosis fungoides (cutaneous T-cell lymphoma) (ICD-10 Group C84.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory non-Hodgkin lymphoma (ICD-10 Group C85) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Jylamvo will be used as part of a metronomic combination chemotherapy regimen
   The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of rheumatoid arthritis (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per 28 days.**
   If no, continue to #5.

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 Group M08) **AND** meet the following criterion?
   The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #6.

6. Does the patient have a diagnosis of severe psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #60mL per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOTREXATE - JYLAMVO** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Acute lymphoblastic leukemia (ALL: a type of blood cancer)
   - Mycosis fungoides (cutaneous T-cell lymphoma) (a type of blood cancer affecting the skin)
   - Relapsed or refractory non-Hodgkin lymphoma (a type of blood cancer that has returned or did not respond to treatment)
   - Rheumatoid arthritis (a type of joint condition)
   - Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   - Severe psoriasis (a type of skin condition)

   If you have acute lymphoblastic leukemia, approval also requires:
   - Jylamvo will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
   - You cannot swallow generic methotrexate tablets

   If you have mycosis fungoides (cutaneous T-cell lymphoma), approval also requires:
   - You are 18 years of age or older
   - You cannot swallow generic methotrexate tablets

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

If you have relapsed or refractory non-Hodgkin lymphoma, approval also requires:
- You are 18 years of age or older
- Jylamvo will be used as part of a metronomic combination chemotherapy regimen (a type of therapy to treat cancer where lower doses are given over a long period to reduce side effects)
- You cannot swallow generic methotrexate tablets

If you have rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- You cannot swallow generic methotrexate tablets

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You cannot swallow generic methotrexate tablets

If you have severe psoriasis, approval also requires:
- You are 18 years of age or older
- You cannot swallow generic methotrexate tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Jylamvo.

REFERENCES
Jylamvo [Prescribing Information]. Cambridge, MA: Shorla Oncology Inc.; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/25/24
Created: 11/23
Client Approval: 11/24
P&T Approval: 01/25

METHOXY PEG-EPOETIN BETA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		GPI-10 (8240104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 3 months and 17 years of age **AND** meets the following criterion?
   The patient is converting from another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after the hemoglobin level has been stabilized with the ESA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for approval:
You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
If you are 18 years of age or older, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
Your hemoglobin level (type of blood test) is less than 10g/dL
If you are between 3 months and 17 years of age, approval also requires:
You are changing from another erythropoiesis-stimulating agent (ESA, such as Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after your hemoglobin level (type of blood test) has been stabilized with the ESA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 10g/dL if not on dialysis
   The patient's hemoglobin level is less than 11g/dL if on dialysis
   The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 3 months and 17 years of age and meets **ONE** of the following criteria?
   The patient's hemoglobin level is less than 12g/dL
   The patient's hemoglobin level has reached 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for renewal:

You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease

If you are 18 years of age or older, renewal also requires ONE of the following:

- Your hemoglobin level (type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level is less than 11g/dL if you are on dialysis
- Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions
- Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

If you are between 3 months and 17 years of age, renewal also requires ONE of the following:

- Your hemoglobin level (type of blood test) is less than 12g/dL
- Your hemoglobin level has reached 12g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mircera.

REFERENCES

Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/24
Created: 02/11
Client Approval: 05/24
P&T Approval: 07/24

METHYLNALTREXONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR	35611		GPI-10 (5258005010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of opioid-induced constipation (OIC) (ICD-10 K59.03) with chronic non-cancer pain (ICD-10 G89.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has chronic non-cancer pain, including chronic pain related to prior cancer or its treatment
   The patient does NOT require frequent opioid dosage escalation
   The patient has been taking opioids for at least four weeks
   The patient had a trial of or contraindication to the preferred agents: Symproic (naldemedine) and Movantik (naloxegol)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   12 mg: #0.6 mL per day.
   150 mg: #3 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of opioid-induced constipation (OIC) (ICD-10 K59.03) with advanced illness or pain caused by active cancer (ICD-10 G89.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The request is for Relistor injection
   The patient requires opioid dosage escalation for palliative care

   If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 with the following quantity limits:**
   12 mg: #0.6 mL per day.
   8 mg: #0.4 mL per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METHYLNALTREXONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLNALTREXONE (Relistor)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Opioid-induced constipation (a type of bowel disorder caused by drugs used to treat pain) with chronic (long-term) non-cancer pain
- Opioid-induced constipation with advanced illness or pain caused by active cancer

If you have opioid-induced constipation with chronic non-cancer pain, approval also requires:
- You are 18 years of age or older
- You have chronic non-cancer pain, including chronic pain related to prior cancer or its treatment
- You do NOT require frequent opioid dosage escalation (increase)
- You have been taking opioids for at least four weeks
- You have tried or have a contraindication to (harmful for you to use) the preferred medications: Symproic (naldemedine) AND Movantik (naloxegol)

If you have opioid-induced constipation with advanced illness or pain caused by active cancer, approval also requires:
- You are 18 years of age or older
- Your request is for Relistor injection
- You require opioid dosage escalation (increase) for palliative care (treatment for comfort from symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES
Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; May 2024.

Created: 11/08
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 08/16

METHYLTESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST, METHYLTESTOS-TERONE		10380 10411	GPI-10 (2310002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient have a previously approved prior authorization for testosterone OR has been receiving any form of testosterone replacement therapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #5.
   If no, continue to #6.

5. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

6. Has the patient had a trial of or contraindication to **TWO** preferred agents: intramuscular testosterone cypionate and intramuscular testosterone enanthate?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, who meets the following criterion?
   The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #8.

8. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets the following criterion?
   The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, continue to #9.
   If no, continue to #10.

9. Does the patient meet **ONE** of the following criteria?
   The patient is postmenopausal
   The patient is premenopausal who benefited from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

10. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Delayed puberty not due to a pathological disorder (not due to a disease) in a male
- Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following:
  - You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
  - You meet ONE of the following criteria showing you have low testosterone levels:
    - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
    - You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
- You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate

If you are a female with metastatic breast cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate
- You meet ONE of the following:
  - You are postmenopausal (after menopause)
  - You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHYLTESTOSTERONE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   The patient has improved symptoms compared to baseline and tolerance to treatment
   The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, who meets the following criterion?
   The patient has not received more than two 6-month courses of testosterone replacement therapy

   If yes, **approve the requested agent for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #5.

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

5. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets **ONE** of the following criteria?
   The patient is postmenopausal
   The patient is premenopausal who benefited from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, continue to #6.

6. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   Delayed puberty not due to a pathological disorder (not due to a disease) in a male
   Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   If you are a male with primary or secondary hypogonadism, renewal also requires:
   You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   (Renewal denial text continues on next page)

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
You have NOT received more than two 6-month courses of testosterone replacement therapy

If you are a female with metastatic breast cancer, renewal also requires ONE of the following:
You are postmenopausal (after menopause)
You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

If you have gender dysphoria, renewal also requires:
Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Testred, Android, and Methitest.

REFERENCES
Android [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2015.
Methitest [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.
Testred [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2015.

Created: 02/23
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOCLOPRAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOCLOPRAMIDE HCL	GIMOTI		48272	GPI-14 (52300020102080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute and recurrent diabetic gastroparesis (ICD-10 K31.84) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to metoclopramide ODT

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #9.8mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:
   A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (a disorder from high blood sugar that causes delayed emptying of food from the stomach)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) metoclopramide ODT (orally disintegrating tablet)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gimoti.

REFERENCES

- Gimoti [Prescribing Information]. Solana Beach, CA: Evoke Pharma, Inc.; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 11/20
Client Approval: 06/24
P&T Approval: 10/20

METRONIDAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METRONIDAZOLE	LIKMEZ	04157		GPI-10 (1600003500)	BRAND = LIKMEZ

GUIDELINES FOR USE

1. Is the request for the treatment of trichomoniasis and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to generic metronidazole tablets
   The patient is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, continue to #2.

2. Is the request for the treatment of acute intestinal amebiasis (amoebic dysentery) or amebic liver abscess, and the patient meets **ALL** of the following criteria?
   The patient had a trial of or contraindication to generic metronidazole tablets
   The patient is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, continue to #3.

3. Is the request for the treatment of serious infections caused by susceptible anaerobic bacteria (e.g., *Bacteroides* species, *Clostridium* species, *Peptococcus* species) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to generic metronidazole tablets
   The patient is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METRONIDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METRONIDAZOLE (Likmez)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Trichomoniasis (a type of infection caused by a parasite)
- Acute intestinal amebiasis (amoebic dysentery: a type of infection of the intestines) OR amebic liver abscess (a collection of pus in the liver caused by a parasite)
- Serious infections caused by susceptible anaerobic bacteria, such as *Bacteroides* species, *Clostridium* species, *Peptococcus* species (infections caused by types of bacteria that can be treated with Likmez)

You have tried or have a contraindication to (harmful for you to use) generic metronidazole tablets
You are unable to swallow metronidazole tablets
For the treatment of trichomoniasis or serious infections caused by susceptible anaerobic bacteria, approval also requires:
You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Likmez.

REFERENCES
Likmez [Prescribing Information]. Hauppauge, NY: Saptalis Pharmaceuticals LLC; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/24
Created: 11/23
Client Approval: 01/24
P&T Approval: 01/24

MIDOSTAURIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIDOSTAURIN	RYDAPT	44227		GPI-10 (2153303000)	

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
   - The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
   - The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #56 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #224 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
      2. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
      3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
      4. Mast cell leukemia (MCL: type of blood cell cancer)

   (Denial text continued on next page)

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MIDOSTAURIN

GUIDELINES FOR USE (CONTINUED)

B. **If you have newly diagnosed acute myeloid leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration (FDA)-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

C. **If you have aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Rydapt.

REFERENCES

- Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/17
Client Approval: 03/22
P&T Approval: 07/17

MIFEPRISTONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIFEPRISTONE	KORLYM, MIFEPRISTONE		31485	GPI-10 (2730405000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's hypercortisolism is NOT a result of chronic glucocorticoids (e.g., prednisone)
   - The patient also has a diagnosis of type 2 diabetes mellitus OR glucose intolerance
   - The patient has failed surgical treatment for Cushing's syndrome OR is not a candidate for surgery

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the diagnosis of endogenous Cushing's syndrome been confirmed by **ONE** of the following tests?
   - 24-hour urine free cortisol (2 or more tests to confirm)
   - Overnight 1mg dexamethasone test
   - Late-night salivary cortisol (2 or more tests to confirm)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:
   A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   (Initial denial text continued on the next page)

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MIFEPRISTONE

INITIAL CRITERIA (CONTINUED)

D. Your diagnosis is confirmed by ONE of the following:
   1. 24-hour urine free cortisol (a type of test that measures the amount of cortisol in the urine) (at least 2 or more tests to confirm)
   2. Overnight 1mg dexamethasone test (a type of diagnostic test)
   3. Late-night salivary cortisol (a type of test that measures the amount of cortisol in the saliva at night) (at least 2 or more tests to confirm)

E. Your hypercortisolism (high levels of cortisol) is NOT due to chronic glucocorticoids (long-term use of a class of drugs that consists of steroids, such as prednisone)

F. You also have type 2 diabetes mellitus (a disorder with high blood sugar) OR glucose intolerance (a condition that results in high blood sugar)

G. You have failed surgical treatment (surgery did not work) for Cushing's syndrome OR you are NOT a candidate for surgery

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIFEPRISTONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of glucose tolerance or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose, etc.)
   - The patient continues to have tolerability to Korlym
   - The patient continues to NOT be a candidate for surgical treatment OR has failed surgery

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:
   A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
   B. You continue to have improvement of glucose tolerance or stable glucose tolerance (such as reduced hemoglobin A1C level [a type of lab test], improved fasting glucose)
   C. You continue to tolerate Korlym
   D. You are NOT a candidate for surgery OR have failed surgery (surgery did not work) for Cushing's syndrome

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Korlym.

REFERENCE

- Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics Incorporated; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 04/12
Client Approval: 01/24
P&T Approval: 07/20

MIGALASTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGALASTAT HCL	GALAFOLD	44433		GPI-10 (3090365010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
   The patient has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data as interpreted by a clinical genetics professional as pathogenic or likely pathogenic (i.e., patient does NOT have a benign amenable GLA variant)
   Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female **AND** the patient meets the following criterion?
   The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, continue to #3.

3. Is the request for a male and the patient meets **ONE** of the following criteria?
   The patient has an alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay
   The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIGALASTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:
You have Fabry disease (a rare genetic disease)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
You have an amenable (responsive) galactosidase alpha (GLA) gene variant (abnormal change in a type of gene) based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by a clinical genetics professional as the cause of disease (pathogenic or likely pathogenic)
You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
You are symptomatic OR have evidence of injury from GL-3 (globotriaosylceramide: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased GFR (glomerular filtration rate: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
If you are a female, approval also requires:
You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
If you are a male, approval also requires ONE of the following:
You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGALASTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) **AND** meet the following criterion?
   Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy?
   Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
   Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
   Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:
   You have Fabry disease (a rare genetic disease)
   You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
   Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, gastrointestinal [GI] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
   Imaging (such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
   Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])
   (Renewal denial text continued on next page)

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MIGALASTAT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

Galafold [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

MIGLUSTAT-OPFOLDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	OPFOLDA	25098		GPI-10 (3090776000)	BRAND = OPFOLDA

GUIDELINES FOR USE

Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient weighs at least 40 kgs (88 lbs.)
The patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme [alglucosidase alfa])
Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #8 per 28 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGLUSTAT-OPFOLDA** requires the following rule(s) be met for approval:
You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)
You are 18 years of age or older
You weigh at least 40 kilograms (88 pounds)
You are NOT improving on your current enzyme replacement therapy (ERT) (such as Lumizyme [alglucosidase alfa])
Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGLUSTAT-OPFOLDA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opfolda.

REFERENCES

Opfolda [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics US, LLC; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/24

MIGLUSTAT-ZAVESCA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	ZAVESCA, YARGESA, MIGLUSTAT		19453	GPI-10 (8270007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate type 1 Gaucher disease (ICD-10 E75.22) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The requested medication will be used as monotherapy
   Enzyme replacement therapy is not a therapeutic option for this patient (e.g., due to allergy, hypersensitivity, poor venous access)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
   The requested medication will be used in combination with Miplyffa (arimoclomol)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

Our guideline named **MIGLUSTAT-ZAVESCA (Yargesa)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Mild to moderate type 1 Gaucher disease (a type of genetic condition)
- Niemann-Pick disease type C (NPC: a type of genetic condition)

If you have mild to moderate type 1 Gaucher disease, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as monotherapy (one drug treatment)
- Enzyme replacement therapy (a type of treatment) is not a therapeutic option for you (due to reasons such as allergy, hypersensitivity [allergic reaction], poor access to veins)

If you have Niemann-Pick disease type C, approval also requires:
- The requested medication will be used in combination with Miplyffa (arimoclomol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGLUSTAT-ZAVESCA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavesca and Yargesa.

REFERENCES

Zavesca [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; August 2022.
Yargesa [Prescribing Information]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 05/05
Client Approval: 10/24
P&T Approval: 10/24

MILTEFOSINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MILTEFOSINE	IMPAVIDO	16200		GPI-10 (1600003600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Leishmaniasis and meet **ALL** of the following criteria?
   - The patient has **ONE** of the following types of infections:
     - Visceral leishmaniasis caused by *Leishmania donovani*
     - Cutaneous leishmaniasis caused by any of the following: *Leishmania braziliensis, Leishmania guyanensis*, or *Leishmania panamensis*
     - Mucosal leishmaniasis caused by *Leishmania braziliensis*
   - Leishmaniasis species is identified via **ONE** of the following CDC recommended tests:
     - Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
     - Culture medium
     - Polymerase chain reaction (PCR)
     - Serologic testing (e.g., rK39 Rapid Test)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:
   A. You have Leishmaniasis (type of parasite disease) with ONE of the following types of infection:
      1. Visceral leishmaniasis (affects your organs) caused by *Leishmania donovani (type of parasite)*
      2. Cutaneous leishmaniasis (affects your skin layers) caused by any of the following types of parasites:
         a. *Leishmania braziliensis*
         b. *Leishmania guyanensis*
         c. *Leishmania panamensis*
      3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by *Leishmania braziliensis*

   B. Species identification must be confirmed via ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
      1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
      2. Culture medium
      3. Polymerase chain reaction (lab method to make copies of genes)
      4. Serologic testing (testing your blood and body fluids such as rK39 Rapid Test)

   (Denial text continued on next page)

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MILTEFOSINE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Impavido.

REFERENCES

- Impavido [Prescribing Information]. Orlando, FL: Profounda, Inc.; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/21
Created: 04/16
Client Approval: 10/21
P&T Approval: 05/16

MINOCYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MINOCYCLINE HCL	EMROSI		56483	GPI-14 (90060044127035)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of rosacea (ICD-10 Group L71) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has inflammatory lesions (papules and pustules) associated with rosacea
   The patient had a trial of or contraindication to ONE generic oral minocycline or doxycycline

   If yes, **approve for 16 weeks by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MINOCYCLINE (Emrosi)** requires the following rule(s) be met for approval:
   You have rosacea (a type of skin condition)
   You are 18 years of age or older
   You have inflammatory lesions (papules and pustules: small bumps on the skin) associated with rosacea
   You have tried or have a contraindication to (harmful for you to use) ONE generic oral minocycline or doxycycline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Emrosi.

REFERENCES
Emrosi [Prescribing Information]. Scottsdale, AZ: Journey Medical Corporation; November 2024.

Created: 11/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/25

MINOCYCLINE MICROSPHERES

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		GPI-10 (8845205010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

1. Is this medication excluded from coverage?

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient have a confirmed diagnosis of periodontitis (ICD-10 Groups K05.2, K05.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oral health care professional
   - The patient does NOT have a history of minocycline or tetracycline sensitivity or allergy
   - The patient does NOT have a history of candidiasis or active oral candidiasis
   - Arestin will be administered by an oral health care professional
   - Arestin will be used as an adjunct to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
   - Arestin will NOT be used for an acutely abscessed periodontal pocket
   - Arestin will NOT be used in an immunocompromised individual, such as those immunocompromised by any of the following conditions: uncontrolled diabetes mellitus, chemotherapy, radiation therapy, HIV infection
   - Arestin will NOT be used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

   If yes, **approve for 3 months by HICL or GPI-10 for the quantity requested up to a maximum of 48 unit-dose cartridges.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MINOCYCLINE MICROSPHERES

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an oral health care professional
D. You do NOT have a history of minocycline or tetracycline sensitivity or allergy
E. You do NOT have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. Arestin will be administered by an oral health care professional
G. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. Arestin will NOT be used for an acutely abscessed periodontal pocket (infection with pus-filled pocket)
I. Arestin will NOT be used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus (a disorder with high blood sugar)
    2. Chemotherapy (a type of drug used to treat cancer)
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. Arestin will NOT be used in the regeneration (reconstruction) of alveolar bone (part of the bone that has tooth sockets), either in preparation for or in conjunction (together) with the placement of endosseous (dental) implants or in the treatment of failing implants

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MINOCYCLINE MICROSPHERES

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient have a confirmed diagnosis of periodontitis (ICD-10 Groups K05.2, K05.3) **AND** meet the following criterion?
   - Arestin will be used as an adjunct to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

   If yes, **approve for 6 months by HICL or GPI-10 for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:
   A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
   B. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Arestin.

REFERENCES

- Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma; May 2024.

Created: 08/16
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 08/16

MIRDAMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRDAMETINIB	GOMEKLI	50277		GPI-10 (2153355000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) (ICD-10 Q85.01) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   The patient has symptomatic plexiform neurofibromas (PN) that cannot be completely resected

   If yes, **approve all formulations of all strengths for 12 months by GPID or GPI-14 as follows:**
   1mg: #8 per day.
   2mg: #4 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRDAMETINIB (Gomekli)** requires the following rule(s) be met for approval:
   You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
   You are 2 years of age or older
   You have symptomatic plexiform neurofibromas (PN: tumors that grow along the nerves) that cannot be completely resected (cannot be completely removed by surgery)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Gomekli.

REFERENCES
Gomekli [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025.

Created: 02/25
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

MIRIKIZUMAB-MRKZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRIKIZUMAB-MRKZ	OMVOH	49282		GPI-10 (5250405040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the 300mg/15mL vial for 3 months by GPID or GPI-14 with a quantity limit of #15mL per 28 days.
   SECOND APPROVAL: Approve for 3 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days. (Please enter a start date of 3 DAYS BEFORE the END date of the first approval).

   If no, continue to #2.

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MIRIKIZUMAB-MRKZ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the 300mg/15mL vial for 3 months by GPID or GPI-14 with a quantity limit of #45mL per 28 days.
   SECOND APPROVAL: Approve for 3 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days. (Please enter a start date of 3 DAYS BEFORE the END date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIRIKIZUMAB-MRKZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRIKIZUMAB-MRKZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MIRIKIZUMAB-MRKZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRIKIZUMAB-MRKZ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omvoh.

REFERENCES

Omvoh [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; January 2025.

Created: 11/23
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 01/25

MITAPIVAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITAPIVAT SULFATE	PYRUKYND	47840		GPI-10 (8587005070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemolytic anemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has pyruvate kinase (PK) deficiency

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for approval:
   A. You have hemolytic anemia (a type of blood condition)
   B. You are 18 years of age or older
   C. You have pyruvate kinase (PK: a type of enzyme) deficiency

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemolytic anemia with and meet **ALL** of the following criteria?
   - The patient has pyruvate kinase (PK) deficiency
   - The patient has had clinical benefit while on Pyrukynd

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial at the end of the guideline.

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MITAPIVAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for renewal:
A. You have hemolytic anemia (a type of blood condition)
B. You have pyruvate kinase (PK: a type of enzyme) deficiency
C. You have had clinical benefit while on Pyrukynd

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pyrukynd.

REFERENCES

- Pyrukynd [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOMELOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOMELOTINIB DIHYDROCHLORIDE	OJJAARA	49208		GPI-10 (2153754030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythemia vera [PV] and post-essential thrombocythemia [ET]), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has anemia

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOMELOTINIB (Ojjaara)** requires the following rule(s) be met for approval:
   A. You have intermediate or high-risk myelofibrosis (MF: a type of blood cancer), including primary MF (MF that developed on its own) or secondary MF (MF that developed from another blood disorder, such as post-polycythemia vera [PV: a type of blood cancer] or post-essential thrombocythemia [ET: a type of blood disease])
   B. You are 18 years of age or older
   C. You have anemia (a type of blood condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojjaara.

REFERENCES

- Ojjaara [Prescribing Information]. Durham, NC: GlaxoSmithKline; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOMETASONE FUROATE	SINUVA		44214	GPI-14 (42200045102350)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Has the patient previously had 4 implants (2 per nostril) per lifetime?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an otolaryngologist
   - The patient previously had ethmoid sinus surgery
   - The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
   - The patient had a previous 90-day trial of **ONE** intranasal corticosteroid (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 2 implants (1 per nostril).**
   APPROVAL TEXT: Renewal requires the patient has nasal polyps and has NOT had 4 implants (2 per nostril) per lifetime. In addition, the patient has ethmoid sinus polyps grade ≥ 1 on any side and does not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MOMETASONE SINUS IMPLANT (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient previously had 4 implants (2 per nostril) per lifetime?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient has ethmoid sinus polyps grade ≥ 1 on any side
   - The patient does **NOT** have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 2 implants (1 per nostril). (Note: maximum #4 implants [2 per nostril] allowed per lifetime.)**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MOMETASONE SINUS IMPLANT (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sinuva.

REFERENCES

- Sinuva [Prescribing Information]. Menlo Park, CA: Intersect ENT.; April 2020.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/18
Client Approval: 08/20
P&T Approval: 07/20

MONOMETHYL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576		GPI-10 (6240555000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to dimethyl fumarate AND **ONE** of the following agents: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta (**Please note:** other MS agents may also require prior authorization)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have previously tried or have a contraindication to (medical reason why you cannot take) dimethyl fumarate AND ONE of the following: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta
   (**Please note:** Other multiple sclerosis medications may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MONOMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bafiertam.

REFERENCES

- Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 11/20
Client Approval: 11/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MYCOPHENOLATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MYCOPHENOLATE MOFETIL	MYHIBBIN		55684	GPI-14 (99403030101830)	

GUIDELINES FOR USE

1. Is the request for the prophylaxis of organ rejection and the patient meets **ALL** of the following criteria?
   The patient has a history of an allogeneic kidney, heart or liver transplant
   Myhibbin will be used in combination with other immunosuppressants (e.g., cyclosporine)
   The patient had a trial of or contraindication to generic mycophenolate mofetil tablets
   The patient is unable to swallow mycophenolate mofetil tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #15mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MYCOPHENOLATE (Myhibbin)** requires the following rule(s) be met for approval:
   The request is for the prophylaxis (prevention) of an organ rejection
   You have a history of an allogeneic (from a donor) kidney, heart or liver transplant
   Myhibbin will be used in combination with other immunosuppressants (such as cyclosporine)
   You have tried or have a contraindication to (harmful for you to use) generic mycophenolate mofetil tablets
   You are unable to swallow mycophenolate mofetil tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Myhibbin.

REFERENCES
Myhibbin [Prescribing Information]. Middlesex, UK: Liqmeds Worldwide Limited; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 06/24
Client Approval: 06/24
P&T Approval: 10/24

NAFARELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAFARELIN ACETATE	SYNAREL	21103		GPI-10 (3008005510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64)?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis (ICD-10 Group N80 and R52) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) OR histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - Synarel will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide])
   - The patient has NOT received more than 6 months of treatment with Synarel per lifetime

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #96mL per 6 months.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.**
   If no, continue to #4.

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      5. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      6. Moderate to severe pain from endometriosis (condition affecting the uterus)
      7. Central precocious puberty (CPP: early sexual development in girls and boys)

   B. **If you have moderate to severe pain from endometriosis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
      3. Your diagnosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
      4. You have tried or have a contraindication to (harmful for you to use) a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
      5. You are NOT using Synarel concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide])
      6. You have NOT received more than 6 months of treatment with Synarel per lifetime

   (Initial denial text continued on next page)

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

C. **If you are female and have central precocious puberty, approval also requires:**
   8. You are 2 years of age or older
   9. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   10. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   11. You are/were younger than 8 years of age when your condition started
   12. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAFARELIN

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or pain from endometriosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has NOT reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have NOT reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synarel.

REFERENCES

- Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 09/18
Client Approval: 06/24
P&T Approval: 04/22

NALTREXONE - BUPROPION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE	41389		GPI-10 (6125990250)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   There is evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient has a body mass index (BMI) of at least 30 kg/m(2)
   The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for a total of 4 months by entering TWO approvals by HICL or GPI-10 as follows:**
   FIRST APPROVAL: #78 for 30 days.
   SECOND APPROVAL: #4 per day for 3 months (please enter a start date of 3 days BEFORE the end of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NALTREXONE - BUPROPION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for approval:
The request is for weight loss OR weight loss management
You are 18 years of age or older
You have evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program
You meet ONE of the following:
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
- You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NALTREXONE - BUPROPION

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for renewal:
   The request is for weight loss OR weight loss management
   You have achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets two times a day)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Contrave.

REFERENCES

Contrave [Prescribing Information]. San Diego, CA: Nalpropion Pharmaceuticals, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 04/24

NATALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NATALIZUMAB	TYSABRI	26750		GPI-10 (6240505000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Tysabri will be used as monotherapy
   Tysabri will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS
   The patient had a trial of TWO agents indicated for the treatment of multiple sclerosis (e.g., Avonex [interferon beta-1a], Copaxone/Glatiramer/Glatopa, Gilenya [fingolimod hcl])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NATALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have a relapsing form of multiple sclerosis, approval also requires:
- You are 18 years of age or older
- Tysabri will be used as monotherapy (one drug treatment)
- You will NOT use Tysabri concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis
- You have tried TWO medications indicated for the treatment of multiple sclerosis (such as Avonex [interferon beta-1a], Copaxone/Glatiramer/Glatopa, Gilenya [fingolimod hcl])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NATALIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50)?

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient received at least 12 months of Tysabri therapy and meets **ALL** of the following criteria?
   The patient has NOT received more than 3 months of corticosteroids within the past 12 months for control of Crohn's disease while on Tysabri
   Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**

   If no, continue to #3.

3. Has the patient received only 6 months of Tysabri therapy and meets **ALL** of the following criteria?
   The patient is NOT currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy)
   Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NATALIZUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   Tysabri will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   - A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

   If you have moderate to severe Crohn's disease, renewal also requires ONE of the following:
   If you have received at least 12 months of Tysabri therapy, renewal also requires:
   - You have NOT received more than 3 months of corticosteroids within the past 12 months to control your Crohn's disease while on Tysabri
   - You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
   - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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NATALIZUMAB

RENEWAL CRITERIA (CONTINUED)

If you have only received 6 months of Tysabri therapy, renewal also requires:
- You are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)
- You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have a relapsing form of multiple sclerosis, renewal also requires:
- You will NOT use Tysabri concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.
This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Review for Tysabri.

REFERENCES
Tysabri [Prescribing Information]. Cambridge, MA: Biogen Inc.; October 2023.

Created: 08/06
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

NEDOSIRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NEDOSIRAN SODIUM	RIVFLOZA	49234		GPI-10 (5662605060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1) and meet **ALL** of the following criteria?
   The patient is 9 years of age and older
   The patient has relatively preserved kidney function (e.g., eGFR is greater than or equal to 30mL/min/1.73m(2))

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   80mg/0.5mL: #1mL per 30 days.
   128mg/0.8mL: #0.8mL per 30 days.
   160mg/mL: #1mL per 30 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NEDOSIRAN (Rivfloza)** requires the following rule(s) be met for approval:
   You have primary hyperoxaluria type 1 (PH1: a type of rare genetic disorder)
   You are 9 years of age and older
   You have relatively preserved kidney function (such as an estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] of at least 30mL/min/1.73m(2))

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rivfloza.

REFERENCES
Rivfloza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 01/24
Client Approval: 01/24
P&T Approval: 04/24

NEMOLIZUMAB-ILTO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NEMOLIZUMAB-ILTO	NEMLUVIO	49814		GPI-10 (9079355510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist, immunologist, or allergist
   The patient has the presence of multiple pruriginous lesions (localized or general)
   The patient had a trial of or contraindication to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine
   The patient had a trial of or contraindication to the preferred agent: Dupixent (dupilumab)
   Nemluvio will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, continue to #2.

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NEMOLIZUMAB-ILTO

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Nemluvio will be used in combination with a topical corticosteroid (e.g., triamcinolone, clobetasol) and/or calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   The patient has atopic dermatitis covering at least 10% of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   The patient has TWO of the following: intractable pruritus, cracking/oozing/bleeding of the affected skin, impaired activities of daily living
   The patient had a trial of or contraindication to THREE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   Nemluvio will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Prurigo nodularis (PN: a type of skin condition)
      Moderate to severe atopic dermatitis (AD: a type of skin condition)
   If you have prurigo nodularis, approval also requires:
      You are 18 years of age or older
      Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
      You have multiple pruriginous lesions (wounds)
   (Initial denial text continued on next page)

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NEMOLIZUMAB-ILTO

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine

You have tried or have a contraindication to the preferred medication: Dupixent (dupilumab)

You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

If you have moderate to severe atopic dermatitis, approval also requires:

You are 12 years of age or older

You will use Nemluvio in combination with a topical corticosteroid (such as triamcinolone, clobetasol) and/or calcineurin inhibitor (such as tacrolimus, pimecrolimus)

Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)

You have atopic dermatitis covering at least 10% of body surface area (BSA), OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)

You have TWO of the following: intractable pruritus (severe itching), cracking/oozing/bleeding of the affected skin, impaired activities of daily living

You have tried or have a contraindication to (harmful for you to use) THREE preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)

You will NOT use Nemluvio concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK inhibitor [such as Rinvoq (upadacitinib)], PDE-4 inhibitor [such as Eucrisa (crisaborole)]) for the treatment of AD

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NEMOLIZUMAB-ILTO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   The patient has had prurigo nodularis improvement (reduction) of pruritus or pruriginous lesions
   Nemluvio will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient has shown improvement while on Nemluvio
   The patient had a trial of or contraindication to THREE preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
   Nemluvio will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Prurigo nodularis (PN: a type of skin condition)
   - Moderate to severe atopic dermatitis (AD: a type of skin condition)

   If you have prurigo nodularis, renewal also requires:
   - You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
   - You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

   (Renewal denial text continued on next page)

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NEMOLIZUMAB-ILTO

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe atopic dermatitis, renewal also requires:
You have shown improvement while on Nemluvio
You have tried or have a contraindication to (harmful for you to use) THREE preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
You will NOT use Nemluvio concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK inhibitor [such as Rinvoq (upadacitinib)], PDE-4 inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nemluvio.

REFERENCES
Nemluvio [Prescribing Information]. Dallas, TX: Galderma Laboratories, L.P.; December 2024.

Created: 08/24
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 10/24

NERATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERATINIB MALEATE	NERLYNX	44421		GPI-10 (2153303510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early stage (stage I-III) breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
   - The requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
   - The medication is being requested within 2 years after completing last trastuzumab dose

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
   - The requested medication will be used in combination with capecitabine
   - The patient has received two or more prior anti-HER2 based regimens in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Early stage (stage I-III) breast cancer
      2. Advanced or metastatic breast cancer
   B. **If you have early stage (stage I-III) breast cancer, approval also requires:**
      1. You are 18 years of age or older
      2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
      3. The requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
      4. The medication is being requested within 2 years of completing the last trastuzumab dose

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NERATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced or metastatic breast cancer, approval also requires:**
1. You are 18 years of age or older
2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
3. The requested medication will be used in combination with capecitabine
4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nerlynx.

REFERENCES

- Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/17
Client Approval: 03/21
P&T Approval: 04/20

NILOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NILOTINIB HCL	TASIGNA	35149		GPI-10 (2153186020)	
NILOTINIB TARTRATE	DANZITEN	49984		GPI-10 (2153186060)	

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) in chronic phase **AND** meet the following criterion?
   The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is resistant or intolerant to prior therapy that included imatinib (Gleevec)
   The patient had a mutational analysis prior to initiation AND the requested medication is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile
   (Please see header CML-5 of the current NCCN guidelines)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   The patient is 1 to 17 years of age
   The patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   The patient had a mutational analysis prior to initiation AND the requested medication is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile
   (Please see header CML-5 of the current NCCN guidelines)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NILOTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NILOTINIB (Tasigna, Danziten)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase
- Previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase or accelerated phase

If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
You are 1 year of age or older

If you have previously treated Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase, approval also requires:
You meet ONE of the following:
- You are 18 years of age or older AND you are resistant (not responding to treatment) or intolerant (side effect) to prior therapy that included Gleevec (imatinib)
- You are 1 to 17 years of age AND you are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKIs, such as Gleevec [imatinib], Sprycel [dasatinib], Bosulif [bosutinib])

You had a mutational analysis (a type of lab test) prior to the start of treatment AND the requested medication is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tasigna or Danziten.

REFERENCES

Tasigna [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.

Danziten [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.

Created: 05/12
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

NIMODIPINE SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIMODIPINE	NYMALIZE, NIMODIPINE		34794 43848 47984 47985 48405	GPI-14 (34000022002050) (34000022002054)	

GUIDELINES FOR USE

1. Does the patient have a history of subarachnoid hemorrhage (SAH) (ICD-10 I60.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's SAH is from a ruptured intracranial berry aneurysm within the past 21 days
   - The patient is unable to swallow nimodipine capsules

   If yes, **approve the requested strength for 1 fill by GPID or GPI-14 up to a maximum 21-day supply with the following quantity limits:**
   - **30mg/10mL: #120mL per day.**
   - **60mg/20mL: #120mL per day.**
   - **30mg/5mL: #60mL per day.**
   - **60mg/10mL: #60mL per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:
   A. You have a history of a subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain)
   B. You are 18 years of age or older
   C. Your SAH is from a ruptured intracranial berry aneurysm (part of blood vessel in your brain has expanded and burst) within the past 21 days
   D. You are unable to swallow nimodipine oral capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIMODIPINE SOLUTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nymalize.

REFERENCES

- Nymalize (nimodipine solution) [Prescribing Information]. Piscataway, NJ: Camber Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 08/13
Client Approval: 09/24
P&T Approval: 07/20

NINTEDANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NINTEDANIB	OFEV	41489		GPI-10 (4555405020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT have other known causes of interstitial lung disease (for example, connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer)
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient has a diagnosis of Systemic Sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
   - The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities e.g., infection, heart failure)
   - The patient has ≥ 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient has a baseline forced vital capacity (FVC) at least 45% of predicted value

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. **If you have idiopathic pulmonary fibrosis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
      3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
      4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
      5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50 percent at baseline

   (Initial denial text continued on next page)

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

C. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You have systemic sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40 percent of predicted value
   6. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   3. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities such as infection, heart failure)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45 percent of predicted value

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF), systemic sclerosis-associated interstitial lung disease (SSc-ILD), or chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ofev.

REFERENCES

- Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 02/15
Client Approval: 07/23
P&T Approval: 04/21

NIRAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		GPI-10 (2153555020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to first-line platinum based-chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used for maintenance treatment
   - The patient's cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*) based on an FDA-approved companion diagnostic for Zejula
   - The requested medication will be used as monotherapy
   - The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient has completed at least 2 or more lines of platinum-based chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)
   2. Recurrent (returning) epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum based-chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to platinum-based chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*
   4. Your cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
   5. The requested medication will be used as monotherapy (used by itself for treatment)
   6. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)
   7. You have completed at least two lines of platinum-based chemotherapy (such as cisplatin, carboplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIRAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zejula.

REFERENCES

- Zejula [Prescribing Information]. Durham, NC: GlaxoSmithKline; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 08/17
Client Approval: 08/23
P&T Approval: 07/23

NIRAPARIB-ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB-ABIRATERONE	AKEEGA	49143		GPI-10 (2140990212)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) based on an FDA-approved test for Akeega
   Akeega will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a bilateral orchiectomy
   The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   Akeega will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIRAPARIB-ABIRATERONE (Akeega)** requires the following rule(s) be met for approval:
   You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   Your cancer has a deleterious (harmful) or suspected deleterious BRCA mutation (BRCAm: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
   Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
   (Denial text continued on the next page)

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NIRAPARIB-ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

You meet ONE of the following:
- You had a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
- Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Akeega.

REFERENCES

Akeega [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

NIROGACESTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIROGACESTAT HYDROBROMIDE	OGSIVEO	49323		GPI-10 (2153235020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of progressing desmoid tumors and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient requires systemic treatment

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   50mg: #6 per day.
   100mg: #2 per day.
   150mg: #2 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIROGACESTAT (Ogsiveo)** requires the following rule(s) be met for approval:
   You have progressing desmoid tumors (noncancerous growths in the connective tissue)
   You are 18 years of age or older
   You require systemic treatment (therapy that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogsiveo.

REFERENCES
Ogsiveo [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/06/24
Created: 12/23
Client Approval: 04/24
P&T Approval: 07/24

NITISINONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NITISINONE	ORFADIN, NITYR, NITISINONE	23253		GPI-10 (3090404500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary tyrosinemia type 1 (HT-1) and meet **ALL** of the following criteria?
   - The patient has elevated urinary or plasma succinylacetone (SA) levels OR a mutation in the fumarylacetoacetate hydrolase (FAH) gene
   - Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
   - The patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg, 20 mg capsules; or Orfadin suspension **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic nitisinone capsule

   If yes, **approve the requested drug for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NITISINONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg, 20 mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have tried or have a contraindication (harmful for) to generic nitisinone capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 **AND** meet the following criterion?
    - The patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested formulation.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NITISINONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orfadin and Nityr.

REFERENCES

- Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc.; May 2019.
- Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 08/16
Client Approval: 03/23
P&T Approval: 07/18

NITROFURANTOIN SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
NITROFURANTOIN	FURADANTIN, NITROFURANTOIN		41870	GPI-14 (16800050001810)	

GUIDELINES FOR USE

1. Is the request for the treatment of a urinary tract infection (UTI) and the patient meets **ALL** of the following criteria?
   The infection is caused by susceptible strains of *Escherichia coli, enterococci, Staphylococcus aureus, Klebsiella,* or *Enterobacter* species
   The patient had a trial of or contraindication to nitrofurantoin capsules
   The patient is unable to swallow nitrofurantoin capsules

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #560mL per 7 days for 1 fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NITROFURANTOIN (Furadantin)** requires the following rule(s) be met for approval:
   You have a urinary tract infection (UTI: a type of infection)
   Your infection is caused by susceptible (can be treated with the drug) strains of *Escherichia coli, enterococci, Staphylococcus aureus, Klebsiella* or *Enterobacter* species (types of bacteria)
   You have tried or have a contraindication to (harmful for you to use) nitrofurantoin capsules
   You are not able to swallow nitrofurantoin capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NITROFURANTOIN SUSPENSION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Furadantin.

REFERENCES

Furadantin (nitrofurantoin oral suspension) [Prescribing Information]. East Brunswick, NJ: Rising Pharma Holdings, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 07/24
Client Approval: 07/24
P&T Approval: 10/23

NIVOLUMAB-HYALURONIDASE-NVHY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB-HYALURONIDASE-NVHY	OPDIVO QVANTIG	50124		GPI-10 (2199000250)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
   Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
   The patient has received prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #4.
   If no, continue to #6.

4. Is the patient's cancer unresectable or metastatic?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

   If no, continue to #5.

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

5. Is the patient's cancer stage IIB, IIC, III, or IV and the patient meets **ALL** of the following criteria?
   The patient has undergone complete resection
   Opdivo Qvantig will be used as an adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer is resectable (node positive or tumor is at least 4cm)

   If yes, continue to #7.
   If no, continue to #11.

7. Will Opdivo Qvantig be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 21 days.**
   If no, continue to #8.

8. Does the patient's cancer have no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Will Opdivo Qvantig be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 21 days.**

   If no, continue to #10.

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

10. Will Opdivo Qvantig be used as monotherapy as adjuvant treatment **AND** the patient meets the following criterion?
    The patient had surgical resection and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, continue to #12.
    If no, continue to #13.

12. Does the patient meet **ONE** of the following criteria?
    The tumor does NOT have EGFR or ALK genomic aberrations
    The tumor has an EGFR mutation, and the patient had disease progression following an FDA-approved EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
    The tumor has an ALK mutation, and the patient had disease progression following an FDA-approved ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

13. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient has disease progression while on or after treatment with a platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, continue to #14.

14. Does the patient have a diagnosis of urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
    The patient is 18 years of age or older

    If yes, continue to #15.
    If no, continue to #18.

15. Is the patient at high risk of recurrence after undergoing radical resection of urothelial carcinoma **AND** meets the following criterion?
    Opdivo Qvantig will be used as an adjuvant treatment

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, continue to #16.

16. Is the patient's cancer unresectable or metastatic **AND** the patient meets the following criterion?
    Opdivo Qvantig will be used in combination with cisplatin and gemcitabine

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 21 days.**

    If no, continue to #17.

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GUIDELINES FOR USE (CONTINUED)

17. Is the patient's cancer locally advanced or metastatic and the patient meets **ONE** of the following criteria?
    The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

18. Does the patient have a diagnosis of metastatic colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
    The patient has disease progression following treatment with a fluoropyrimidine (e.g., fluorouracil, capecitabine), oxaliplatin, and irinotecan

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, continue to #19.

19. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab)
    The patient has been previously treated with Nexavar (sorafenib)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, continue to #20.

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

20. Does the patient have a diagnosis of esophageal or gastroesophageal junction cancer (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has undergone complete resection
Opdivo Qvantig will be used as an adjuvant treatment
The patient has a residual pathologic disease
The patient has received neoadjuvant chemoradiotherapy (CRT)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**
    If no, continue to #21.

21. Does the patient have a diagnosis of esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) **AND** meet the following criterion?
The patient is 18 years of age or older

    If yes, continue to #22.
    If no, continue to #24.

22. Is the patient's cancer unresectable advanced or metastatic **AND** the patient meets the following criterion?
Opdivo Qvantig will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, continue to #23.

23. Is the patient's cancer unresectable advanced, recurrent or metastatic **AND** the patient meets the following criterion?
The patient has received prior fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

24. Does the patient have a diagnosis of advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Opdivo Qvantig will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10mL per 21 days.**

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **NIVOLUMAB-HYALURONIDASE-NVHY (Opdivo Qvantig)** requires the following rule(s) be met for approval:
    You have ONE of the following:
    - Advanced renal cell carcinoma (RCC) (a type of kidney cancer)
    - Melanoma (a type of skin cancer)
    - Non-small cell lung cancer (NSCLC) (a type of lung cancer)
    - Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
    - Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (a type of head/neck cancer that has returned or has spread to other parts of the body)
    - Urothelial carcinoma (UC: urinary system cancer)
    - Metastatic colorectal cancer (CRC) (a type of digestive cancer that has spread to other parts of the body)
    - Hepatocellular carcinoma (HCC: a type of liver cancer)
    - Esophageal or gastroesophageal junction cancer (types of digestive system cancer)
    - Esophageal squamous cell carcinoma (ESCC) (a type of digestive system cancer)
    - Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

    (Denial text continued on the next page)

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

If you have advanced renal cell carcinoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
  - Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
  - You have received prior anti-angiogenic therapy (a type of medication that stops tumors from growing new blood vessels, such as Sutent [sunitinib], Votrient [pazopanib])

If you have melanoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body)
  - Your cancer is stage IIB, IIC, III, or IV; you have undergone complete resection (removal by surgery); and Opdivo Qvantig will be used as an adjuvant (add-on) treatment

If you have non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer is resectable (node positive or tumor is at least 4 cm) (can be removed by surgery)
- You meet ONE of the following:
  - Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment)
  - Your cancer has no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation), and you meet ONE of the following:
    - Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)
    - Opdivo Qvantig will be used alone as adjuvant (add-on) treatment after surgical resection (removal by surgery) and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

(Denial text continued on the next page)

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
  - Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic aberrations (types of abnormal gene)
  - Your tumor has an EGFR mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
  - Your tumor has an ALK mutation, and your disease has worsened after treatment with an FDA-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])

If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
- You are 18 years of age or older
- Your disease has worsened while on or after treatment with a platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

If you have urothelial carcinoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma, and Opdivo Qvantig will be used as an adjuvant (add-on) treatment
  - Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), and Opdivo Qvantig will be used in combination with cisplatin and gemcitabine
  - Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), and you meet ONE of the following:
    - Your disease has worsened during or following platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
    - Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

(Denial text continued on the next page)

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GUIDELINES FOR USE (CONTINUED)

If you have metastatic colorectal cancer, approval also requires:
- You are 18 years of age or older
- Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
- Your disease has worsened after treatment with a fluoropyrimidine (a type of cancer treatment, such as fluorouracil, capecitabine), oxaliplatin, and irinotecan

If you have hepatocellular carcinoma, approval also requires:
- You are 18 years of age or older
- Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab)
- You have been previously treated with Nexavar (sorafenib)

If you have esophageal or gastroesophageal junction cancer, approval also requires:
- You are 18 years of age or older
- You have undergone complete resection (removal by surgery)
- Opdivo Qvantig will be used as an adjuvant (add-on) treatment
- You have a residual pathologic disease (disease is still present)
- You have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

If you have esophageal squamous cell carcinoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is unresectable (cannot be removed by surgery) advanced or metastatic (has spread to other parts of the body), and Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
  - Your cancer is unresectable advanced, recurrent (has returned) or metastatic and you have previously received treatment with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:
- You are 18 years of age or older
- Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIVOLUMAB-HYALURONIDASE-NVHY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdivo Qvantig.

REFERENCES

Opdivo Qvantig [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb; December 2024.

Created: 01/25
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 01/25

OBETICHOLIC ACID

Generic	Brand	HICL	GCN	MEDISPAN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		GPI-10 (5275006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   The patient has an elevated alkaline phosphatase (ALP) level
   The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210 if AMA is negative
   The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient does not have cirrhosis OR has compensated cirrhosis with no evidence of portal hypertension
   Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   The patient does NOT have complete biliary obstruction
   Ocaliva will NOT be used concurrently with any other second-line PBC treatment (i.e., Iqirvo [elafibranor], Livdelzi [seladelpar])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   Ocaliva will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   Ocaliva will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

- You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
  - You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
  - You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210 if AMA is negative
  - You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)
- You are 18 years of age or older
- You do not have cirrhosis (liver damage and scarring) OR you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
- You do NOT have complete biliary obstruction (blockage of bile ducts)
- You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])
- You meet ONE of the following:
  - Ocaliva will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
  - Ocaliva will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBETICHOLIC ACID

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   The patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Ocaliva
   The patient has NOT developed complete biliary obstruction
   Ocaliva will NOT be used concurrently with any other second-line PBC treatment (i.e., Iqirvo [elafibranor], Livdelzi [seladelpar])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:
   You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Ocaliva
   You have NOT developed complete biliary obstruction (blockage of bile ducts)
   You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

REFERENCES

Ocaliva [Prescribing Information]. Morristown, NJ: Intercept Pharmaceuticals, Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/16/24
Created: 08/16
Client Approval: 09/24
P&T Approval: 04/24

OCTREOTIDE - IM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE, MI-SPHERES	SANDOSTATIN LAR DEPOT, OCTREOTIDE ACETATE, MI-SPHERES	19000		GPI-12 (301700701064)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient had an inadequate response to surgery or radiotherapy, OR surgery or radiotherapy is not an option
   The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve all strengths for 3 months by GPID or GPI-14 with the following quantity limits:**
   10mg: #6mL per 28 days.
   20mg: #12mL per 28 days.
   30mg: #6mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) **AND** meet the following criterion?
   The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-12 with a quantity limit of #6mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPoma) (ICD-10 C25.4) **AND** meet the following criterion?
   The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-12 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

OCTREOTIDE - IM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acromegaly (a type of hormone disorder)
- Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
- Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of cancer that starts from hormone producing cells)

If you have acromegaly, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You had an inadequate response (drug did not work) to surgery or radiotherapy (another type of cancer treatment), OR surgery or radiotherapy is not an option for you
- You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:
- You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, approval also requires:
- You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - IM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   The patient had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   10mg: #6mL per 28 days.
   20mg: #12mL per 28 days.
   30mg: #6mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) **AND** meet the following criterion?
   The patient has shown improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-12 with a quantity limit of #6mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPoma) (ICD-10 C25.4) **AND** meet the following criterion?
   The patient has shown improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-12 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OCTREOTIDE - IM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Acromegaly (a type of hormone disorder)
- Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
- Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of cancer that starts from hormone producing cells)

If you have acromegaly, renewal also requires:
- You have had a reduction, normalization, or maintenance of insulin-like growth factor (IGF-1: a type of hormone) levels based on your age and gender
- You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, renewal also requires:
- You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms

If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, renewal also requires:
- You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - IM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sandostatin LAR Depot.

REFERENCES

Sandostatin LAR Depot [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 08/22
Client Approval: 10/24
P&T Approval: 07/22

OCTREOTIDE - ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	MYCAPSSA		48334	GPI-14 (30170070106520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has responded to and tolerated treatment with octreotide or lanreotide

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a type of hormone disorder)
   B. Therapy is prescribed by or in consultation with an endocrinologist (doctor who specializes in hormones)
   C. You have responded to and tolerated treatment with octreotide or lanreotide

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - ORAL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient has a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mycapssa.

REFERENCES

- Mycapssa [Prescribing Information]. Scotland, UK: MW Encap Ltd., March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/20
Client Approval: 09/22
P&T Approval: 07/22

OCTREOTIDE - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	BYNFEZIA		47454	GPI-14 (3017007010D220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)
   - The patient had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OCTREOTIDE - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)
   4. You had an inadequate response to or cannot be treated with **ALL** of the following:
      i. Surgical resection (removal by surgery)
      ii. Pituitary irradiation (radiation therapy directed at the pituitary)
      iii. Bromocriptine mesylate at maximally tolerated doses

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma), approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient has a reduction, normalization or maintenance of IGF-1 levels based on age and gender
   - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma) **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Acromegaly (a type of hormone disorder)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

   (Renewal denial text continued on next page)

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OCTREOTIDE - SQ

RENEWAL CRITERIA (CONTINUED)

B. **If you have acromegaly, renewal also requires:**
   1. You have a reduction, normalization or maintenance of insulin-like growth factor (IGF-1: a growth hormone) levels based on age and gender
   2. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor OR profuse watery diarrhea associated with vasoactive intestinal peptide tumor, renewal also requires:**
   1. You have an improvement or sustained remission (symptoms have gone away) of clinical symptoms

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bynfezia.

REFERENCES

- Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc., January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/20
Client Approval: 09/22
P&T Approval: 07/22

ODEVIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ODEVIXIBAT	BYLVAY	47501		GPI-10 (5235006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   The patient is 3 months of age or older
   Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis
   Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   200mcg pellets: #30 per day.
   400mcg capsule: #15 per day.
   600mcg pellets: #10 per day.
   1200mcg capsule: #5 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and meet **ALL** of the following criteria?
   The patient is 12 months of age or older
   Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in ALGS cholestasis
   Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   200mcg pellets: #36 per day.
   400mcg capsule: #18 per day.
   600mcg pellets: #12 per day.
   1200mcg capsule: #6 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ODEVIXIBAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
- Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

If you have pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:
- You are 3 months of age or older
- Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
- You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:
- You are 12 months of age or older
- Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
- You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ODEVIXIBAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   The patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein
   Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   200mcg pellets: #30 per day.
   400mcg capsule: #15 per day.
   600mcg pellets: #10 per day.
   1200mcg capsule: #5 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   200mcg pellets: #36 per day.
   400mcg capsule: #18 per day.
   600mcg pellets: #12 per day.
   1200mcg capsule: #6 per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ODEVIXIBAT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
- Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

If you have pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:
- You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
- You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
- You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:
- You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
- You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ODEVIXIBAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bylvay.

REFERENCES

Bylvay [Prescribing Information]. Boston, MA: Albireo Pharma, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/21
Client Approval: 05/24
P&T Approval: 04/24

OFATUMUMAB-SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OFATUMUMAB	KESIMPTA		48513	GPI-10 (6240506500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve the requested drug for a total of 12 months by GPID or GPI-10 as follows:**
   INITIAL REQUEST:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #1.2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #0.4mL per 28 days (Enter a start date 3 weeks AFTER THE START DATE of the first approval).**

   SUBSEQUENT/CONTINUATION REQUEST:
   - **Approve for 12 months with a quantity limit of #0.4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OFATUMUMAB-SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kesimpta.

REFERENCES

- Kesimpta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 09/20
Client Approval: 11/20
P&T Approval: 04/20

OLANZAPINE/SAMIDORPHAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLANZAPINE/ SAMIDORPHAN MALATE	LYBALVI	47406		GPI-10 (6299480250)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of schizophrenia (ICD-10 Group F20) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a psychiatrist
   The patient is at high risk for weight gain
   The patient had a trial and failure of or contraindication to ONE of the following preferred brand agents: Vraylar, Rexulti

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of bipolar I disorder (ICD-10 Group F31 except Group F31.8) and meet **ONE** of the following criteria?
   Lybalvi will be used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
   Lybalvi will be used as maintenance monotherapy treatment

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a psychiatrist
   The patient is at high risk for weight gain
   The patient had a trial and failure of or contraindication to ONE of the following preferred brand agents: Vraylar, Rexulti

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OLANZAPINE/SAMIDORPHAN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Schizophrenia (type of mental health disorder)
- Bipolar I disorder (type of mood disorder)

If you have schizophrenia, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
- You are at high risk for weight gain
- You have tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred brand medications: Vraylar, Rexulti

If you have bipolar I disorder, approval also requires:
- You are 18 years of age or older
- Lybalvi will be used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate, OR used as maintenance monotherapy treatment
- Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
- You are at high risk for weight gain
- You have tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred brand medications: Vraylar, Rexulti

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lybalvi.

REFERENCES
Lybalvi [Prescribing Information]. Waltham, MA: Alkermes, Inc., January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/12/24
Created: 09/21
Client Approval: 08/24
P&T Approval: 10/20

OLAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLAPARIB	LYNPARZA	41642		GPI-10 (2153556000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used for maintenance treatment
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient's diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation
   - The patient's cancer is associated with a homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability, AND Lynparza will be used in combination with bevacizumab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation, as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient is in complete or partial response to their most recent platinum based-chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient has completed two or more lines of platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - Lynparza will be used as monotherapy for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of HER2-negative high risk early breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used as adjuvant treatment
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with neoadjuvant or adjuvant chemotherapy (e.g., doxorubicin, paclitaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of HER2-negative metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient does not have hormone receptor (HR)-positive breast cancer
   - The patient has a hormone receptor (HR)-positive breast cancer and has been treated with a prior endocrine therapy or is considered inappropriate for endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used for maintenance treatment
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient meet **BOTH** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has progressed following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa, Zytiga)

   If yes, continue to #11.
   If no, continue to #10.

10. Does the patient meet **BOTH** of the following criteria?
    - Lynparza will be used in in combination with abiraterone (Yonsa, Zytiga) AND prednisone or prednisolone
    - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

11. Does the patient meet **ONE** of the following criteria?
    - The patient previously had a bilateral orchiectomy
    - The patient has a castrate testosterone level (i.e., less than 50 ng/dL)
    - Lynparza will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
        1. Recurrent (returning) or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
        2. HER2 ((human epidermal growth factor receptor 2: a type of protein)-negative high risk early breast cancer (a type of breast cancer)
        3. HER2-negative metastatic breast cancer (a type of breast cancer that has spread to other parts of the body)
        4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
        5. Homologous recombination repair (HRR) gene-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
        6. BRCA-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)

    (Denial text continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   5. You meet ONE of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
      b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation) positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You are in complete or partial response to your most recent platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. You have completed at least two or more lines of platinum-based chemotherapy such as paclitaxel, docetaxel, cisplatin, carboplatin
   5. Lynparza will be used as monotherapy (used alone) for maintenance treatment

D. **If you have HER2-negative high risk early breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used as adjuvant (add-on) treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before main treatment or as add-on therapy such as doxorubicin, paclitaxel)

(Denial text continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   4. You meet ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and you have been treated with a prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered inappropriate for you

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (such as paclitaxel, docetaxel, cisplatin, carboplatin)

G. **If you have homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa or Zytiga)
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

H. **If you have BRCA-mutated metastatic castration-resistant prostate cancer, approval also requires, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used in in combination with abiraterone (Yonsa or Zytiga) AND prednisone or prednisolone
   3. Your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynparza.

REFERENCES

- Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/23/23
Created: 12/14
Client Approval: 10/23
P&T Approval: 10/23

OLEZARSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLEZARSEN SODIUM	TRYNGOLZA	50111		GPI-10 (3090626530)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Tryngolza will be used as an adjunct therapy to diet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for approval:
   You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   You are 18 years of age or older
   Tryngolza will be used as an adjunct (add-on) therapy to diet

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryngolza.

REFERENCES
Tryngolza [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; December 2024.

Created: 01/25
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLUTASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLUTASIDENIB	REZLIDHIA	48490		GPI-10 (2153496000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLUTASIDENIB (Rezlidhia)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezlidhia.

REFERENCES

- Rezlidhia [Prescribing Information]. Greenville, NC: Forma Therapeutics, Inc., December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 01/23
Client Approval: 02/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMACETAXINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMACETAXINE MEPESUCCINATE	SYNRIBO	24243		GPI-10 (2170004010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a resistance or intolerance to TWO or more tyrosine kinase inhibitors (e.g., Gleevec, Sprycel, Tasigna, Bosulif, Iclusig)

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:
   A. You have chronic or accelerated phase chronic myeloid leukemia (CML: type of blood cell cancer)
   B. You are 18 years of age or older
   C. You had a resistance or intolerance to TWO or more tyrosine kinase inhibitors (such as Gleevec, Sprycel, Tasigna, Bosulif, Iclusig)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Synribo.

REFERENCES

- Synribo [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/11/22
Created: 12/12
Client Approval: 03/22
P&T Approval: 05/13

OMADACYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMADACYCLINE	NUZYRA		45478	GPI-14 (04200050200320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, continue to #5.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp.* (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, continue to #7.

7. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Community-acquired bacterial pneumonia (CABP: type of lung infection)
   2. Acute (severe and sudden) bacterial skin or skin structure infection (ABSSSI)

B. **If you have community-acquired bacterial pneumonia, approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (*Includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of or contraindication to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

- Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/19
Client Approval: 04/20
P&T Approval: 01/19

OMALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB	XOLAIR	25399		GPI-10 (4460306000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
- The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
- The patient has a baseline IgE serum level of at least 30 IU/mL
- Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
- Xolair will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

If yes, continue to #2.
If no, continue to #4.

Does the patient meet **ONE** of the following criteria?
- The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
- The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
150mg: #6 per 28 days.
75mg/0.5mL: #5mL per 28 days.
150mg/mL: #4mL per 28 days.
300mg/2mL: #4mL per 28 days.

If no, continue to #3.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
- Daytime asthma symptoms more than twice per week
- Any night waking due to asthma
- Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
- Any activity limitation due to asthma

If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
150mg: #6 per 28 days.
75mg/0.5mL: #5mL per 28 days.
150mg/mL: #4mL per 28 days.
300mg/2mL: #4mL per 28 days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
- There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
- The patient has inadequately controlled disease
- The patient had a 56-day trial of ONE intranasal corticosteroid (e.g., mometasone nasal spray)
- Xolair will be used as add-on maintenance treatment
- Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
If no, continue to #5.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
- The patient is 1 year of age or older
- The patient will continue to avoid food allergens while on Xolair
- The patient has an IgE serum level of at least 30 IU/mL
- The patient has an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test to at least one food, OR a positive medically monitored food challenge to at least one food
- Therapy is prescribed by or in consultation with an allergist or immunologist
- The patient has an active prescription for epinephrine auto-injector/injection while on Xolair
- Xolair will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
If no, continue to #6.

Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
- The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
- The patient had a trial of and is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (i.e., Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
- Xolair will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
150mg: #2 per 28 days.
150mg/mL: #2mL per 28 days.
300mg/2mL: #2mL per 28 days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe persistent asthma (a type of lung condition)
- Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
- IgE-mediated food allergy (body's reaction to a food allergy)
- Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

If you have moderate to severe persistent asthma, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
- You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
- You have a baseline IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
- Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
- You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
- You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
  - Daytime asthma symptoms more than twice per week
  - Any night waking due to asthma
  - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
  - Any activity limitation due to asthma

If you have chronic rhinosinusitis with nasal polyps, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
- You have inadequately controlled disease
- You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
- Xolair will be used as add-on maintenance treatment (taken on a regular basis)
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have an IgE-mediated food allergy, approval also requires:
- You are 1 year of age or older
- You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Xolair
- You have an IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
- You have an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
- You have an active prescription for epinephrine auto-injector/injection while on Xolair
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
- You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMALIZUMAB

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
- The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
- Xolair will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

If yes, continue to #2.
If no, continue to #3.

Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
- Reduction in asthma exacerbations from baseline
- Decreased utilization of rescue medications (e.g., albuterol)
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
150mg: #6 per 28 days.
75mg/0.5mL: #5mL per 28 days.
150mg/mL: #4mL per 28 days.
300mg/2mL: #4mL per 28 days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
- The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
- Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**

If no, continue to #4.

Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
- The patient has persistent IgE-mediated food allergy
- The patient has an active prescription for epinephrine auto-injector/injection while on Xolair
- Xolair will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**

If no, continue to #5.

Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
- The patient is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (i.e., Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
- Xolair will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
150mg: #2 per 28 days.
150mg/mL: #2mL per 28 days.
300mg/2mL: #2mL per 28 days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe persistent asthma (a type of lung condition)
- Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
- IgE-mediated food allergy (body's reaction to a food allergy)
- Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

If you have moderate to severe persistent asthma, renewal also requires:
- You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
- You have shown a clinical response as evidenced by ONE of the following:
  - You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Xolair)
  - You have decreased your use of rescue medications (such as albuterol)
  - You have an increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline (before starting Xolair)
  - You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
- You have shown a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

(Renewal denial text continued on next page)

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

If you have an IgE-mediated food allergy, renewal also requires:
- You have persistent IgE-mediated food allergy
- You have an active prescription for epinephrine auto-injector/injection while on Xolair
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
- You will NOT use Xolair concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES

Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

Created: 08/03
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

OMAVELOXOLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMAVELOXOLONE	SKYCLARYS	48741		GPI-10 (7413506000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Friedreich's ataxia **AND** meet the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for approval:
   A. You have Friedreich's ataxia (a type of nervous system and movement disorder)
   B. You are 16 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyclarys.

REFERENCES

- Skyclarys [Prescribing Information]. Plano, TX: Reata Pharmaceuticals, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 04/23
Client Approval: 05/23
P&T Approval: 04/23

OPICAPONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OPICAPONE	ONGENTYS	45536		GPI-10 (7315306000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing “OFF” episodes
   - The patient is currently being treated with carbidopa/levodopa
   - The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's disease agents from **TWO** different classes of the following:
     - Dopamine agonist (e.g., ropinirole, pramipexole, rotigotine)
     - Monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline)
     - Adenosine receptor antagonist A2A (e.g., istradefylline)
     - Catechol-O-methyltransferase (COMT) inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (times when you have symptoms return due to medication wearing off)
   D. You are currently being treated with carbidopa/levodopa
   E. You have tried or failed or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
      1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
      2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
      3. Adenosine receptor antagonist A2A (such as istradefylline)
      4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPICAPONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ongentys.

REFERENCES

- Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 09/20
Client Approval: 11/20
P&T Approval: 10/20

OPIOID-ANTIPSYCHOTIC CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1205: OPIOID-ANTIPSYCHOTIC CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_PSY'.**
   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid and an antipsychotic medication is intended and clinically appropriate for the patient?
   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_PSY'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid-Antipsychotic Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and an antipsychotic drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-ANTIPSYCHOTIC CONCURRENT USE** allows an approval for use of an opioid with an antipsychotic medication (type of mental health drug) together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the use of an opioid and an antipsychotic medication together is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

RATIONALE

To mitigate the risk of overdose from dangerous combinations of antipsychotics and opioids while preserving patient access to drug regimens if deemed medically necessary.

In addition, align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and are listed below:

- Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations
- Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics
- Monitoring antipsychotic prescribing for children
- Process that identifies potential fraud or abuse by enrolled individuals and pharmacies
- Report to the Secretary annually on state DUR activities
- Have in place managed care contracts that include these provisions

The guideline also allows an override for patients with one of the following conditions:

- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease
- Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

REFERENCES

- SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 7/30/19].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-ANTIPSYCHOTIC CONCURRENT USE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25

Created: 08/19
Client Approval: 08/24

P&T Approval: 10/24

OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1201: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
   If no, continue to #3.

3. Has the prescriber provided attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication?

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a benzodiazepine drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor agrees to proceed with the concurrent use (at the same time) of an opioid and a benzodiazepine for a clinically appropriate indication (reason)
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.
(*Denial text continued on next* page)

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OPIOID-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed**.**

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019."*CMS 2019 Call Letter, page 251*
The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.
This guideline allows an approval for patients with one of the following conditions:

- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease
- Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine
- Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-BENZODIAZEPINE CONCURRENT USE

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 8/12/24].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/12/24].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 8/12/24].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25
Created: 10/17
Client Approval: 08/24
P&T Approval: 10/24

OPIOID-BUPRENORPHINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with **ONE** of the following error codes?
   - **REJ-433-1200 (DUR CONCURRENT USE): CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY**
   - **REJ-1064 (DUR_DD_DENY): DRUG-DRUG INTERACTION FOUND**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set OVR_RES to 'Y'**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, continue to #3.

3. Has the prescriber provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and needs to resume chronic opioid treatment? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

   If yes, **approve for 4 months by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set OVR_RES to 'Y'**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, continue to #4.

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OPIOID-BUPRENORPHINE CONCURRENT USE

GUIDELINES FOR USE

4. Is the prescriber aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

   If yes, **approve for 30 days by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set OVR_RES to 'Y'**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a buprenorphine-containing drug together.

   [Proceed to enter Denial Text below]

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:
   A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   B. You are enrolled in a hospice (end of life care)
   C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
   D. You have sickle cell disease (a type of blood disorder)
   E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
   F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

   (Denial text continued on next page)

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OPIOID-BUPRENORPHINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from CMS guidance. For further information, please refer to the Drug Monograph for Opioid-Buprenorphine Concurrent Use.

Prior authorization will be required for opioid prescriptions when in concurrent use with buprenorphine. This edit will be utilized to stop opioid claims, which overlap with buprenorphine use. The edit will stop the claim for pharmacy submission of PPS codes. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.

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OPIOID-BUPRENORPHINE CONCURRENT USE

RATIONALE (CONTINUED)

The guideline requires that the prescriber is aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication, or the prescriber has provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and to proceed with opioid treatment. Consultation with an addiction medicine specialist is recommended.
In addition, the guideline allows an override for patients with one of the following conditions:

- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease
- Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
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Created: 12/18
Effective: 01/23/25 Client Approval: 01/25 P&T Approval: 10/24

OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold or hard-stop threshold as noted in the POS reject messaging?

   NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with Soft_DENY_LIMIT= X or HARD_DENY_LIMIT= X (i.e., Cumulative morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [**soft-stop threshold**-mg MME or **hard-stop threshold**-mg MME]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Approval duration should be for 12 months by HICL or GPI-10.**
   - **NOTE: Please enter a class override to override the MME cumulative dosing for the duration of 12 months.**
   - **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

   If no, continue to #3.

3. Is the prescriber aware of multiple prescribers for opioid prescriptions?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

4. Have **TWO** of the following criteria been met?
   - The patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - The patient has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   - The patient has a pain contract in place
   - The patient does NOT have a history of substance abuse or addiction
   - The prescriber has committed to monitoring the state's Prescription Monitoring Program to ensure the controlled substance history is consistent with the prescribing record

   If yes, **approve as follows:**
   - **Approval duration should be for 12 months by HICL or GPI-10.**
   - **NOTE: Please enter a class override to override the MME cumulative dosing for the duration of 12 months.**
   - **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
   While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the amount of opiates prescribed and because your opiate amount exceeds or is equal to **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) or **[enter hard stop threshold]**-mg morphine milligram equivalent (MME).
   [Proceed to enter Denial Text below]

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

A claim for a pain medication will be denied when there are two or more providers prescribing opioid medications for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   2. You are enrolled in a hospice (end of life care)
   3. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   4. You have sickle cell disease (a type of blood disorder)
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your prescriber is aware that there is more than one provider prescribing opiates for you, AND you meet **TWO** of the following:
   1. Your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do NOT have a history of substance abuse or addiction
   5. Your prescriber has committed to monitoring the state's Prescription Monitoring Program to make sure your controlled substance history is consistent with prescribing record

This safety edit allows for an override for an opioid product equal to or exceeding the **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) or **[enter hard stop threshold]**-mg morphine milligram equivalent (MME). Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

(Denial text continued on next page)

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT: Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter.
Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. This requirement should not apply to patients with, in hospice, those receiving palliative or end of life care, residents of a long-term facility, patients approved by case management or retrospective DUR Programming or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be overriden by the pharmacy via DUR PPS codes or as part of coverage determination process and by certain PPS codes. Hard-thresholds are overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MME days' criterion as it would not prevent beneficiaries from reaching high opioid doses.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID CUMULATIVE DOSING OVERRIDE

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]
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- The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/14/24].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25
Created: 09/16
Client Approval: 08/24
P&T Approval: 10/24

OPIOID LONG-ACTING DUPLICATIVE THERAPY

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1045: THERAPEUTIC DUPLICATION DENIAL (DRUG_TD)**
     (The incoming claim for a long-acting (LA) opioid will reject when the patient is concurrently taking a different long-acting opioid [different HICL] from a different prescriber.)

     If yes, continue to #2.
     If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

     If yes, **approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes.**
     If no, continue to #3.

3. Is the prescriber aware that the patient is concurrently receiving more than one long-acting opioid therapy?

     If yes, **approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes.**
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUE ON NEXT PAGE

OPIOID LONG-ACTING DUPLICATIVE THERAPY

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of two long-acting opioid drugs together that are from different prescribers. **[Proceed to enter Denial Text below]**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID LONG ACTING DUPLICATIVE THERAPY** allows approval of the requested drug taken together with other long-acting opioid drug(s) from different prescribers when ONE of the following conditions are met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that they are aware that you are concurrently receiving more than one long-acting opioid medication
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID LONG-ACTING DUPLICATIVE THERAPY

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"…we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion." *CMS 2019 Call Letter, page 252*
Prior authorization will be required for Long Acting (LA) opioid prescriptions when an incoming claim for a long-acting opioid overlaps with another a long acting opioid (different HICL) claim(s) from a different prescriber(s). The edit can be overridden by professional pharmacy professional service (PPS) code at POS or by a PA. This requirement does not apply to patients receiving palliative care or end-of-life care, those enrolled in hospice, patients that are a resident of a long-term care facility or intermediate care for intellectually disabled, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is physician attestation that the prescriber is aware that the patient is concurrently receiving long acting duplicative therapy and would like to proceed with treatment for a clinically appropriate indication.

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf. [Accessed 8/14/24].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25
Created: 12/18
Client Approval: 08/24
P&T Approval: 10/24

OPIOID-NAIVE CUMULATIVE DOSING (ONCD)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - The request is for an opioid product equal to or exceeding the soft-stop threshold or hard-stop threshold as noted in the POS reject messaging?
     NOTE: The following reject code(s) may also be present:
     - For Soft-Stop: **REJ-88-1080**
     - For Hard-Stop: **REJ-88-1081**

     If yes, continue to #2.
     If no, guideline does not apply.

2. Is the patient opioid-naive meaning they have not used an opioid drug(s) in the past 60 days (starting the day prior to the fill date of the incoming claim)?
   [NOTE: Please refer to the claims history in MedAcess, Medication Request Form (MRF) or chart notes (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, continue to #3.
   If no, **approve for one (1) month, for one (1) fill count by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

3. Does the patient meet at least **ONE** of the following criteria?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

   If no, continue to #4.

CONTINUE ON NEXT PAGE

OPIOID-NAIVE CUMULATIVE DOSING

GUIDELINES FOR USE (CONTINUED)

4. Have **BOTH** of the following criteria been met?
   - The provider has indicated that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

   If yes, **approve for one (1) month, for one (1) fill count by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
   [NOTE: Enter proactive PAs for other UM overrides not including Opioid-Naive Cumulative Dosing, if applicable.]

   While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because you are considered opioid naive (those who have not used opioid drugs within the past 60 days) and the opiate amount exceeds or is equal to **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) or **[enter hard stop threshold]**-mg morphine milligram equivalent (MME). **[Proceed to enter Denial Text below]**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID-NAIVE CUMULATIVE DOSING** allows approval of a higher quantity of an opioid medication if at least ONE of the following conditions is met:
   - You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   - You are enrolled in hospice (end of life care)
   - You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
   - You have sickle cell disease (a type of blood disorder)
   - You are not opioid naive (you have been consistently using opioid pain medications)
   - You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

   (Denial text continued on next page)

CONTINUE ON NEXT PAGE

OPIOID-NAIVE CUMULATIVE DOSING

GUIDELINES FOR USE (CONTINUED)

If none of these conditions apply, BOTH of the following criteria must be met:

- The provider has indicated that your current level of opioid utilization (use) is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

Please consult your physician and/or your pharmacist to discuss your options or if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and address the prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.
The guideline is based on CDC dosage recommendations stated in the “Initial Opioid Prescribing at High Dosage” measures from the Pharmacy Quality Alliance (PQA) and Managed Medicaid program limits.

This requirement does not apply to patients in palliative care, hospice patients, patients living in a long-term care facility or intermediate care for intellectually disabled, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease.
In addition, approval is granted if BOTH of the following conditions are met:

- The provider has indicated that the patient’s current level of opioid utilization is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state’s Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

CONTINUE ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-NAIVE CUMULATIVE DOSING

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1 [Accessed 6/28/18].
- Jones B, Cynthia. (2016). Implementation of CDC Guideline for Prescribing Opioids for Chronic Pain Coverage of Non-Opioid Pain Relievers and Uniform, Streamlines Prior Authorization for New Opioid Prescription Effective December 1, 2016. Department of Medical Assistance Services. Available at https://www.msv.org/sites/default/files/PDFs/12.1.16_guideline_for_opioids_non_opioid_pain_relievers_revised_final.pdf [Accessed 6/28/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf Accessed 8/14/24].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25

Created: 12/19
Client Approval: 08/24

P&T Approval: 10/24

OPIOID-NAIVE DAY SUPPLY LIMITATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1044: INITIAL FILL DAYS SUPPLY EXCEEDS LIMITS (DS-NAIVE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only
   - The patient is NOT opioid naive
     (**NOTE:** For new patients with no claims history, please refer to the MRF or MedAccess).

   If yes, **approve for one month, for one fill count by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes.**

   If no, continue to #3.

3. Has the prescriber provided attestation that the opioid medication with the requested day supply is the intended and medically necessary amount for the beneficiary?

   If yes, **approve for one month, for one fill count by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUE ON NEXT PAGE

OPIOID-NAIVE DAY SUPPLY LIMITATION

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the day supply you are requesting for this opioid medication.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for a longer day supply when you meet at least **ONE** of the following conditions:

A. You are enrolled in hospice (end of life care)
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. You are NOT opioid naïve (you have been consistently using opioid pain medications)
F. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary
G. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your doctor if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this medication.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
“Beginning in 2019, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days’ supply…”. *CMS 2019 Call Letter, page 237*

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OPIOID-NAIVE DAY SUPPLY LIMITATION

RATIONALE (CONTINUED)

Prior authorization will be required for opioid prescriptions with a longer day supply for opioid naive patients. This requirement does not apply to patients receiving palliative care or end-of-life care, those enrolled in hospice, residents of a long-term care facility or intermediate care for intellectually disabled, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

In addition, if the patient is determined to NOT be opioid naive during the coverage determination process, they are exempt from this safety edit. This exemption is based on the following guidance: "If during the coverage determination process, it becomes known that the patient is not opioid naive, he or she should be excluded from the opioid naive edit." *CMS Additional Guidance memo from October 23, 2018, page 8.*

Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is attestation from the prescriber that the prescribed dose of opioids with the requested day supply is intended and medically necessary.

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]
- The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/12/24].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-NAIVE DAY SUPPLY LIMITATION

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25

Created: 02/19
Client Approval: 08/30

P&T Approval: 10/24

OPIOID NAIVE FILL LIMIT

Generic	Brand	HICL	GCN	Medi-Span	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-306-1066: THIS CLAIM EXCEEDS LIMIT OF 2 OPIOID FILLS IN 30 DAYS**

   [**NOTE**: The incoming opioid analgesic claim will reject if an initially opioid-naive member exceeds two opioid fills regardless of day supply, for the same drug (HICL), within the past 30 days. In addition, the patient is considered opioid-naive if they have no history of an opioid analgesic drug(s) in the past 60 days (not counting same day claims).]

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set FILL_LIMIT_OVR to 'Y' for Yes.**
   If no, continue to #3.

3. Has the prescriber indicated that the additional fill of the requested opioid analgesic medication is intended and clinically appropriate for the patient?

   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 1 month, for one fill count by HICL or GPI-10 and set FILL_LIMIT_OVR to 'Y' for Yes.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID NAIVE FILL LIMIT

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid Naive Fill Limit, if applicable.]

While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because you exceeded the fill limit of the requested opioid analgesic.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID NAIVE FILL LIMIT** allows an approval of the requested drug when it exceeds the fill limit for an initially opioid-naïve patient (those who have not used opioid drugs within the past 60 days) when ONE of the following conditions is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the additional fill of the requested opioid medication is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID NAIVE FILL LIMIT

RATIONALE

To ensure appropriate use of opioids and to address prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, the goal is to align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and they are listed below:

- Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations
- Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics
- Monitoring antipsychotic prescribing for children
- Process that identifies potential fraud or abuse by enrolled individuals and pharmacies
- Report to the Secretary annually on state DUR activities
- Have in place managed care contracts that include these provisions

The guideline also allows an override for patients with one of the following conditions:

- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease
- Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

REFERENCES

- SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 7/30/19]
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/14/24].

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OPIOID NAIVE FILL LIMIT

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25

Created: 08/19
Client Approval: 08/24

P&T Approval: 10/24

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
OPIOIDS	OPIOIDS	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold hard-stop threshold as noted in the POS reject messaging?

   NOTE: Claims should stop for DUR_MAX_SINGLE_DOSE edit with Soft_DENY_LIMIT = X or HARD_DENY_LIMIT = X (i.e., morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [**soft-stop threshold**-mg MME or **hard-stop threshold**-mg MME]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for an opioid product less than or equal to the hard-stop threshold-1 MME?

   If yes, **approve 12 months by HICL or GPI-10 up to hard-stop threshold-1 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #3.

3. Does the patient meet **ANY** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5)
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is enrolled in hospice
   - The prescriber is a pain management specialist
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve 12 months by HICL or GPI-10. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #4.

4. Has the physician provided attestation that the requested high dose is considered medically necessary?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

5. Is the request for an opioid with an MME equal to or exceeding the hard-stop threshold and the prescriber has not indicated an opioid MME threshold value?

   If yes, **approve for 12 months by HICL or GPI-10 up to 25% greater than the previously approved MME via the patient's claim profile or physician attestation, up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #6.

6. Did the physician indicate a maximum opioid threshold for the requested drug that is less than 300 MME?

   If yes, **approve for 12 months by HICL or GPI-10 as requested up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #7**.**

7. Is the request for an opioid with an MME equal to or exceeding the maximum threshold (300 MME) for a patient who is currently stable on this MME?

   If yes, **approve for 3 months by HICL or GPI-10. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   APROVAL TEXT: While your prior authorization for (enter requested drug) has been granted, your opiate amount is equal to or exceeds [300 morphine milligram equivalent (MME)] and is considered a high dose of opiate. Please consult with your pain management specialist regarding your treatment options.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID SINGLE CLAIM DOSING AT POS** allows for an override of an opioid product equal to or exceeding the soft-stop threshold of **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) at the pharmacy or by a prior authorization. The hard-stop threshold of **[enter hard stop threshold]**-mg morphine milligram equivalent (MME) is not overridable and requires a prior authorization.
   (Denial text continued on next page)

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

An override will be provided if ONE (A or B) of the following rule(s) are met:

A. You meet ONE of the following conditions:
   1. You are receiving treatment for palliative care (treatment for comfort from symptoms)
   2. You have sickle cell disease (a type of blood disorder)
   3. You are enrolled in a hospice (end of life care)
   4. Your doctor is a pain management specialist
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your physician confirms that the requested high dose is considered medically necessary.
   1. If the requested dose is lower than 300 MME, your prescriber must provide a maximum opioid threshold. If your prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding **[enter hard-stop threshold]**-mg morphine milligram equivalent (MME), the claim will be approved up to 25 percent greater than the previously approved MME.
   2. If the requested dose is equal to or greater than 300 MME, approval will be granted if you are stable on the dose.

Please consult your pain management specialist regarding your treatment options.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To align with opioid restrictions required by several states and to prevent overutilization of opioids and increase safety.

This advanced POS intervention blocks an incoming claim when a single claim's Morphine Milligram Equivalent (MME) is equal to or exceeds a specified hard-stop threshold (e.g. over 90 MME). The hard-stop is non-overridable except via prior authorization. The edit allows a soft stop on an incoming claim with an MME equal to or over a lower threshold (e.g. over 50 MME) that can be overridden by Pharmacy Professional Service (PPS) codes at the point-of-sale (POS) or by prior authorization. Overriding the hard threshold for OSCDP will also override the OSCDP soft threshold, but does not affect Opioid Cumulative Dosing Program (OCDP).

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

RATIONALE (CONTINUED)

This requirement does not apply to patients with sickle cell disease, patients in palliative care, hospice patients, patients with a prescription from a pain management specialist, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

REFERENCES

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1 [Accessed June 28, 2018].
- Jones B, Cynthia. (2016). Implementation of CDC Guideline for Prescribing Opioids for Chronic Pain Coeverage of Non-Opioid Pain Relievers and Uniform, Streamlines Prior Authorization for New Opioid Prescription Effective December 1, 2016. Department of Medical Assitance Services. Available at https://www.msv.org/sites/default/files/PDFs/12.1.16_guideline_for_opioids_non_opioid_pain_relievers_revised_final.pdf [Accessed June 28, 2018].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/14/24].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25
Created: 06/18
Client Approval: 08/24
P&T Approval: 10/24

OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1204: SOMA-OPIOID-BENZODIAZEPINE CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'SOMA_OP_BZD'.**

   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid with Soma (carisoprodol) and a benzodiazepine medication is intended and clinically appropriate for the patient?

   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for one (1) month by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'SOMA_OP_BZD'.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including Opioid-Soma-Benzodiazepine Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you
E. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

RATIONALE

To mitigate the risk of the overdose from dangerous combinations of CNS depressants while preserving patient access to drug regimens if deemed medically necessary.

The Opioid-Benzodiazepine-Soma Concurrent Use at POS edit will identify and deny concurrent use of opioids, benzodiazepines, and carisoprodol when there is an overlap in day supply (for at least one drug from each 'class'). This edit will reject the claim that creates the three-drug overlap.

The edit will have internal reject codes REJ- 433- 1204, and the following parameters:

1. Triple drug overlap = 1 day
2. Prescriber threshold = 1 prescriber
3. Exceptions =
   a) Cancer diagnosis (edit will lookback for presence of claims related to these diseases in the past 180 days to automatically exclude from the edit)
   b) Hospice or palliative care (edit will look for hospice attribute on claims to automatically exclude from the edit)
   c) Long Term Care residence (edit will look for patient residence code to automatically exclude from the edit)
   d) Cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only

Please note that sickle cell disease will not be included in the exception criteria. Although opioids and benzodiazepines can be used in managing pain crises, treatment guidelines do not mention skeletal muscle relaxants such as carisoprodol as a typical treatment modality.

REFERENCES

- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-july-5-2024.pdf Accessed 8/14/24].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/25
Created: 07/19
Client Approval: 08/24
P&T Approval: 10/24

ORLISTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ORLISTAT	XENICAL, ORLISTAT		95213	GPI-14 (61253560000120)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) **AND** the patient meets the following criterion?
   There is evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient has a body mass index (BMI) of at least 30 kg/m(2)
   The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

ORLISTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ORLISTAT (Xenical)** requires the following rule(s) be met for approval:
The request is for weight loss OR weight loss management
You have evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program
You meet ONE of the following:
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
- You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

ORLISTAT

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 18 years of age or older **AND** meets the following criterion?
   The patient has achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, continue to #3.

3. Is the patient younger than 18 years of age **AND** meets the following criterion?
   The patient has achieved or maintained at least a 5 percent decrease from baseline BMI after 3 months of treatment

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ORLISTAT (Xenical)** requires the following rule(s) be met for renewal:
   The request is for weight loss OR weight loss management
   If you are 18 years of age or older, approval also requires:
   You have achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment
   If you are younger than 18 years of age, approval also requires:
   You have achieved or maintained at least a 5 percent decrease from baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

ORLISTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenical.

REFERENCES

Xenical (orlistat) [Prescribing Information]. Montgomery, AL: H2-Pharma, LLC; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 05/24
Client Approval: 08/24
P&T Approval: 07/24

OSILODROSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT PHOSPHATE	ISTURISA	46396		GPI-10 (3002206060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Pituitary surgery is not an option or has not been curative for the patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
   E. You had a trial of or contraindication (harmful for) to oral ketoconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OSILODROSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Isturisa

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (a type hormone disorder)
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   C. You continue to tolerate treatment with Isturisa

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES

- Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 08/20
Client Approval: 06/23
P&T Approval: 07/20

OSIMERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		GPI-10 (2136006820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Tagrisso be used as adjuvant therapy after tumor resection **AND** the patient meets the following criterion?
   The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the cancer locally advanced and unresectable (stage III) and the patient meets **ALL** of the following criteria?
   The patient's disease has NOT progressed during or following concurrent or sequential platinum-based (e.g., cisplatin, carboplatin) chemoradiation therapy
   The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Is the cancer metastatic and the patient meets **ONE** of the following criteria?
   The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
   The patient's tumor has an epidermal growth factor receptor (EGFR) T790M mutation, as detected by an FDA-approved test, AND the patient's disease has progressed while on or after EGFR tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #5.

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

5. Is the cancer locally advanced or metastatic and the patient meets **ALL** of the following criteria?
   Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:
   You have non-small cell lung cancer (NSCLC: a type of lung cancer)
   You are 18 years of age or older
   You meet ONE of the following:
   - Tagrisso will be used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor), and your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   - Your cancer is locally advanced and unresectable (stage III) (cancer that has spread to nearby tissue or lymph nodes and cannot be surgically removed), and you meet ALL of the following:
     - Your disease has NOT worsened during or following concurrent (at the same time) or sequential (one after the other) platinum-based (such as cisplatin, carboplatin) chemoradiation therapy (a type of treatment that combines chemotherapy and radiation)
     - Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

Your cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
- Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- Your tumor has an epidermal growth factor receptor (EGFR) T790M mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND your disease has worsened while on or after EGFR tyrosine kinase-inhibitor therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body), and you meet ALL of the following:
- Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (such as cisplatin, carboplatin)
- Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tagrisso.

REFERENCES

Tagrisso [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/21/24
Created: 11/15
Client Approval: 10/24
P&T Approval: 10/24

OTESECONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OTESECONAZOLE	VIVJOA	47976		GPI-10 (1140805000)	

GUIDELINES FOR USE

1. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) and the patient meets **ALL** of the following criteria?
   - The patient is female
   - The patient is NOT of reproductive potential (defined as a biological female who is postmenopausal or has another reason for permanent infertility [e.g., tubal ligation, hysterectomy, salpingo-oophorectomy])
   - The patient is NOT currently on ibrexafungerp for RVVC

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vivjoa?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #18 per 12 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Vivjoa for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #18 per 12 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OTESECONAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OTESECONAZOLE (Vivjoa)** requires the following rule(s) be met for approval:

A. You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
B. You are female
C. You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or you have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
D. You are NOT currently on ibrexafungerp for RVVC
E. **If you have not previously received Vivjoa, approval also requires:**
   1. You had 3 or more episodes of RVVC in the past 12 months
F. **If you have previously received Vivjoa, approval also requires:**
   1. You have successfully completed a course of Vivjoa for prevention of RVVC
   2. You are either being treated or have just completed treatment for a new recurrence of VVC

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vivjoa.

REFERENCES

- Vivjoa [Prescribing Information]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 07/22
Client Approval: 02/23
P&T Approval: 01/23

OXYMETAZOLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OXYMETAZOLINE HCL/PF	UPNEEQ	46701		GPI-10 (8680223610)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of blepharoptosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has been evaluated for surgical intervention
   - The patient had a trial of TWO ophthalmic alpha-adrenergic agonists (e.g., apraclonidine, tetrahydrozoline, naphazoline)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #1 droperette per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for approval:
   A. You have blepharoptosis (drooping of the upper eyelid)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   D. You have been evaluated for surgical intervention
   E. You had a trial of TWO ophthalmic alpha-adrenergic agonists (such as apraclonidine, tetrahydrozoline, naphazoline)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OXYMETAZOLINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of blepharoptosis **AND** meet the following criterion?
   - The patient continues to have benefit from Upneeq

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 droperette per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for renewal:
   D. You have blepharoptosis (drooping of the upper eyelid)
   E. You continue to have benefit from Upneeq

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Upneeq.

REFERENCES

- Upneeq [Prescribing Information]. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/21
Client Approval: 02/22
P&T Approval: 10/21

OZANIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OZANIMOD HYDROCHLORIDE	ZEPOSIA	46431		GPI-10 (6240705020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Zeposia will NOT be used concurrently with another systemic biologic (e.g., Tysabri [natalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial text at the end of the guideline.

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for approval:
You have ONE of the following:
- A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have a relapsing form of multiple sclerosis, approval also requires:
- You are 18 years of age or older
- You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Tysabri [natalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OZANIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for renewal:
   You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
   You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OZANIMOD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

Zeposia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; August 2024.

Created: 06/20
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

PACRITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PACRITINIB CITRATE	VONJO	47850		GPI-10 (2153755010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytopenia) myelofibrosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet count below 50,000/uL

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do no approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for approval:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You have a platelet count below 50,000/uL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PACRITINIB

RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of 35% or greater from baseline
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)**requires the following rule(s) be met for renewal:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of 35% or greater from baseline
      2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vonjo.

REFERENCES

- Vonjo [Prescribing Information]. Seattle, WA: CTI BioPharma Corp.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 03/22
Client Approval:03/22
P&T Approval: 10/21

PALBOCICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALBOCICLIB	IBRANCE	41725		GPI-10 (2153106000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Groups C50, C79.81) **AND** meet the following criterion?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Ibrance be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) as initial endocrine-based therapy and the patient meets **ALL** of the following criteria?
   The patient's cancer is advanced or metastatic
   The patient had a trial of or contraindication to ONE of the following preferred agents: Kisqali (ribociclib), Verzenio (abemaciclib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #3.

3. Will Ibrance be used in combination with fulvestrant (Faslodex) and the patient meets **ALL** of the following criteria?
   The patient's cancer is advanced or metastatic
   The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)
   The patient had a trial of or contraindication to ONE of the following preferred agents: Kisqali (ribociclib), Verzenio (abemaciclib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #4.

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PALBOCICLIB

GUIDELINES FOR USE (CONTINUED)

4. Will Ibrance be used in combination with Itovebi (inavolisib) and fulvestrant (Faslodex) and the patient meets **ALL** of the following criteria?
   The patient's cancer is locally advanced or metastatic
   The patient's tumor has a PIK3CA mutation as detected by an FDA-approved test
   The patient has experienced disease recurrence on or after completing adjuvant endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:
   You have breast cancer
   Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   If you are using Ibrance in combination with an aromatase inhibitor (such as anastrozole, letrozole, exemestane), approval also requires:
   Your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body)
   Ibrance will be used as initial endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen)
   You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
   If you are using Ibrance in combination with fulvestrant (Faslodex), approval also requires:
   Your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body)
   Your disease has worsened after endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)
   You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
   (Denial text continued on next page)

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PALBOCICLIB

GUIDELINES FOR USE (CONTINUED)

If you are using Ibrance in combination with Itovebi (inavolisib) and fulvestrant (Faslodex), approval also requires:

Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)

Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test

You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibrance.

REFERENCES

Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories; September 2023.
Itovebi [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/25/24
Created: 05/15
Client Approval: 11/24
P&T Approval: 04/23

PALOPEGTERIPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALOPEGTERIPARATIDE	YORVIPATH	49810		GPI-10 (3090516000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hypoparathyroidism (ICD-10 Group E20) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis
   The patient had a trial of activated vitamin D (e.g., calcitriol) and calcium

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with a quantity limit as follows:**
   168 mcg/0.56 mL: #1.12 mL per 28 days.
   294 mcg/0.98 mL: #1.96 mL per 28 days.
   420 mcg/1.4 mL: #2.8 mL per 28 days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for approval:
   You have hypoparathyroidism (low levels of parathyroid hormone)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   Your hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis (balance)
   You have tried activated vitamin D (such as calcitriol) and calcium

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOPEGTERIPARATIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hypoparathyroidism (ICD-10 Group E20) **AND** meet the following criterion?
   The patient is independent of or managed on a lowered dose of vitamin D and calcium supplementation

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   168 mcg/0.56 mL: #1.12 mL per 28 days.
   294 mcg/0.98 mL: #1.96 mL per 28 days.
   420 mcg/1.4 mL: #2.8 mL per 28 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for renewal:
   You have hypoparathyroidism (low levels of parathyroid hormone)
   You are independent of or managed on a lowered dose of vitamin D and calcium supplements

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yorvipath.

REFERENCES

Yorvipath [Prescribing Information]. Princeton, NJ: Ascendis Pharma; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/23/24
Created: 09/24
Client Approval: 09/24
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOVAROTENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALOVAROTENE	SOHONOS	49043		GPI-10 (7588606000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of fibrodysplasia ossificans progressiva (FOP) and meet **ONE** of the following criteria?
   - The patient is a female and 8 years of age or older
   - The patient is a male and 10 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for approval:
   A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
   B. You meet ONE of the following:
      1 You are female and 8 years of age or older
      2. You are male and 10 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sohonos.

REFERENCES

- Sohonos [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

PANITUMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PANITUMUMAB	VECTIBIX	34054		GPI-10 (2136007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patien'ts cancer wild-type RAS (defined as wild-type in both KRAS and NRAS), as determined by an FDA-approved test?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
   Vectibix will be used as monotherapy AND the patient has disease progression after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient's cancer have a KRAS G12C-mutation, as determined by an FDA-approved test, and meet **ALL** of the following criteria?
   Vectibix will be used in combination with Lumakras (sotorasib)
   The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PANITUMUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PANITUMUMAB (Vectibix)** requires the following rule(s) be met for approval:

You have metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)

You are 18 years of age or older

Your cancer is wild-type RAS (defined as wild-type in both KRAS and NRAS [types of genes without a specific mutation]), OR you have a KRAS G12C-mutation [type of abnormal change in a gene], as determined by a Food and Drug Administration (FDA)-approved test

If your cancer is wild-type RAS, approval also requires ONE of the following:

- Vectibix will be used in combination with FOLFOX (treatment regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
- Vectibix will be used as monotherapy (one drug treatment) AND you have disease progression (worsening) after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy (drugs used to treat cancer)

If your cancer has a KRAS G12C-mutation, approval also requires:

- Vectibix will be used in combination with Lumakras (sotorasib)
- You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vectibix.

REFERENCES

Vectibix [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; January 2025.

Created: 02/13
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/25

PARATHYROID HORMONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PARATHYROID HORMONE	NATPARA	34000		GPI-10 (3004405510)	ROUTE = SUBCUTANE.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypocalcemia secondary to hypoparathyroidism and meets the following criteria?
   - Previous trial of activated vitamin D (calcitriol) and calcium
   - Patient's hypoparathyroidism is **not** due to a calcium sensing receptor (CSR) mutation
   - Patient's hypoparathyroidism is **not** considered acute post-surgical hypoparathyroidism (surgery in past 30 days)
   - Therapy is prescribed by or given in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-10 for quantity of #2 cartridges per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **PARATHYROID HORMONE** requires the following rule(s) be met for approval:
   A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
   B. You have previously tried activated vitamin D (calcitriol) and calcium
   C. Your hypoparathyroidism (low levels of a type of hormone) is not due to a calcium sensing receptor (CSR) mutation (changes in your DNA that make up your gene)
   D. Your hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery in past 30 days)
   E. Therapy is prescribed by or given in consultation with an endocrinologist (hormone specialist)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PARATHYROID HORMONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Natpara.

REFERENCES

1. Natpara [Prescribing Information]. Bedminster, NJ: NPS Pharmaceuticals, Inc. December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/15
Client Approval: 04/20
P&T Approval: 05/15

PASIREOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PASIREOTIDE	SIGNIFOR	39866		GPI-10 (3017007520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an endocrinologist
   - The patient has undergone pituitary surgery or pituitary surgery is not an option for this patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
   D. You have undergone pituitary (a major hormone gland) surgery OR pituitary surgery is not an option
   E. You have previously tried oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PASIREOTIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Signifor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor.

REFERENCES

- Signifor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/13
Client Approval: 08/20
P&T Approval: 07/20

PATIROMER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PATIROMER CALCIUM SORBITEX	VELTASSA	42767		GPI-10 (9945006020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hyperkalemia (ICD-10 E87.5) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist or cardiologist
   Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia
   The patient is NOT currently receiving dialysis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried **ONE** of the following approaches to reduce the modifiable risks for hyperkalemia?
   The patient is not taking both an angiotensin converting enzyme inhibitor (ACE-I; e.g., lisinopril, benazepril) and an angiotensin receptor blocker (ARB; e.g., valsartan, losartan) at the same time
   The patient has reduced the dose of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., lisinopril, valsartan, spironolactone)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have an estimated glomerular filtration rate (eGFR) of less than 30mL/min/1.73m^2 **AND** meet the following criterion?
   The patient has tried a loop diuretic (e.g., bumetanide, ethacrynic acid, furosemide, torsemide)

   If yes, continue to #5.
   If no, continue to #4.

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have an estimated glomerular filtration rate (eGFR) of at least 30mL/min/1.73m^2 and meet **ONE** of the following criteria?
   The patient has tried a loop diuretic (e.g., bumetanide, ethacrynic acid, furosemide, torsemide)
   The patient has tried a thiazide diuretic (e.g., chlorthalidone, hydrochlorothiazide, metolazone)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   The patient is 12 to 17 years of age
   The patient is 18 years of age or older AND had a trial of Lokelma (sodium zirconium cyclosilicate)

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   1 gm: #12 per day.
   8.4 gm: #1 per day.
   16.8 gm: #1 per day.
   25.2 gm: #1 per day.

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:
   You have hyperkalemia (high level of potassium in the blood)
   You are 12 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor) or cardiologist (a type of heart doctor)
   Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia (high level of potassium in the blood)
   You are NOT currently receiving dialysis (process of removing excess water, toxins from the blood)
   (Denial text continued on next page)

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

You have tried ONE of the following to lower the risks for hyperkalemia (high level of potassium in the blood):
- You are not taking both an angiotensin converting enzyme inhibitor (ACE-I, such as lisinopril, benazepril) and an angiotensin receptor blocker (ARB, such as valsartan, losartan) at the same time
- You have lowered the dose of a renin-angiotensin-aldosterone system (RAAS) inhibitor (such as lisinopril, valsartan, spironolactone)

You meet ONE of the following:
- Your estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) is less than 30mL/min/1.73m^2, AND you have tried a loop diuretic (such as bumetanide, ethacrynic acid, furosemide, torsemide)
- Your estimated glomerular filtration rate (eGFR) is at least 30 mL/min/1.73m^2, AND you have tried a loop diuretic (such as bumetanide, ethacrynic acid, furosemide, torsemide) OR a thiazide diuretic (such as chlorthalidone, hydrochlorothiazide, metolazone)

If you are 18 years of age or older, you have tried Lokelma (sodium zirconium cyclosilicate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Veltassa.

REFERENCES

Veltassa [Prescribing Information]. Redwood City, CA: Vifor Pharma, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 2/16
Client Approval: 09/24
P&T Approval: 01/19

PAZOPANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PAZOPANIB HCL	VOTRIENT, PAZOPANIB HCL	36709		GPI-10 (2153304210)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced soft tissue sarcoma (STS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior chemotherapy (e.g., anthracycline treatment)
   - The patient does NOT have a diagnosis of adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
      2. Advanced soft tissue sarcoma (STS: cancer that starts in soft tissues [muscle, tendons, fat, lymph vessels, blood vessels, nerves])

   B. **If you have advanced renal cell carcinoma, approval also requires:**
      1. You are 18 years of age or older

   C. **If you have advanced soft tissue sarcoma, approval also requires:**
      1. You are 18 years of age or older
      2. You have received prior chemotherapy (a type of cancer therapy such as anthracycline treatment)
      3. You do NOT have adipocytic soft tissue sarcoma (STS: a type of fat cell cancer) or gastrointestinal stromal tumors (GIST: a type of digestive tumor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PAZOPANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Votrient.

REFERENCES

- Votrient [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/06/23
Created: 05/11
Client Approval: 10/23
P&T Approval: 08/16

PEANUT ALLERGEN POWDER-DNFP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEANUT ALLERGEN POWDER-DNFP	PALFORZIA	46332		GPI-10 (2010004020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a peanut allergy (ICD-10 Z91.010) and meet **ALL** of the following criteria?
   The patient is 4 to 17 years of age
   Therapy is prescribed by or in consultation with an allergist or immunologist
   The patient has a clinical history of allergic reaction to peanuts
   Palforzia will be used in conjunction with a peanut-avoidance diet
   Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge and meets **ONE** of the following criteria?
   The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   The patient has a peanut-specific immunoglobulin E level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   300 mg powder packet/sachet: #1 per day.
   All other strengths: No quantity limit.

   If no, continue to #3.

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PEANUT ALLERGEN POWDER-DNFP

INITIAL CRITERIA (CONTINUED)

3. Has the patient NOT completed a purposeful food challenge and meets **ONE** of the following criteria?
   The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   The patient has a peanut-specific immunoglobulin E level of at least 14 kUA/L within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   300 mg powder packet/sachet: #1 per day.
   All other strengths: No quantity limit.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:
   You have an allergy to peanuts
   You are 4 to 17 years of age
   Therapy is prescribed by or in consultation with an allergist (allergy doctor) or immunologist (immune system doctor)
   You have a clinical history of an allergic reaction to peanuts
   Palforzia will be used together with a peanut-avoidance diet
   Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
   You meet ONE of the following:
   - If you have completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
   - If you have NOT completed a purposeful food challenge: you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a peanut allergy (ICD-10 Z91.010) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an allergist or immunologist
   Palforzia will be used in conjunction with a peanut-avoidance diet
   Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have a persistent peanut allergy and meet **ONE** of the following criteria?
   The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   The patient has a peanut-specific immunoglobulin E level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve for 24 months by GPID or GPI-14 for all of the following:**
   300 mg powder packet/sachet: #1 per day.
   All other strengths: No quantity limit.

   If no, do not approve.

4. Does the patient have a persistent peanut allergy and meet **ONE** of the following criteria?
   The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   The patient has a peanut-specific immunoglobulin E level of at least 14 kUA/L within the past 24 months

   If yes, **approve for 24 months by GPID or GPI-14 for all of the following:**
   300 mg powder packet/sachet: #1 per day.
   All other strengths: No quantity limit.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:
You have an allergy to peanuts
Therapy is prescribed by or in consultation with an allergist (allergy doctor) or immunologist (immune system doctor)
Palforzia will be used together with a peanut-avoidance diet
Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
You meet ONE of the following:
- If you have completed a purposeful food challenge (a type of test): you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
- If you have NOT completed a purposeful food challenge: you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Palforzia.

REFERENCES
Palforzia [Prescribing Information]. Brisbane, CA: Aimmune Therapeutics, Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/20
Client Approval: 06/24
P&T Approval: 07/20

PEGCETACOPLAN - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGCETACOPLAN	EMPAVELI	47380		GPI-10 (8580406500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a hematologist
   The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) or has a contraindication to Ultomiris (ravulizumab-cwvz) or Soliris (eculizumab)
   Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (e.g., Fabhalta [iptacopan]) or Factor D inhibitor therapy (e.g., Voydeya [danicopan])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGCETACOPLAN - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for approval:
You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Ultomiris (ravulizumab-cwvz) or Soliris (eculizumab)
You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGCETACOPLAN - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline (baseline defined as patient condition post treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (e.g., Fabhalta [iptacopan]) or Factor D inhibitor therapy (e.g., Voydeya [danicopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for renewal:
   You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (baseline is defined as your condition after treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGCETACOPLAN - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empaveli.

REFERENCES

Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 05/21
Client Approval: 08/24
P&T Approval: 07/24

PEGFILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM	NEULASTA, NEULASTA ONPRO	23255		GPI-10 (8240157000)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Neulasta **AND** the patient meets the following criterion?
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve Neulasta for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Is the request for Neulasta Onpro **AND** the patient meets the following criterion?
   The patient had a trial of or contraindication to the preferred agent: Udenyca Onbody (pegfilgrastim-cbqv)

   If yes, **approve Neulasta Onpro for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM (Neulasta, Neulasta Onpro)** requires the following rule(s) be met for approval:
You meet ONE of the following:
- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
- You have a non-myeloid malignancy (cancer not affecting bone marrow)
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
- You meet ONE of the following:
  - You are requesting Neulasta AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)
  - You are requesting Neulasta Onpro AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Udenyca Onbody (pegfilgrastim-cbqv)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
- You meet ONE of the following:
  - You are requesting Neulasta AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)
  - You are requesting Neulasta Onpro AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Udenyca Onbody (pegfilgrastim-cbqv)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGFILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neulasta.

REFERENCES

Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 08/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

PEGFILGRASTIM-APGF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-APGF	NYVEPRIA	46612		GPI-10 (8240157002)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-APGF (Nyvepria)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   - You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

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PEGFILGRASTIM-APGF

GUIDELINES FOR USE (CONTINUED)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
You have a non-myeloid malignancy (cancer not affecting bone marrow)
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nyvepria and Neulasta.

REFERENCES

Nyvepria [Prescribing Information]. New York, NY: Pfizer; April 2021.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

PEGFILGRASTIM-BMEZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-BMEZ	ZIEXTENZO	46183		GPI-10 (8240157005)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

Our guideline named **PEGFILGRASTIM-BMEZ (Ziextenzo)** requires the following rule(s) be met for approval:
You meet ONE of the following:
- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
- You have a non-myeloid malignancy (cancer not affecting bone marrow)
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

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PEGFILGRASTIM-BMEZ

GUIDELINES FOR USE (CONTINUED)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziextenzo and Neulasta.

REFERENCES
Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

PEGFILGRASTIM-CBQV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-CBQV	UDENYCA, UDENYCA ONBODY	45445		GPI-10 (8240157010)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Udenyca **AND** the patient meets the following criterion?
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve Udenyca for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Is the request for Udenyca Onbody?

   If yes, **approve Udenyca Onbody for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM-CBQV

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM - CBQV (Udenyca, Udenyca Onbody)** requires the following rule(s) be met for approval:
You meet ONE of the following:
- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
- You have a non-myeloid malignancy (cancer not affecting bone marrow)
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
- If you are requesting Udenyca, approval also requires you have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
- If you are requesting Udenyca, approval also requires you have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Udenyca and Neulasta.

REFERENCES
Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

PEGFILGRASTIM-FPGK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-FPGK	STIMUFEND	48269		GPI-10 (8240157015)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-FPGK (Stimufend)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   - You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

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PEGFILGRASTIM-FPGK

GUIDELINES FOR USE (CONTINUED)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
You have a non-myeloid malignancy (cancer not affecting bone marrow)
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stimufend and Neulasta.

REFERENCES

Stimufend [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 12/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

PEGFILGRASTIM-JMDB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-JMDB	FULPHILA	45010		GPI-10 (8240157020)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-JMDB (Fulphila)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   - You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

   (Denial text continued on next page)

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PEGFILGRASTIM-JMDB

GUIDELINES FOR USE (CONTINUED)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
You have a non-myeloid malignancy (cancer not affecting bone marrow)
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fulphila and Neulasta.

REFERENCES

Fulphila [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; June 2023.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

PEGFILGRASTIM-PBBK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-PBBK	FYLNETRA	48035		GPI-10 (8240157060)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   The patient has a non-myeloid malignancy
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hematologist or oncologist
   The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   - You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

   (Denial text continued on next page)

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PEGFILGRASTIM-PBBK

GUIDELINES FOR USE (CONTINUED)

If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
You have a non-myeloid malignancy (cancer not affecting bone marrow)
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fylnetra and Neulasta.

REFERENCES

Fylnetra [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2022.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

PEG-INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEG-INTERFERON ALFA-2B	SYLATRON, SYLATRON 4-PACK		29809 29811 29812	GPI-10 (2170007520)	

GUIDELINES FOR USE

1. Is the patient currently taking the requested medication?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received 5 years of therapy with Sylatron?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**

3. Does the patient have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
      2. You have melanoma (skin cancer) with the presence of cancer cells in your lymph nodes (microscopic or gross nodal involvement), within 84 days of surgical removal of the cancer

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEG-INTERFERON ALFA-2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sylatron.

REFERENCES

1. Sylatron [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/11
Client Approval: 08/20
P&T Approval: 07/20

PEGINTERFERON ALFA 2A OR 2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	24035		GPI-10 (1235306005)	
PEGINTERFERON ALFA-2B	PEGINTRON	21367		GPI-10 (1235306010)	FDB: GCN ≠ 29809, 29811, 29812

GUIDELINES FOR USE

1. Is the request for the treatment of chronic hepatitis C virus infection (HCV)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for Pegasys?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have chronic hepatitis B **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient between 3 to 17 years of age and meet **ALL** of the following criteria?
   - The patient does NOT have cirrhosis
   - The patient has serum HBeAg-positive chronic hepatitis B
   - The patient has evidence of viral replication with elevated serum alanine aminotransferase (ALT)

   If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, continue to #5.

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PEGINTERFERON ALFA 2A OR 2B

GUIDELINES FOR USE (CONTINUED)

5. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient has serum HBeAg-positive or HBeAg-negative chronic hepatitis B
   - The patient has compensated liver disease with evidence of viral replication and liver inflammation

   If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys, PegIntron)** requires the following rule(s) be met for approval:
   A. You have chronic hepatitis B (a type of liver infection)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   C. **If you are between 3 to 17 years of age, approval also requires:**
      1. You do NOT have cirrhosis (liver damage)
      2. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive chronic hepatitis B
      3. You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)
   D. **If you are 18 years of age or older, approval also requires:**
      1. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive or HBeAg-negative chronic hepatitis B
      2. You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

   Note: Pegasys and PegIntron will not be approved for the treatment of hepatitis C.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGINTERFERON ALFA 2A OR 2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pegasys/PegIntron.

REFERENCES

- Pegasys [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2021.
- Pegintron [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/23

Created: 02/14
Client Approval: 04/23

P&T Approval: 01/17

PEGVALIASE-PQPZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		GPI-10 (3090855040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of phenylketonuria and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
   - The patient has had a trial of Kuvan (sapropterin)
   - The patient is not concurrently receiving Kuvan (sapropterin)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **20mg/mL: #3mL (3 syringes) per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for approval:
   A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
   B. You are 18 years of age or older
   C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
   D. You have tried Kuvan (sapropterin)
   E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGVALIASE-PQPZ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria **AND** meet the following criterion?
   - The patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **20mg/mL: #3mL (3 syringes) per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for renewal:
   A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
   B. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Palynziq.

REFERENCES

- Palynziq [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 08/18
Client Approval: 03/23
P&T Approval: 07/18

PEMETREXED DIPOTASSIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMETREXED DIPOTASSIUM	AXTLE, PEMETREXED DIPOTASSIUM	49734		GPI-10 (2130005308)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ONE** of the following criteria?
   The requested medication will be used in combination with cisplatin
   The requested medication will be used as a single agent, for maintenance therapy, AND the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The requested medication will be used as a single agent
   The patient has received prior chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of malignant pleural mesothelioma (ICD-10 C45.0) and meet **ALL** of the following criteria?
   The requested medication is being used in combination with cisplatin
   The patient's disease is unresectable OR the patient is not a candidate for curative surgery

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the request for an FDA-approved indication **AND** the requested medication will be used in combination with another chemotherapy agent(s)?
   (NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with pemetrexed. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.**)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEMETREXED DIPOTASSIUM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEMETREXED DIPOTASSIUM (Axtle)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to nearby tissue or lymph nodes or other parts of the body)
- Recurrent, metastatic, non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has returned and spread to other parts of the body)
- Malignant pleural mesothelioma (a type of cancer)
- The requested medication is being used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:
- The requested medication will be used in combination with cisplatin
- The requested medication will be used as a single agent, for maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)

If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:
- The requested medication will be used as a single agent
- You have received prior chemotherapy

If you have malignant pleural mesothelioma, approval also requires:
- The requested medication will be used in combination with cisplatin
- Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEMETREXED DIPOTASSIUM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for pemetrexed dipotassium.

REFERENCES

Axtle [Prescribing Information]. New Jersey, USA: Avyxa Pharma, LLC; December 2024.
Pemetrexed dipotassium [Prescribing Information]. Parsippany, NJ: Avyxa Pharma, LLC; June 2024.

Created: 12/24
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

PEMIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462		GPI-10 (2153226000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 for #14 per 21 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a fibroblast growth factor receptor 1 (FGFR1) rearrangement
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
      2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

   (Denial text continued on next page)

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PEMIGATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
   3. You have a fibroblast growth factor receptor 2 (FGFR2: a type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
   4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

C. **If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:**
   1. You are 18 years of age or older
   2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
   3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES

- Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 07/20
Client Approval: 11/22
P&T Approval: 10/22

PENICILLAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENICILLAMINE	CUPRIMINE, PENICILLAMINE		7091	GPI-14 (99200030000110)	
PENICILLAMINE	DEPEN, PENICILLAMINE		7100	GPI-14 (99200030000305)	
PENICILLAMINE	D-PENAMINE		7101	GPI-14 (99200030000302)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for D-Penamine and the patient has an active prior authorization approval for Depen? ***[Note: D-Penamine is temporarily available to address a critical drug shortage of Depen. Patients previously approved for Depen will be allowed access without additional criteria during this shortage.]***

   If yes, **approve D-Penamine for 12 months by GPID or GPI-14 for the requested indication as follows:**
   - **Wilson's Disease: #16 per day.**
   - **Active Rheumatoid Arthritis: #12 per day.**
   - **Cystinuria: #32 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Wilson's disease and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a Leipzig score of 4 or greater
   - The patient is willing to follow a diet avoiding high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat)

   If yes, continue to #3.
   If no, continue to #5.

3. Is the request for Depen or D-Penamine?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #8 per day.**
   - **D-Penamine: #16 per day.**

   If no, continue to #4.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Cuprimine and the patient had a trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

   If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity limit of #8 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of cystinuria and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has a daily cystine output that is greater than 300mg per 24 hours following urine cystine excretion testing
   - The patient has failed to respond to an adequate trial of or has a contraindication to conventional therapy which includes ALL of the following: increased fluid intake, modest reductions in sodium and protein intake, and urinary alkalinization

   If yes, continue to #6.
   If no, continue to #9.

6. Does the patient have nephrolithiasis and meet **ONE** of the following criteria?
   - The patient's stone analysis shows a presence of cystine
   - The patient's urinalysis shows pathognomonic hexagonal cystine crystals
   - The patient has a family history of cystinuria AND a positive cyanide-nitroprusside screening

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for Depen or D-Penamine?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #16 per day.**
   - **D-Penamine: #32 per day.**

   If no, continue to #8.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

8. Is the request for Cuprimine and has the patient had a trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin)?

   If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #16 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient does not have a history or other evidence of renal insufficiency
   - The patient has failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Is the request for Depen or D-Penamine?

    If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
    - **Depen: #6 per day.**
    - **D-Penamine: #12 per day.**

    If no, continue to #11.

11. Is the request for Cuprimine and has the patient had a trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

    If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #6 per day.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
   2. Cystinuria (a type of genetic metabolic disorder)
   3. Active rheumatoid arthritis (a type of joint condition)

B. I**f you have Wilson's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   2. You have a Leipzig score of 4 or greater (a type of diagnostic score)
   3. You are willing to follow a diet avoiding high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   4. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine)

C. **If you have cystinuria, approval also requires:**
   1. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
   2. You have a daily cystine output greater than 300mg per 24 hours after urine cystine excretion testing
   3. You have failed to respond to an adequate trial of or has a contraindication (harmful for) to conventional therapy which includes ALL of the following:
      a. Increased fluid intake
      b. Modest reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   4. You have nephrolithiasis (kidney stones) and ONE of the following:
      a. Your kidney stone analysis shows that there is a presence of cystine (an amino acid)
      b. Your urine analysis shows that there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria and positive test results in the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body)
   5. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine) AND Thiola (tiopronin)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You do not have a history or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine)

E. **If you have an active prior authorization approval for Depen, D-Penamine** will be approved without meeting additional criteria during the period of Depen shortage.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
   - The patient has achieved a free serum copper of less than 10 mcg/dL

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #8 per day.**
   - **Cuprimine: #8 per day.**
   - **D-Penamine: #16 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of cystinuria **AND** meet the following criterion?
   - The patient has achieved a cystine excretion of less than 200 mg/day

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #16 per day.**
   - **D-Penamine: #32 per day.**
   - **Cuprimine: #16 per day.**

   If no, continue to #3.

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PENICILLAMINE

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?
   - The patient does not have a history of or other evidence of renal insufficiency
   - The patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #6 per day.**
   - **D-Penamine: #12 per day.**
   - **Cuprimine: #6 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
      2. Cystinuria (a type of genetic metabolic disorder)
      3. Active rheumatoid arthritis (a type of joint condition)
   B. **If you have Wilson's disease, approval also requires:**
      1. You have achieved a free serum copper of less than 10 mcg/dLl
   C. **If you have cystinuria, approval also requires:**
      1. You have achieved a cystine excretion of less than 200 mg/day
   D. **If you have active rheumatoid arthritis, approval also requires:**
      1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
      2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PENICILLAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuprimine/Depen/Thiola EC.

REFERENCES

- Cuprimine [Prescribing Information]. Bridgewater, NJ: Bausch Health Companies Inc.; October 2020.
- Thiola [Prescribing Information]. San Antonio, TX: Mission Pharmacal; March 2021.
- Depen [Prescribing Information]. Somerset, NJ: Meda Pharmaceuticals; January 2019.
- FDA Website: Penicillamine (Depen) Titratable Tablets Drug Shortage. Available at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine%20(Depen)%20Titratable%20Tablets&st=c. Accessed on January 21, 2019

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/08/23
Created: 05/16
Client Approval: 04/23
P&T Approval: 10/22

PENTOSAN POLYSULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENTOSAN POLYSULFATE SODIUM	ELMIRON	08734		GPI-10 (5650006010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of interstitial cystitis/bladder pain syndrome ongoing for at least six weeks?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced clinical improvement from baseline secondary to treatment.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of interstitial cystitis/bladder (painful bladder condition) pain syndrome ongoing for at least six weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced clinical improvement from baseline secondary to treatment?

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PENTOSAN POLYSULFATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:
A. You have experienced clinical improvement from baseline secondary to treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Elmiron.

REFERENCES

- Elmiron [Prescribing Information]. Titusville, New Jersey: Janssen Pharmaceuticals, Inc. September 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
Client Approval: 02/20
P&T Approval: 01/20

PEXIDARTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEXIDARTINIB HYDROCHLORIDE	TURALIO	45912		GPI-10 (2153304501)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) and meet **ALL** of the following criteria?
   - TGCT is associated with severe morbidity or functional limitations
   - TGCT is NOT amenable to improvement with surgery
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:
   A. You have symptomatic tenosynovial giant cell tumor (TGCT: type of non-cancerous growth in or around a joint causing tissue damage and reducing function)
   B. TGCT is associated with severe morbidity (disease) or functional limitations
   C. TGCT is NOT responsive to improvement with surgery
   D. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Turalio.

REFERENCES

- Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 08/19
Client Approval: 03/21
P&T Approval: 07/19

PHENOXYBENZAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENOXYBENZAMINE HCL	DIBENZYLINE, PHENOXYBENZA -MINE HCL	02098		GPI-10 (3630001010)	FDB: ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pheochromocytoma and meet **ALL** of the following criteria?
   - The requested medication is used for the treatment of pheochromocytoma prior to pheochromocytoma resection/removal
   - Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist - oncologist
   - The patient has had a previous trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, or prazosin)

   If yes, **approve for one fill by HICL or GPI-10 with a quantity limit of #10 capsules per day for 21 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:
   A. You have pheochromocytoma (tumor in your adrenal gland)
   B. The requested drug is used to treat pheochromocytoma before pheochromocytoma surgery to remove the tumor
   C. The requested drug is prescribed by an endocrinologist (hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist/oncologist (cancer doctor)
   D. You must have tried an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PHENOXYBENZAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dibenzyline.

REFERENCES

- Dibenzyline [Prescribing Information]. Concordia Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/18
Client Approval: 04/20
P&T Approval: 07/18

PHENTERMINE - TOPIRAMATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENTERMINE/ TOPIRAMATE	QSYMIA	39347		GPI-10 (6120990230)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) **AND** the patient meets the following criterion?
   There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   The patient has a body mass index (BMI) of at least 30 kg/m(2)
   The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for a total of 14 weeks by entering TWO authorizations by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve 3.75/23mg for 2 weeks with a quantity limit of #1 per day.
   SECOND APPROVAL: Approve 7.5/46mg for 3 months with a quantity limit of #1 per day (please enter a start date of 3 days BEFORE the end of the first approval).

   If no, continue to #4.

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PHENTERMINE - TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

4. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   The patient's initial body mass index (BMI) is in the 95th percentile or greater for age and sex (see table below)

95th Percentile BMI Value for Age and Sex

Age (in years)	Male	Female
	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

If yes, **approve for a total of 14 weeks by entering TWO authorizations by GPID or GPI-14 as follows:**
FIRST APPROVAL: Approve 3.75/23mg for 2 weeks with a quantity limit of #1 per day.
SECOND APPROVAL: Approve 7.5/46mg for 3 months with a quantity limit of #1 per day (please enter a start date of 3 days BEFORE the end of the first approval).

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PHENTERMINE - TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for approval:
The request is for weight loss OR weight loss management
You are 12 years of age or older
You are actively enrolled in an exercise and caloric reduction program which may include use of an optional weight loss/behavioral modification program
If you are 18 years of age or older, approval also requires:
You meet ONE of the following:
You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
If you are 12 to 17 years of age, approval also requires:
Your initial body mass index (BMI: a tool for evaluating body fat) is in the 95th percentile or greater for age and sex

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PHENTERMINE - TOPIRAMATE

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Qsymia 7.5/46mg and the patient meets **ONE** of the following criteria?
   The patient is 18 years of age or older AND has achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment
   The patient is 12 to 17 years of age AND has achieved or maintained at least a 3% weight loss of baseline BMI after at least 3 months of treatment

   If yes, **approve Qsymia 7.5/46mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the request for dose escalation to Qsymia 11.25/69mg for 2 weeks, followed by Qsymia 15/92mg?

   If yes, **approve for a total of 14 weeks by entering TWO authorizations by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve 11.25/69mg for 2 weeks with a quantity limit of #1 per day.
   SECOND APPROVAL: Approve 15/92mg for 3 months with a quantity limit of #1 per day (please enter a start date of 3 days BEFORE the end of the first approval).

   If no, continue to #4.

4. Is the request for continuation of therapy after at least 12 weeks on Qsymia 15/92mg and the patient meets **ONE** of the following criteria?
   The patient is 18 years of age or older AND has achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment
   The patient is 12 to 17 years of age AND has achieved or maintained at least a 5% weight loss of baseline BMI after 3 months of treatment

   If yes, **approve Qsymia 15/92mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, do not approve.
   (**NOTE:** If the request is for **Qsymia 15/92mg**, please also enter a partial approval for ONE fill of Qsymia by HICL or GPI-10 for up to #4 total to taper off dose and discontinue therapy.)
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PHENTERMINE - TOPIRAMATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for renewal:
The request is for weight loss OR weight loss management
If you are requesting Qsymia 7.5/46mg, renewal also requires ONE of the following:
- You are 18 years of age or older AND have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment
- You are 12 to 17 years of age AND have achieved or maintained at least a 3% weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after at least 3 months of treatment

If you are requesting Qsymia 15/92mg, renewal also requires ONE of the following:
- You are 18 years of age or older AND have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment
- You are 12 to 17 years of age AND have achieved or maintained at least a 5% weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qsymia.

REFERENCES
Qsymia [Prescribing Information]. Campbell, CA: Vivus LLC; September 2024.

Created: 05/24
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

PILOCARPINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PILOCARPINE HCL	VUITY		51425	GPI-14 (86501030102017)	
PILOCARPINE HCL	QLOSI		54887	GPI-14 (86501030102008)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of presbyopia (ICD-10 H52.4) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   The patient is not using corrective lenses OR corrective lenses are insufficient to completely correct the patient's vision
   The patient had a trial of or contraindication to generic pilocarpine ophthalmic solution
   The requested medication will NOT be used concurrently with another pilocarpine eyedrop

   If yes, **approve the requested medication for 3 months by GPID or GPI-14 with the following quantity limits:**
   Vuity: #10mL per 30 days.
   Qlosi: #2 vials per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PILOCARPINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PILOCARPINE (Vuity, Qlosi)** requires the following rule(s) be met for approval:
You have presbyopia (not able to focus on nearby objects)
You are 18 years of age or older
Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
You have tried or have a contraindication to (harmful for you to use) generic pilocarpine ophthalmic (eye) solution
You will NOT use the requested medication concurrently (at the same time) with another pilocarpine eyedrop

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PILOCARPINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of presbyopia (ICD-10 H52.4) and meet **ALL** of the following criteria?
   The patient is not using corrective lenses OR corrective lenses are insufficient to completely correct the patient's vision
   The requested medication will NOT be used concurrently with another pilocarpine eyedrop
   The patient continues to have benefit from the requested medication

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with the following quantity limits:**
   Vuity: #10mL per 30 days.
   Qlosi: #2 vials per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PILOCARPINE (Vuity, Qlosi)** requires the following rule(s) be met for renewal:
   You have presbyopia (not able to focus on nearby objects)
   You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
   You will NOT use the requested medication concurrently (at the same time) with another pilocarpine eyedrop
   You continue to have benefit from the requested medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vuity and Qlosi.

REFERENCES

Vuity [Prescribing Information]. North Chicago, IL: AbbVie Inc.; March 2023.
Qlosi [Prescribing Information]. Ponte Vedra, FL: Orasis Pharmaceuticals, Inc.; June 2024.

Created: 11/21
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 10/23

PIMAVANSERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIMAVANSERIN	NUPLAZID	43373		GPI-10 (5940002820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease psychosis and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as psychiatrist)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Nuplazid 34mg capsules: #30 capsules per 30 days.**
   - **Nuplazid 17mg tablets: #60 tablets per 30 days.**
   - **Nuplazid 10mg tablets: #30 tablets per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named drug named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:
   A. You have a diagnosis of psychosis associated with Parkinson's disease (a mental disorder that causes you to have false beliefs or to hear or see things that are not really there and is related to a movement disorder)
   B. You are at least 18 years old; and
   C. The drug is prescribed by a doctor specializing in one of the following areas: neurology (brain doctor), geriatric medicine (specialty that focuses on health care of elderly people), or behavioral health (such as a psychiatrist).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIMAVANSERIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the past 12 months of therapy, has the patient experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Nuplazid 34mg capsules: #30 capsules per 30 days.**
   - **Nuplazid 17mg tablets: #60 tablets per 30 days.**
   - **Nuplazid 10mg tablets: #30 tablets per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIMAVANSERIN (Nuplazid)** requires that you have experienced an improvement in psychosis symptoms (mental issues such as false beliefs or hearing or seeing things that are not really there) from baseline during the past 12 months of therapy and you show a continued need for treatment.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuplazid.

REFERENCES
6. Nuplazid [Prescribing Information]. San Diego, CA. Arcadia Pharmaceuticals Inc.; May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/16
Client Approval: 04/20
P&T Approval: 05/16

PIRFENIDONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRFENIDONE	ESBRIET, PIRFENIDONE	40237		GPI-10 (4555006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient does NOT have other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
   - The patient does NOT currently smoke cigarettes

   If yes, **enter two authorizations for a total of 12 months as follows:**
   <u>FIRST APPROVAL:</u> Approve for 1 month by GPID or GPI-14 for all dosage strengths with the following quantity limits:
   - **267mg: #9 per day.**
   - **534mg: #3 per day.**
   - **801mg: #3 per day.**

   <u>SECOND APPROVAL:</u> Approve for 11 months by HICL or GPI-10 with a quantity limit of #3 per day (enter a start date of 2 days before the end of the first approval).

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:
   A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   (Initial denial text continued on next page)

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PIRFENIDONE

INITIAL CRITERIA (CONTINUED)

D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (a type of joint condition), radiation, sarcoidosis (a type of inflammatory disorder), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (HIV: a type of immune disorder), viral hepatitis (a type of liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air exhaled from lungs) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
   A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIRFENIDONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Esbriet.

REFERENCES

- Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 02/15
Client Approval: 11/22
P&T Approval: 10/22

PIRTOBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRTOBRUTINIB	JAYPIRCA	48657		GPI-10 (2153216500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received at least TWO lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   50 mg: #3 per day.
   100 mg: #2 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received at least TWO prior lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib]) AND a B-cell lymphoma-2 (BCL-2) inhibitor (e.g., Venclexta [venetoclax])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   50 mg: #3 per day.
   100 mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PIRTOBRUTINIB

GUIDELINES FOR USE (CONTINUED FOR USE)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRTOBRUTINIB (Jaypirca)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Relapsed or refractory mantle cell lymphoma (MCL: type of white blood cell cancer)
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (types of blood cancers)

If you have relapsed or refractory mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have previously received at least TWO lines of systemic therapy (treatment that targets the entire body) for mantle cell lymphoma, including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
- You are 18 years of age or older
- You have previously received at least TWO prior lines of therapy (treatment that targets the entire body), including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib]) AND a BCL-2 inhibitor (B-cell lymphoma-2 inhibitor such as Venclexta [venetoclax])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jaypirca.

REFERENCES

Jaypirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 05/23
Client Approval: 12/23
P&T Approval: 01/24

PITOLISANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PITOLISANT HCL	WAKIX	45575		GPI-10 (6145007010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy and narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one generic typical stimulant (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cataplexy with narcolepsy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried **TWO** of the following: venlafaxine, fluoxetine or a TCA (e.g., clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:
   A. You have one of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
      2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. **If you have excessive daytime sleepiness with narcolepsy, approval also requires:**
      1. You have narcolepsy that is confirmed by **ONE** of the following:
         a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
         b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
         c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
      2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
      3. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
      4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

C. **If you have cataplexy with narcolepsy, approval also requires:**
   1. Wakix is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or cataplexy with narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline
   - The patient has shown improvement in cataplexy symptoms compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
      2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. You meet ONE of the following:
      1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
      2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline
      3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep) from baseline

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PITOLISANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wakix.

REFERENCES

- Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 10/19
Client Approval: 11/22
P&T Approval: 10/22

PIVMECILLINAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIVMECILLINAM HCL	PIVYA	07565			

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an uncomplicated urinary tract infection (uUTI) (ICD-10 N39.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is a female

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist
   Therapy is a continuation of care from an inpatient setting

   If yes, **approve for 1 month by HICL with a quantity limit of #21 for #1 fill.**
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   The culture shows that the patient's infection is caused by a multidrug-resistant bacteria
   The organism from the culture is sensitive to Pivya
   The organism from the culture is resistant OR the patient has a contraindication to other beta-lactams (e.g., cefdinir, cefaclor), fluoroquinolones (e.g., ciprofloxacin, levofloxacin), cephalosporins, penicillins, nitrofurantoin, and TMP-SMX

   If yes, **approve for 1 month by HICL with a quantity limit of #21 for #1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PIVMECILLINAM

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIVMECILLINAM (Pivya)** requires the following rule(s) be met for approval:
You have uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
You are 18 years of age or older
You are a female
You meet ONE of the following:
- Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist (a doctor who specializes in the treatment of infections)
- Therapy is a continuation of care from an inpatient setting
- You meet ALL of the following:
  - There is a culture (a type of laboratory test) that shows your infection is caused by a multidrug-resistant (other medications did not work well) bacteria
  - Pivya will work against the bacteria from the culture
  - The bacteria is resistant (other medication did not work well), or you have a contraindication to (harmful for you to use) other beta-lactams medications (such as cefdinir, cefaclor), fluoroquinolone medications (such as ciprofloxacin, levofloxacin), cephalosporins, penicillins, nitrofurantoin, and sulfamethoxazole/trimethoprim medications

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pivya.

REFERENCES
Pivya [Prescribing Information]. Florham Park, NJ: UTILITY therapeutics Ltd; April 2024.

Created: 11/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

PLASMINOGEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PLASMINOGEN HUMAN-TVMH	RYPLAZIM	47437		GPI-10 (8540005070)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLASMINOGEN (Ryplazim)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia: a type of genetic condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ryplazim.

REFERENCES

- Ryplazim [Prescribing Information]. Laval, Quebec, Canada: Prometic Bioproduction, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 01/22
Client Approval: 02/22
P&T Approval: 01/22

POMALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POMALIDOMIDE	POMALYST	39996		GPI-10 (2145008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Kaposi sarcoma (KS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient meets ONE of the following criteria:
     - The patient has AIDS-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART)
     - The patient is HIV-negative

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (MM: cancer that forms in your white blood cells)
      2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)
   B. **If you have multiple myeloma, approval also requires:**
      1. You are 18 years of age or older
      2. The requested medication is used in combination with dexamethasone
      3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

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POMALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

C. **If you have Kaposi sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
      b. You are human immunodeficiency virus (HIV)-negative

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pomalyst.

REFERENCES

- Pomalyst [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/13
Client Approval: 06/20
P&T Approval: 07/20

PONATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONATINIB HCL	ICLUSIG	39859		GPI-10 (2153187510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a mutational analysis prior to initiation AND Iclusig is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have T315I-positive CML (chronic phase, accelerated phase, or blast phase)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have chronic phase (CP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - The patient has a resistance or intolerance to at least TWO prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is positive for the T315I mutation
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
   - The patient is newly diagnosed AND Iclusig will be used in combination with chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic myeloid leukemia (CML: type of blood cancer)
      2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of white blood cell cancer)
   B. **If you have chronic myeloid leukemia, approval also requires:**
      1. You are 18 years of age or older
      2. You had a mutational analysis (a type of test) before starting therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
      3. You meet ONE of the following:
         a. You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
         b. You have chronic phase CML AND have a resistance to or are not able to safely use at least TWO prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)
         c. You have accelerated phase or blast phase CML AND there are no other kinase inhibitors, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), that can be used for your disease

   (Denial text continued on next page)

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is positive for the T315I mutation (a type of abnormal gene)
      b. There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
      c. You are newly diagnosed AND Iclusig will be used in combination with chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iclusig.

REFERENCES

- Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 01/13
Client Approval: 03/24
P&T Approval: 04/24

PONESIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONESIMOD	PONVORY	47221		GPI-10 (6240706000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial and failure of ONE sphingosine-1-phosphate receptor modulator (e.g., fingolimod, Mayzent [siponimod]) and ONE other agent indicated for the treatment of MS (Please note: these MS agents may also require prior authorization)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried ONE sphingosine-1-phosphate receptor modulator (such as fingolimod, Mayzent [siponimod]) AND ONE other medication indicated for the treatment of multiple sclerosis (PLEASE NOTE: these medications may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ponvory.

REFERENCES

- Ponvory [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/21
Client Approval: 05/24
P&T Approval: 01/21

POSACONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL, POSACONAZOLE	33461		GPI-10 (1140706000)	ROUTE = ORAL

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #2.

2. Is the request for the treatment of invasive aspergillosis and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The request is for posaconazole (Noxafil) tablets

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   If no, continue to #3.

3. Is the request for prophylaxis of invasive aspergillus or candida infections **AND** the patient meets the following criterion?
   - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or has a hematologic malignancy with prolonged neutropenia from chemotherapy

   If yes, continue to #4.
   If no, continue to #7.

4. Is the request for posaconazole (Noxafil) tablets and the patient meets **ONE** of following criteria?
   - The patient is 18 years of age or older
   - The patient is 2 years of age or older AND weighs greater than 40 kg

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

5. Is the request for posaconazole (Noxafil) oral suspension and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #6.

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

6. Is the request for posaconazole (Noxafil) PowderMix and the patient meets **ALL** of the following criteria?
   - The patient is 2 to less than 18 years of age AND weighs less than 40 kg
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of oropharyngeal candidiasis (OPC) and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial of or contraindication to fluconazole OR itraconazole
   - The request is for posaconazole (Noxafil) oral suspension

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, continue to #8.

8. Does the patient have a diagnosis of esophageal candidiasis and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial and failure of or contraindication to two of the following: fluconazole, itraconazole solution, or voriconazole

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POSACONAZOLE (Noxafil)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Continuation of therapy after hospital discharge
      2. Treatment of invasive aspergillosis (type of fungal infection)
      3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
      4. Oropharyngeal candidiasis (fungal infection of the throat)
      5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach)

   (Denial text continued on next page)

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

B. **If the request is for treatment of invasive aspergillosis, approval also requires:**
   1. You are 13 years of age or older
   2. You are requesting Noxafil (posaconazole) tablets

C. **If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:**
   1. You are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or you have hematologic malignancies (cancer affecting the blood) with prolonged neutropenia (low levels of a type of white blood cell) from chemotherapy (cancer treatment)
   2. If the request is for posaconazole (Noxafil) tablets, you meet ONE of the following:
      You are 18 years of age or older
      You are 2 years of age or older AND weigh greater than 40 kg
   3. If the request is for posaconazole (Noxafil) suspension, you meet ALL of the following:
      You are 13 years of age or older
      You are unable to swallow tablets
   4. If the request is for posaconazole (Noxafil) PowderMix, you meet the following:
      You are 2 to 18 years of age AND weigh less than 40 kg
      You are unable to swallow tablets

D. **If the request is for oropharyngeal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial of or contraindication (harmful for) to fluconazole OR itraconazole
   3. You are requesting Noxafil (posaconazole) oral suspension

E. **If the request is for esophageal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial and failure of or contraindication (harmful for) to TWO of the following: fluconazole, itraconazole solution, or voriconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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POSACONAZOLE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES

- Noxafil [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23

Created: 11/07
Client Approval: 11/22

P&T Approval: 10/22

PRALSETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALSETINIB	GAVRETO	46818		GPI-10 (2153575000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a *RET* fusion-positive tumor as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic thyroid cancer and meet ALL of the following criteria?
   - The patient is 12 years of age or older
   - The patient has a *RET* fusion-positive tumor
   - The patient requires systemic therapy
   - The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
      2. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)
   B. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. You are 18 years of age or older
      2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor that has been detected by a Food and Drug Administration (FDA)-approved test

   (Denial text continued on next page)

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PRALSETINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced or metastatic thyroid cancer, approval also requires:**
1. You are 12 years of age or older
2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor
3. You need systemic therapy (treatment that targets the entire body)
4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is an appropriate treatment option)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gavreto.

REFERENCES

- Gavreto [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/11/23
Created: 10/20
Client Approval: 08/23
P&T Approval: 10/23

PYRIMETHAMINE

Generic	Brand	HICL	GCN	Medi-Span		Exception/Other
PYRIMETHAMINE	DARAPRIM		42930	GPI-10 (1300004000)		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes**, approve for 6 weeks by GPID or GPI-10. Please enter two authorizations as follows:**
   - **Approve one fill for #8 per day.**
   - **Approve for 6 weeks with a quantity limit of #3 per day.**

   APPROVAL TEXT: Renewal requires that the patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging).

   If no, continue to #2.

2. Is the patient being treated for chronic maintenance of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #3.

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

3. Is the patient being treated for primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The medication is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of or contraindication to Bactrim (SMX/TMP)
   - The patient is positive for *Toxoplasma gondii* IgG
   - The patient has a CD4 count of less than 100 cells/mm(3)

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #4.

4. Does the patient have a diagnosis of congenital toxoplasmosis **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a neonatologist or pediatric infectious disease specialist

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
      4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)
   B. **If you are being treated for acute toxoplasmosis, approval also requires:**
      1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

   (Initial denial text continued on next page)

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV)
   2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
   3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm(3)

E. **If you have congenital toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

   If yes, **approve for 6 weeks by GPID or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

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PYRIMETHAMINE

RENEWAL CRITERIA (CONTINUED)

2. Is the patient being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has a CD4 count of less than 200 cells/mm(3)
   - The patient is currently taking ART (anti-retroviral therapy)

   If yes, **approve for 6 months by GPID or GPI-10 as follows:**
   - **Chronic maintenance of toxoplasmosis: #2 per day.**
   - **Primary prophylaxis of toxoplasmosis: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
      1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)
   C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
      1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
      2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm(3)
      3. You are currently taking ART (anti-retroviral therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PYRIMETHAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daraprim.

REFERENCES

- Daraprim [Prescribing Information]. New York, NY: Vyera Pharmaceuticals LLC., August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 10/15
Client Approval: 02/20
P&T Approval: 01/20

QUIZARTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
QUIZARTINIB DIHYDROCHLORIDE	VANFLYTA	49083		GPI-10 (2153304710)	

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is FLT3 internal tandem duplication (ITD)-positive as detected by a Food and Drug Administration (FDA)-approved test

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Vanflyta be used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) for induction therapy, followed by use with cytarabine as consolidation therapy?

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   17.7 mg: #28 per fill for a total of 6 fills.
   26.5 mg: #14 per fill for a total of 6 fills.

   If no, continue to #3.

3. Will Vanflyta be used as maintenance monotherapy following consolidation chemotherapy?

   If yes, **approve for 34 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **QUIZARTINIB (Vanflyta)** requires the following rule(s) be met for approval:
   A. You have newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
   B. You are 18 years of age or older
   C. Your cancer is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD: a type of mutation) positive as detected by a Food and Drug Administration (FDA)-approved test
   (Denial text continued on the next page)

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QUIZARTINIB

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following:
   1. Vanflyta will be used in combination with standard cytarabine and anthracycline (such as daunorubicin, idarubicin) as induction therapy (a type of therapy to treat cancer), followed by use with cytarabine as consolidation therapy (type of therapy to treat cancer)
   2. Vanflyta will be used as maintenance monotherapy (one drug treatment) following consolidation chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vanflyta.

REFERENCES

- Vanflyta [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 11/23
Client Approval: 11/23
P&T Approval: 10/23

RANIBIZUMAB-SUSVIMO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RANIBIZUMAB, RANIBIZUMAB/INIT FILL NEEDLE	SUSVIMO		51414 52174	GPI-14 (86655060002040, 86655060002042)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   The patient has previously responded to at least TWO intravitreal injections of a VEGF inhibitor (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])
   Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of nAMD

   If yes, **approve the requested medication for 6 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**

   If no, continue to #2.

2. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) **AND** meet the following criterion?
   The patient has previously responded to at least TWO intravitreal injections of a VEGF inhibitor (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RANIBIZUMAB-SUSVIMO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RANIBIZUMAB (Susvimo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal VEGF inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of neovascular (wet) age-related macular degeneration

If you have diabetic macular edema, approval also requires:
- You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RANIBIZUMAB-SUSVIMO

RENEWAL CRITERIA

NOTE: For the diagnosis of diabetic macular edema (DME), please refer to the Initial Criteria section.

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) 1. (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of nAMD

If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RANIBIZUMAB (Susvimo)** requires the following rule(s) be met for renewal:
You have neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of neovascular (wet) age-related macular degeneration

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Susvimo.

REFERENCES

Susvimo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2025.

Created: 05/22
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/25

RANOLAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RANOLAZINE	ASPRUZYO SPRINKLE		52005 52006	GPI-14 (32200040003020, 32200040003040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic angina and meet **ALL** the following criteria?
   - The patient had a trial of or contraindication to ranolazine ER tablets
   - The patient is unable to swallow ranolazine ER tablets
   - The patient had a trial of or contraindication to a nitrate (e.g., nitroglycerin, isosorbide mononitrate, isosorbide dinitrate)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **500mg: #2 per day.**
   - **1000mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANOLAZINE (Aspruzyo Sprinkle)** requires the following rule(s) be met for approval:
   A. You have chronic angina (a type of heart condition)
   B. You had a trial of or contraindication (harmful for) to ranolazine ER (extended release) tablets
   C. You are unable to swallow ranolazine ER tablets
   D. You had a trial of or contraindication (harmful for) to a nitrate (such as nitroglycerin, isosorbide mononitrate, isosorbide dinitrate)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RANOLAZINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aspruzyo Sprinkle.

REFERENCES

- Aspruzyo Sprinkle [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

REGORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REGORAFENIB	STIVARGA	39665		GPI-10 (2153305000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC) and meet **ALL** of the following criteria?
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the colorectal cancer RAS wild-type (mutation negative)?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**

3. Has the patient received previous treatment with an anti-EGFR therapy (e.g., Erbitux [cetuximab], Vectibix [panitumumab])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) **AND** meet the following criterion?
   - The patient has received previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has received previous treatment with Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (CRC: a type of digestive cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, unable to remove by surgery, or has spread to other parts of the body)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
   2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
   3. If you have RAS wild-type (a type of unmutated gene) metastatic colorectal cancer, approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. **If you have hepatocellular carcinoma, approval also requires:**
   1. You had previous treatment with Nexavar (sorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REGORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stivarga.

REFERENCES

- Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 10/12
Client Approval: 03/22
P&T Approval: 07/17

RELUGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX	ORGOVYX	47035		GPI-10 (2140557000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months as follows:**
   FOR INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 with a quantity limit of #30 per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months by HICL or GPI-10 with a quantity limit of #1 per day (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   FOR SUBSEQUENT/MAINTENANCE REQUESTS:
   - **Approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orgovyx.

REFERENCES

- Orgovyx [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

RELUGOLIX-ESTRADIOL-NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE	47392		GPI-10 (2499350380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - The patient's diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) or histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Lupron Depot, Synarel)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. Your diagnosis of endometriosis is confirmed via surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   5. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   6. You have not received a total of 24 months cumulative (total) treatment with Myfembree

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis and the patient meets **ALL** of the following criteria?
   - The patient has had improvement in pain related to endometriosis
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Lupron Depot, Synarel)

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:
   A. The request is for ONE of the following:
      1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
      2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

   (Renewal denial text continued on next page)

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RENEWAL CRITERIA (CONTINUED)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:**
   1. You had improvement of heavy menstrual bleeding on therapy
   2. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:**
   1. You have had improvement in pain related to endometriosis while on therapy
   2. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myfembree.

REFERENCES

- Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc., August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/12/22
Created: 06/21
Client Approval: 08/22
P&T Approval: 04/22

REPOTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REPOTRECTINIB	AUGTYRO	49312		GPI-10 (2153386500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has *ROS1*-positive tumors

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   40mg: #8 per day.
   160mg: #2 per day.

   If no, continue to #2.

2. Does the patient have solid tumors and meet **ALL** of the following criteria?
   The patient is 12 years of age and older
   The tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion
   The tumors are locally advanced or metastatic, OR surgical resection is likely to result in severe morbidity
   The patient has progressed following treatment OR has no satisfactory alternative therapy

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   40mg: #8 per day.
   160mg: #2 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REPOTRECTINIB (Augtyro)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   Solid tumors
   (Denial text continued on next page)

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REPOTRECTINIB

GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You have *ROS1*-positive (abnormal change in a type of gene) tumors

If you have solid tumors, approval also requires:
- You are 12 years of age and older
- Your tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (abnormal change in a type of gene)
- Yours tumors are locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body), OR surgical resection (removal by surgery) is likely to result in severe morbidity (illness)
- You have progressed following treatment OR have no satisfactory alternative (other) therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Augtyro.

REFERENCES
Augtyro [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 11/23
Client Approval: 06/24
P&T Approval: 10/24

RESMETIROM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RESMETIROM	REZDIFFRA	49451		GPI-10 (5260106000)	

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient does not have cirrhosis
   Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   The patient is enrolled in or has already completed a lifestyle intervention (e.g., dietary, exercise, psychology)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the NASH diagnosis been confirmed by biopsy or noninvasive testing (e.g., elastography), obtained within the past 12 months, which demonstrates **ONE** of the following?
   The patient has liver fibrosis stage 2 or 3
   The patient has a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) of at least 4

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for approval:
   You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
   You are 18 years of age or older
   You do not have cirrhosis (liver damage and scarring)
   Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (doctor who treats digestive conditions)
   You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
   (Initial denial text continued on next page)

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RESMETIROM

INITIAL CRITERIA (CONTINUED)

Your diagnosis has been confirmed by biopsy (removal of cells or tissue from the body for examination) or noninvasive testing (such as elastography [type of imaging test]) within the past 12 months which demonstrates ONE of the following:
You have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)
You have a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS: a scoring system used to measure disease activity and severity) of at least 4

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RESMETIROM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH) (ICD-10 K75.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient a non-responder as defined by meeting **ALL** of the following criteria?
   The patient's NAFLD Activity Score (NAS) has not decreased by at least 2 points from baseline
   The patient has had no reduction in fibrosis stage

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #3.

3. Has the patient experienced NASH resolution as defined by meeting **ALL** of the following criteria?
   The patient has an NAFLD Activity Score (NAS) of less than or equal to 3
   The patient has liver fibrosis stage 0 to 1

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for renewal:
   You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
   You do NOT meet any of the following:
   - You are a non-responder (defined as NAFLD [non-alcoholic fatty liver disease] Activity Score [NAS: a scoring system used to measure disease activity and severity] not decreasing by at least 2 points from baseline [before start of treatment] AND no reduction [no improvement] in liver fibrosis stage [scoring system to measure liver damage])
   - You have experienced NASH resolution (defined as NAFLD Activity Score [NAS] of less than or equal to 3 AND liver fibrosis stage 0 to 1)

(Renewal denial text continued on next page)

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RESMETIROM

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezdiffra.

REFERENCES

Rezdiffra [Prescribing Information]. West Conshohocken, PA: Madrigal Pharmaceuticals; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/12/24
Created: 03/24
Client Approval: 08/24
P&T Approval: 10/24

REVUMENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REVUMENIB CITRATE	REVUFORJ	50008		GPI-10 (2148007020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute leukemia (ICD-10 C91.00, C91.02, C92.00, C92.02, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C95.00, C95.02) and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient has a lysine methyltransferase 2A gene (KMT2A) translocation

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   110mg: #4 per day.
   160mg: #2 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REVUMENIB (Revuforj)** requires the following rule(s) be met for approval:
   You have relapsed or refractory acute leukemia (a type of blood cancer that has returned or did not respond to treatment)
   You are 1 year of age or older
   You have a lysine methyltransferase 2A gene (KMT2A) translocation (a type of gene abnormality)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Revuforj.

REFERENCES
Revuforj [Prescribing Information]. Waltham, MA: Syndax Pharmaceuticals, Inc.; November 2024.

Created: 11/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/25

RIBOCICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE	KISQALI	44151		GPI-10 (2153107050)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage II or III early breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   Kisqali will be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) for adjuvant treatment
   The patient is at high risk of recurrence

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   200mg daily dose: #21 per 28 days.
   400mg daily dose: #42 per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Groups C50, C79.81) **AND** meet the following criterion?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

3. Will Kisqali be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) as initial endocrine-based therapy?

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   200mg daily dose: #21 per 28 days.
   400mg daily dose: #42 per 28 days.
   600mg daily dose: #63 per 28 days.

   If no, continue to #4.

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RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

4. Will Kisqali be used in combination with fulvestrant (Faslodex), and the patient meets **ONE** of the following criteria?
   Kisqali will be used as initial endocrine-based therapy
   The patient has experienced disease progression on endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   200mg daily dose: #21 per 28 days.
   400mg daily dose: #42 per 28 days.
   600mg daily dose: #63 per 28 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIBOCICLIB (Kisqali)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Stage II or III early breast cancer (initial stage of breast cancer)
   - Advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)

   If you have stage II or III early breast cancer, approval also requires:
   - Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   - You will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) for adjuvant (add-on) treatment
   - You are at high risk of recurrence (disease returning)

   If you have advanced or metastatic breast cancer, approval also requires:
   - Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   - You meet ONE of the following:
     - You will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) as initial endocrine (hormone)-based therapy
     - You will use Kisqali in combination with fulvestrant (Faslodex), and meet ONE of the following:
       - You will use Kisqali as initial endocrine (hormone)-based therapy
       - You have experienced disease progression (your condition worsened) on endocrine therapy (a type of hormone-based treatment such as anastrozole, letrozole, tamoxifen)

   (Denial text continued on next page)

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RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali.

REFERENCES

Kisqali [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/21/24
Created: 05/17
Client Approval: 10/24
P&T Approval: 10/24

RIBOCICLIB-LETROZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI FEMARA CO-PACK	44246		GPI-10 (2199000260)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage II or III early breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   Kisqali Femara Co-Pack will be used for adjuvant treatment
   The patient is at high risk of recurrence

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   200mg-2.5mg daily dose: #49 per 28 days.
   400mg-2.5mg daily dose: #70 per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Groups C50, C79.81) and meet **ALL** of the following criteria?
   The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   Kisqali Femara Co-Pack will be used as initial endocrine-based therapy

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   200mg-2.5mg daily dose: #49 per 28 days.
   400mg-2.5mg daily dose: #70 per 28 days.
   600mg-2.5mg daily dose: #91 per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RIBOCICLIB-LETROZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIBOCICLIB-LETROZOLE (Kisqali Femara Co-Pack)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Stage II or III early breast cancer (initial stage of breast cancer)
- Advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)

If you have stage II or III early breast cancer, approval also requires:
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
- Kisqali Femara Co-Pack will be used for adjuvant (add-on) treatment
- You are at high risk of recurrence (disease returning)

If you have advanced or metastatic breast cancer, approval also requires:
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
- Kisqali Femara Co-Pack will be used as initial endocrine (hormone)-based therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali Femara Co-Pack.

REFERENCES
Kisqali Femara Co-Pack [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/21/24
Created: 03/23
Client Approval: 10/24
P&T Approval: 10/24

RIFAXIMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIFAXIMIN	XIFAXAN		28530 93749	GPI-14 (16000049000340, 16000049000320)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

XIFAXAN 550MG TABLETS

1. Will the requested medication be used for the reduction in risk of overt hepatic encephalopathy (HE) (ICD-10 K76.82) recurrence and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a hepatologist
   The patient had a trial of lactulose or is currently on lactulose monotherapy

   If yes, **approve the 550mg tablet for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) (ICD-10 K58.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   The patient had a trial of or contraindication to a tricyclic anti-depressant (e.g., amitriptyline, nortriptyline) or dicyclomine
   The patient had a trial of or contraindication to the preferred agent: Viberzi (eluxadoline)

   If yes, **approve the 550mg tablet for 8 weeks by GPID or GPI-14 for 1 fill of #42.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 550MG TABLETS (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550mg tablets)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- Reduction in risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence (return)
- Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor)
- You have tried lactulose or you are currently taking lactulose monotherapy (one drug treatment)

If you have irritable bowel syndrome with diarrhea, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
- You have tried or have a contraindication to (harmful for you to use) a tricyclic anti-depressant (such as amitriptyline, nortriptyline) or dicyclomine
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Viberzi (eluxadoline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIFAXIMIN

INITIAL CRITERIA (CONTINUED)

XIFAXAN 200MG TABLETS

1. Does the patient have a diagnosis of travelers' diarrhea (TD) (ICD-10 A09) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient had a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

   If yes, **approve the 200mg tablet for 3 days by GPID or GPI-14 for 1 fill of #9.**
   If no, continue to #2.

2. Does the patient have a diagnosis of overt hepatic encephalopathy (HE) (ICD-10 K76.82) **AND** meet the following criterion?
   Xifaxan will be used in combination with lactulose

   If yes, **approve the 200mg tablet for 10 days by GPID or GPI-14 with a quantity limit of #6 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of *Clostridium difficile* infection (CDI) (ICD-10 Group A04.7) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an infectious disease specialist
   The patient had at least one previous occurrence of Clostridium difficile infection
   The patient has been treated with vancomycin for the current *Clostridium difficile* infection

   If yes, **approve the 200mg tablet for 20 days by GPID or GPI-14 with a quantity limit of #6 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 200MG TABLETS (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 200mg tablets)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Travelers' diarrhea
- Overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage)
- *Clostridium difficile* infection (a type of bacterial infection)

If you have traveler's diarrhea, approval also requires:
- You are 12 years of age or older
- You have tried or have a contraindication to (harmful for you to use) oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

If you have overt hepatic encephalopathy, approval also requires:
- Xifaxan will be used in combination with lactulose

If you have *Clostridium difficile* infection, approval also requires:
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You had at least one previous occurrence of *Clostridium difficile* infection
- You have been treated with vancomycin for the current *Clostridium difficile* infection

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

RIFAXIMIN

RENEWAL CRITERIA

1. Is the request for renewal of Xifaxan 550mg tablets?

   If yes, continue to #2.
   If no, please refer to the Initial Criteria section above for Xifaxan 200mg tablet requests.

2. Will the requested medication be used for the reduction in risk of overt hepatic encephalopathy (HE) (ICD-10 K76.82) recurrence?

   If yes, **approve the 550mg tablet for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) (ICD-10 K58.0) and meet **ALL** of the following criteria?
   The patient's last treatment course of Xifaxan was at least 6 weeks ago
   The patient has experienced at least a 30 percent decrease in abdominal pain (on a 0-10 point pain scale)
   The patient has experienced at least a 50 percent reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool Scale type 6) or entirely liquid stool (Bristol Stool Scale type 7)

   If yes, **approve the 550mg tablet for 12 months by GPID or GPI-14 for up to 2 fills of #42 each fill, separated by at least 8 weeks (total of 2 fills in 12 months).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIFAXIMIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550mg tablets)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Reduction in risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence (return)
- Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

If you have irritable bowel syndrome with diarrhea, renewal also requires:
- Your last treatment course of Xifaxan was at least 6 weeks ago
- You have experienced at least a 30 percent decrease in abdominal pain (on a 0-10 point pain scale)
- You have experienced at least a 50 percent reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool Scale [a tool that helps assess digestive issues] type 6) or entirely liquid stool (Bristol Stool Scale type 7)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information for Xifaxan.

REFERENCES
Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; October 2023.

Created: 02/05
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/22

RILONACEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILONACEPT	ARCALYST	35438		GPI-10 (6645006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) (ICD-10 M04.2) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein [SAA] or S100 proteins)
   The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   Arcalyst will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS

   If yes, **enter TWO approvals by HICL or GPI-10 as follows:**
   FIRST APPROVAL:
   Approve for 1 month with a quantity limit of #5 per 28 days.
   SECOND APPROVAL:
   Approve for lifetime with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).

   If no, continue to #2.

2. Does the patient have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (ICD-10 M04.8) and meet **ALL** of the following criteria?
   The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   Arcalyst will NOT be used concurrently with another systemic biologic (e.g., Kineret [anakinra]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DIRA

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #3.

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RILONACEPT

GUIDELINES FOR USE (CONTINUED)

3. patient meets **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient had an episode of acute pericarditis
   The patient has been symptom-free for an interval of 4 to 6 weeks
   The patient has TWO of the following: chest pain consistent with pericarditis, pericardial friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, and new or worsening pericardial effusion
   The patient had a trial of or contraindication to two NSAIDs (e.g., ibuprofen, indomethacin) AND colchicine
   Arcalyst will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of recurrent pericarditis

   If yes, **approve for 12 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #5 per 28 days.
   SECOND APPROVAL: Approve for 11 months with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).

   SUBSEQUENT REQUESTS:
   Approve for 12 months with a quantity limit of #4 per 28 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:
   You meet ONE of the following:
      You have Cryopyrin-Associated Periodic Syndromes (CAPS: a type of immune disorder) including, Familial Cold Autoinflammatory Syndrome (FCAS: a type of immune disorder) or Muckle-Wells Syndrome (MWS: a type of gene disorder)
      You have Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)
      Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)
   (Denial text continued on next page)

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RILONACEPT

GUIDELINE FOR USE (CONTINUED)

If you have Cryopyrin-Associated Periodic Syndromes including Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:
- You are 12 years of age or older
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
- You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes

If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body])
- You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
- You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist

(Denial text continued on next page)

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RILONACEPT

GUIDELINE FOR USE (CONTINUED)

If the request is for the treatment or reduction in risk of recurrent pericarditis, approval also requires:

You are 12 years of age or older
You had an episode of acute pericarditis (a type of short-term heart condition)
You have been symptom-free for 4 to 6 weeks
You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), and new or worsening pericardial effusion (a type of heart condition)
You have tried or have a contraindication to (harmful for you to use) two NSAIDS (non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin) AND colchicine
You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of recurrent pericarditis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arcalyst.

REFERENCES

Arcalyst [Prescribing Information]. London, UK: Kiniksa Pharmaceuticals; May 2021.

Created: 08/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

RILUZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILUZOLE	EXSERVAN, TIGLUTIK		47362 44091	GPI-14 (74503070008220, 74503070001820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has had a trial of riluzole tablets
   - The patient is unable to take riluzole tablet formulation

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Exservan: #2 per day.**
   - **Tiglutik: #20mL per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
   B. You are 18 years of age or older
   C. You have tried riluzole tablets
   D. You are unable to take riluzole tablet formulation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Exservan or Tiglutik.

REFERENCES

- Exservan. [Prescribing Information]. Warren, NJ: Aquestive Therapeutics; April 2020.
- Tiglutik. [Prescribing Information]. Berwyn, PA: ITF Pharma, Inc.; September 2018.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21
Created: 11/18
Client Approval: 05/21
P&T Approval: 01/20

RIMEGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIMEGEPANT SULFATE	NURTEC ODT	46383		GPI-10 (6770106070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, continue to #2.

2. Is the request for the preventive treatment of episodic migraines and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
   The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIMEGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- Acute (quick onset) treatment of migraines (a type of headache)
- Preventive treatment of episodic migraines (a type of headache)

If the request is for the acute treatment of migraines, approval also requires:
- You are 18 years of age or older
- You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
- You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

If the request is for the preventive treatment of episodic migraines, approval also requires:
- You are 18 years of age or older
- You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) **AND** the patient meets the following criterion?
   Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, continue to #3.

3. Has the patient experienced clinical improvement defined as **ONE** of the following criteria?
   Ability to function normally within 2 hours of dose
   Headache pain disappears within 2 hours of dose
   Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for the preventive treatment of episodic migraines **AND** the patient meets the following criterion?
   Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month
   The patient has experienced a reduction in migraine severity
   The patient has experienced a reduction in migraine duration

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIMEGEPANT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:
The request is for ONE of the following:
- Acute (quick onset) treatment of migraines (a type of headache)
- Preventive treatment of episodic migraines (a type of headache)

If the request is for the acute treatment of migraines, renewal also requires:
- You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
- You meet ONE of the following:
  - You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
  - You have experienced clinical improvement as defined by ONE of the following:
    - Ability to function normally within 2 hours of dose
    - Headache pain disappears within 2 hours of dose
    - Treatment works consistently in a majority of migraine attacks

If the request is for the preventive treatment of episodic migraines, renewal also requires:
- You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
- You meet ONE of the following:
  - You have experienced a reduction in migraine or headache frequency of at least 2 days per month
  - You have experienced a reduction in migraine severity
  - You have experienced a reduction in migraine duration

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nurtec ODT.

REFERENCES

Nurtec ODT [Prescribing Information]. New York, NY: Pfizer Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 03/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

RIOCIGUAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIOCIGUAT	ADEMPAS	40644		GPI-10 (4013405000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) (ICD-10 I27.24) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The patient has persistent or recurrent disease after surgical treatment OR is not a candidate for surgery OR has inoperable CTEPH
   The patient has NYHA-WHO Functional Class II to IV symptoms
   Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIOCIGUAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
- Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)

If you have pulmonary arterial hypertension, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  Pulmonary vascular resistance (PVR) greater than 2 Wood units
- You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

If you have chronic thromboembolic pulmonary hypertension, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- You have persistent or recurrent disease after surgical treatment (condition continues to exist or returns after surgery) OR you are not a candidate for surgery OR you have inoperable (not able to operate on) chronic thromboembolic pulmonary hypertension
- You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
- You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

RIOCIGUAT

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) (ICD-10 I27.24)
   Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Adempas be taken concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)
   - Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adempas.

REFERENCES

Adempas [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 11/13
Client Approval: 06/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIPRETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIPRETINIB	QINLOCK	46544		GPI-10 (2153305300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior treatment with 3 or more kinase inhibitors (e.g. sunitinib, avapritinib, regorafenib), including imatinib

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:
   A. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
   B. You are 18 years of age or older
   C. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qinlock.

REFERENCES

- Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/20
Client Approval: 03/21
P&T Approval: 07/20

RISANKIZUMAB-RZAA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		GPI-10 (9025057070, 5250406070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Skyrizi
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month with the following quantity limits:
   150mg/1.66mL: #1 kit per 28 days.
   150mg/mL: #1mL per 28 days.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months with the following quantity limits (please enter a start date of 3 WEEKS AFTER the START date of the first approval):
   150mg/1.66mL: #1 kit per 84 days.
   150mg/mL: #1mL per 84 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve all formulations of the requested strength for 1 month with the following quantity limits:
   150mg/1.66mL: #1 kit per 28 days.
   150mg/mL: #1mL per 28 days.
   SECOND APPROVAL: Approve all formulations of the requested strength for 5 months with the following quantity limits (please enter a start date of 3 WEEKS AFTER the START date of the first approval):
   150mg/1.66mL: #1 kit per 84 days.
   150mg/mL: #1mL per 84 days.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #6.
   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

6. Is the prescriber requesting an intravenous infusion induction dose of **Skyrizi 600mg/10mL?**

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve 600mg/10mL for 3 months with a quantity limit of #10mL per 28 days.
   SECOND APPROVAL: Approve the requested strength for 3 months with the following quantity limits (Please enter a start date of 11 WEEKS AFTER the START date of the first approval):
   180mg/1.2mL: #1.2mL per 56 days.
   360mg/2.4mL: #2.4mL per 56 days.

   If no, **approve a maintenance dose for 6 months by GPID or GPI-14 for the requested strength as follows:**
   180mg/1.2mL: #1.2mL per 56 days.
   360mg/2.4mL: #2.4mL per 56 days.

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

8. Is the prescriber requesting an intravenous infusion induction dose of **Skyrizi 600mg/10mL?**

If yes, approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:
FIRST APPROVAL: Approve 600mg/10mL for 3 months with a quantity limit of #20mL per 28 days.
SECOND APPROVAL: Approve the requested strength for 3 months with the following quantity limits (Please enter a start date of 11 WEEKS AFTER the START date of the first approval):
180mg/1.2mL: #1.2mL per 56 days.
360mg/2.4mL: #2.4mL per 56 days.

If no, **approve a maintenance dose for 6 months by GPID or GPI-14 for the requested strength as follows:**
180mg/1.2mL: #1.2mL per 56 days.
360mg/2.4mL: #2.4mL per 56 days.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:
You have ONE of the following:
Moderate to severe plaque psoriasis (PsO: a type of skin condition)
Psoriatic arthritis (PsA: a type of skin and joint condition)
Moderate to severe Crohn's disease (CD: a type of bowel disorder)
Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
(Initial denial text continued on next page)

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Skyrizi
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   150mg/1.66mL: #1 kit per 84 days.
   150mg/mL: #1mL per 84 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   150mg/1.66mL: #1 kit per 84 days.
   150mg/mL: #1mL per 84 days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   180mg/1.2mL: #1.2mL per 56 days.
   360mg/2.4mL: #2.4mL per 56 days.

   If no, continue to #4.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   180mg/1.2mL: #1.2mL per 56 days.
   360mg/2.4mL: #2.4mL per 56 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   If you have moderate to severe plaque psoriasis, renewal also requires:
   - You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   - You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   If you have psoriatic arthritis, renewal also requires:
   - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:
You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES
Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; June 2024.

Created: 05/19
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

RISDIPLAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISDIPLAM	EVRYSDI	46765		GPI-10 (7470656000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
   The diagnosis is confirmed by gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient pre-symptomatic **AND** meets the following criterion?
   The patient has up to (i.e., no more than) THREE copies of the survival motor neuron 2 (SMN2) gene based on newborn screening

   If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
   5 mg: #1 per day.
   0.75 mg/mL: #8mL per day.
   If no, continue to #3.

3. Is the patient symptomatic and meets **ALL** of the following criteria?
   The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
   The patient had a baseline motor function assessment by a neuromuscular specialist or SMA specialist
   If the patient received prior gene therapy, the patient had a less than expected clinical benefit with gene therapy

   If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
   5 mg: #1 per day.
   0.75 mg/mL: #8mL per day.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISDIPLAM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:
You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
Your diagnosis is confirmed by a gene mutation (abnormal change) analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
If you are pre-symptomatic (symptoms have not yet appeared), approval also requires:
You have up to (no more than) THREE copies of the survival motor neuron 2 (SMN2: type of protein) gene based on a screening that was done when you were a newborn
If you are symptomatic (symptoms have appeared), approval also requires:
The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
You had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
If you have received prior gene therapy, you experienced a less than expected clinical benefit with gene therapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISDIPLAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ONE** of the following criteria?
   The patient has improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
   The patient has improved, maintained, or demonstrated a less than expected decline in other muscle function (e.g., pulmonary)

   If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
   5 mg: #1 per day.
   0.75 mg/mL: #8mL per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:
   You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
   You meet ONE of the following:
   - You have improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
   - You have improved, maintained, or demonstrated a less than expected decline in other muscle function (such as pulmonary [lung/breathing] function)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.

REFERENCES

Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2025.

Created: 08/20
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 04/25

RITLECITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITLECITINIB TOSYLATE	LITFULO	49026		GPI-10 (9073106010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has experienced at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT), for at least 6 months
   Litfulo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Olumiant (baricitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for approval:
   You have severe alopecia areata (a type of hair loss)
   You are 12 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   You have experienced at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for at least 6 months
   You will NOT use Litfulo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Olumiant (baricitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITLECITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
   The patient has shown improvement while on therapy (e.g., scalp hair coverage)
   Litfulo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Olumiant (baricitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for renewal:
   You have severe alopecia areata (a type of hair loss)
   You have shown improvement while on therapy (such as scalp hair coverage)
   You will NOT use Litfulo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Olumiant (baricitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Litfulo.

REFERENCES

Litfulo [Prescribing Information]. New York, NY: Pfizer Inc.; June 2023.

Created: 07/23
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 10/24

RITUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB	RITUXAN	16848		GPI-10 (2135186000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Rituxan will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL
   The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #4.

4. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   The patient is 6 months to 17 years of age
   Therapy is prescribed by or in consultation with an oncologist
   Rituxan will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL
   The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #5.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Rituxan will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL
   The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #6.

6. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Rituxan will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
   If no, continue to #7.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV
   The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Rituxan will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Rituxan. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for approval:
You have ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
- Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
- Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
- Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
- Rituxan will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have non-Hodgkin's lymphoma, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin’s lymphoma
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
- You are 6 months to 17 years of age
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- Rituxan will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
- You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

If you have chronic lymphocytic leukemia, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- Rituxan will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
- You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
- You are 2 years of age or older
- Rituxan will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
- You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe pemphigus vulgaris, approval also requires:
- You are 18 years of age or older
- You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RITUXIMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Rituxan will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for renewal:
You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count from baseline while on therapy
You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
- You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rituxan.

REFERENCES

Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 01/09
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

RITUXIMAB-ABBS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-ABBS	TRUXIMA	45522		GPI-10 (2135186010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Truxima will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Truxima will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #4.
   If no, continue to #5.

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Truxima will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, continue to #7.

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

7. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   The patient is 6 months to 17 years of age
   Therapy is prescribed by or in consultation with an oncologist
   Truxima will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Truxima will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Truxima. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
- Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
- Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
- Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
- Truxima will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have non-Hodgkin's lymphoma, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin’s lymphoma

If you have chronic lymphocytic leukemia, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- Truxima will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
- You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
- You are 2 years of age or older
- Truxima will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
- You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener’s granulomatosis) or microscopic polyangiitis

If you have moderate to severe pemphigus vulgaris, approval also requires:
- You are 18 years of age or older
- You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:

You are 6 months to 17 years of age

Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)

Truxima will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])

You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RITUXIMAB-ABBS

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Truxima will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB-ABBS

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for renewal:

- You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truxima and Rituxan.

REFERENCES

Truxima [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; July 2024.
Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 11/19
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

RITUXIMAB-ARRX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-ARRX	RIABNI	47033		GPI-10 (2135186014)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Riabni will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #3.

3. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Riabni will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
   If no, continue to #4.

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Riabni will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, continue to #7.

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

7. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   The patient is 6 months to 17 years of age
   Therapy is prescribed by or in consultation with an oncologist
   Riabni will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Riabni will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Riabni. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
- Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
- Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
- Riabni will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have non-Hodgkin's lymphoma, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma

If you have chronic lymphocytic leukemia, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- Riabni will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
- You are 2 years of age or older
- Riabni will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe pemphigus vulgaris, approval also requires:
- You are 18 years of age or older
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
- You are 6 months to 17 years of age
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- Riabni will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RITUXIMAB-ARRX

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Riabni will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB-ARRX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for renewal:

- You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Riabni and Rituxan.

REFERENCES

Riabni [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 02/21
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

RITUXIMAB AND HYALURONIDASE HUMAN - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB/ HYALURONIDASE, HUMAN	RITUXAN HYCELA	44378		GPI-10 (2199000264)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of Rituxan Hycela
   Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of FL

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient has relapsed or refractory FL
   The patient has previously untreated FL AND Rituxan Hycela will be used in combination with chemotherapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
   The patient has achieved a complete or partial response to rituximab in combination with chemotherapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   The patient has non-progressing (including stable disease) FL AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

   If yes, **approve the 1,400 mg-23,400 units/11.7mL strength for 12 months by GPID or GPI-14.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of Rituxan Hycela
   The patient has not been previously treated for DLBCL
   Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen
   Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL

   If yes, **approve the 1,400 mg-23,400 units/11.7mL strength for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of Rituxan Hycela
   Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
   Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve the 1,600 mg-26,800 units/13.4mL strength for 12 months by GPID or GPI-14.**

   If no, continue to #5.

5. Is the request for an FDA-approved indication **AND** Rituxan Hycela will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Rituxan Hycela. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Follicular lymphoma (FL: a type of blood cancer)
- Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Rituxan Hycela will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have follicular lymphoma, approval also requires:
- You are 18 years of age or older
- You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
- You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of follicular lymphoma
- You meet ONE of the following:
  - You have relapsed or refractory follicular lymphoma (cancer that has returned or does not fully respond to treatment)
  - You have previously untreated follicular lymphoma AND Rituxan Hycela will be used in combination with chemotherapy (a type of cancer treatment, such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
  - You have achieved a complete or partial response to rituximab in combination with chemotherapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
  - You have non-progressing (including stable disease) follicular lymphoma (cancer that is not worsening), AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

GUIDELINES FOR USE (CONTINUED)

If you have diffuse large B-cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
- You have not been previously treated for diffuse large B-cell lymphoma
- Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen (a type of cancer treatment)
- You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma

If you have chronic lymphocytic leukemia (CLL), approval also requires:
- You are 18 years of age or older
- You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
- Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
- You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rituxan Hycela.

REFERENCES

Rituxan Hycela [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2021.

Created: 08/17
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

RITUXIMAB-PVVR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-PVVR	RUXIENCE	45899		GPI-10 (2135186060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an oncologist
   Ruxience will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #3.

3. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Ruxience will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
   If no, continue to #4.

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   The patient is currently using or has a contraindication to methotrexate
   Ruxience will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, continue to #7.

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

7. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   The patient is 6 months to 17 years of age
   Therapy is prescribed by or in consultation with an oncologist
   Ruxience will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Ruxience will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Ruxience. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
- Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
- Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
- Ruxience will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have non-Hodgkin's lymphoma, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

If you have chronic lymphocytic leukemia, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
- Ruxience will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
- You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
- You are 2 years of age or older
- Ruxience will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
- You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using or have a contraindication to (harmful for you to use) methotrexate
- You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
- You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have moderate to severe pemphigus vulgaris, approval also requires:

You are 18 years of age or older

You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris

If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:

You are 6 months to 17 years of age

Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)

Ruxience will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])

You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RITUXIMAB-PVVR

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Ruxience will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB-PVVR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for renewal:

- You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruxience and Rituxan.

REFERENCES

Ruxience [Prescribing Information]. New York, NY: Pfizer Labs; October 2023.
Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 02/20
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.15% CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		55978	GPI-10 (9023006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   The patient had a trial of or contraindication to a topical corticosteroid of medium potency or greater (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
   The patient had a trial of or contraindication to ONE of the following topical non-steroidal immunomodulating agents: Eucrisa (crisaborole), Opzelura (ruxolitinib)
   The patient had a trial of or contraindication to ONE of the following topical calcineurin inhibitors: Elidel (pimecrolimus), Protopic (tacrolimus)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Will Zoryve be used concurrently with **ANY** of the following for atopic dermatitis?
   Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

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ROFLUMILAST 0.15% CREAM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for approval:
You have mild to moderate atopic dermatitis (a type of skin condition)
You are 6 years of age or older
You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
You have tried or have a contraindication to ONE of the following topical non-steroidal immunomodulating medications (a type of medication): Eucrisa (crisaborole), Opzelura (ruxolitinib)
You have tried or have a contraindication to ONE of the following topical calcineurin inhibitors (a type of medication): Elidel (pimecrolimus), Protopic (tacrolimus)
You will NOT use Zoryve concurrently (at the same time) with ANY of the following for atopic dermatitis:
Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)])
Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.15% CREAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
   The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Zoryve be used concurrently with **ANY** of the following for atopic dermatitis?
   Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

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ROFLUMILAST 0.15% CREAM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for renewal:
You have mild to moderate atopic dermatitis (a type of skin condition)
You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
You will NOT use Zoryve concurrently (at the same time) with ANY of the following for atopic dermatitis:
Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)])
Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES
Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.

Created: 07/24
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 07/24

ROFLUMILAST 0.3% CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		52657	GPI-10 (9025004500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
   Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   Topical retinoid (e.g., tazarotene cream/gel)
   Anthralin

   If yes, **approve for 2 months by GPID or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for approval:
   You have plaque psoriasis (a type of skin condition)
   You are 6 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   (Initial denial text continued on next page)

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ROFLUMILAST 0.3% CREAM

INITIAL CRITERIA (CONTINUED)

You have psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
- High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
- Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
- Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
- Topical retinoid (such as tazarotene cream/gel)
- Anthralin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.3% CREAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease
   Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for renewal:
   You have plaque psoriasis (a type of skin condition)
   You have achieved or maintained clear or minimal disease
   You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 08/22
Client Approval: 07/24
P&T Approval: 01/24

ROFLUMILAST - FOAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		55119	GPI-10 (9030004500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of seborrheic dermatitis and meet **ALL** of the following criteria?
   The patient is 9 years of age or older
   The patient's seborrheic dermatitis covers less than or equal to 20 percent of their body surface area (BSA) (may involve scalp, face, trunk, or intertriginous areas)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   Topical antifungal (e.g., ketoconazole, ciclopirox)
   Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)

   If yes, **approve for 8 weeks by GPID or GPI-10.**
   If no, continue to #3.

3. Has the patient had a prior successful treatment with roflumilast foam?

   If yes, **approve for 8 weeks by GPID or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for approval:
   You have seborrheic dermatitis (a type of skin condition)
   You are 9 years of age or older
   Your seborrheic dermatitis covers less than or equal to 20 percent of your body surface area (BSA) (may involve scalp, face, trunk [the central part of your body], or intertriginous areas [between skin folds])
   (Denial text continued on the next page)

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ROFLUMILAST - FOAM

GUIDELINES FOR USE (CONTINUED)

You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
  - High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
  - Topical antifungal (such as ketoconazole, ciclopirox)
  - Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
- You previously had a successful treatment with roflumilast foam

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 12/23
Client Approval: 10/24
P&T Approval: 10/23

ROPEGINTERFERON ALFA-2B-NJFT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROPEGINTERFERON ALFA-2B-NJFT	BESREMI	47669		GPI-10 (2170007750)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of polycythemia vera **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROPEGINTERFERON ALFA-2B-NJFT (Besremi)** requires the following rule(s) be met for approval:
   A. You have polycythemia vera (a type of blood cancer)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Besremi.

REFERENCES

- Besremi [Prescribing Information]. Burlington, MA: PharmaEssentia, Corp., November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 01/22
Client Approval: 02/22
P&T Approval: 01/22

RUCAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUCAPARIB CAMSYLATE	RUBRACA	44002		GPI-10 (2153557020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic)
   - The patient is in complete or partial response to platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic) based on an FDA-approved companion diagnostic for Rubraca
   - The patient has been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RUCAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
   2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
   3. You are in complete or partial response to platinum-based chemotherapy (a type of therapy to treat cancer)
   4. The requested medication will be used for maintenance treatment

C. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
   3. You have been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy (types of therapy to treat cancer)
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (removal of testicles)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUCAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rubraca.

REFERENCES

- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23

Created: 12/16
Client Approval: 01/23

P&T Approval: 01/23

RUXOLITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	JAKAFI	38202		GPI-10 (2153756020)	ROUTE ≠ TOPICAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (ICD-10 D75.81), including primary myelofibrosis (ICD-10 D47.1), post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID or GPI-10 for all strengths with a quantity limit of #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of polycythemia vera (ICD-10 D45) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, **approve for 12 months by GPID or GPI-10 for all strengths with a quantity limit of #2 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of steroid-refractory acute graft-versus-host disease (ICD-10 D89.810, D89.812) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by GPID or GPI-10 for all strengths with a quantity limit of #2 per day.**

   If no, continue to #4.

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RUXOLITINIB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil)
   - Jakafi will NOT be used concurrently with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

   If yes, **approve for 12 months by GPID or GPI-10 for all strengths with a quantity limit of #2 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis (types of blood cancer)
      2. Polycythemia vera (a type of blood cancer)
      3. Steroid-refractory Acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
      4. Chronic graft-versus-host disease (a type of long-term immune disorder)

   B. **If you have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
      1. You are 18 years of age or older

   C. **If you have polycythemia vera, approval also requires:**
      1. You are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) hydroxyurea

   D. **If you have steroid-refractory acute graft-versus-host disease, approval also requires:**
      1. You are 12 years of age or older

   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

RUXOLITINIB

INITIAL CRITERIA (CONTINUED)

E. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   3. You will NOT use Jakafi concurrently (at the same time) with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera, steroid-refractory acute graft-versus-host disease, or chronic graft-versus-host disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (ICD-10 D75.81), including primary myelofibrosis (ICD-10 D47.1), post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has had at least a 50 percent reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has had at least a 50 percent reduction in palpable spleen length
   - The patient has had a spleen volume reduction of at least 35 percent from baseline

   If yes, **approve for 12 months by GPID or GPI-10 for all strengths with a quantity limit of #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for renewal:
   A. You have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis (types of blood cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have had at least a 50 percent reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      2. You have had at least a 50 percent reduction in palpable (can be felt by external examination) spleen length
      3. You have had a spleen volume reduction of at least 35 percent from baseline

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jakafi.

REFERENCES

- Jakafi [Prescribing Information]. Wilmington, DE. Incyte Corporation; January 2023.

Created: 12/11
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

RUXOLITINIB TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	OPZELURA	38202		GPI-10 (9027206050)	ROUTE ≠ ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient is NOT immunocompromised
   The patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical non-steroidal immunomodulating agent (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, continue to #2.
   If no, continue to #3.

2. Will Opzelura be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   Other non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

3. Does the patient have a diagnosis of nonsegmental vitiligo (ICD-10 L80) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient has depigmented areas covering 10 percent or less of total body surface area
   The patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

4. Will Opzelura be used concurrently with **ANY** of the following?
   Other non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 6 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Mild to moderate atopic dermatitis (a type of skin condition)
      Nonsegmental vitiligo (a type of skin condition)
   If you have mild to moderate atopic dermatitis, approval also requires:
      You are 12 years of age or older
      You are NOT immunocompromised (low immune system)
      You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical non-steroidal immunomodulating agent (such as Elidel [pimecrolimus], Protopic [tacrolimus])
      You will NOT use Opzelura concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis:
         Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
         Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
         Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
         Potent immunosuppressants (such as azathioprine, cyclosporine)
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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

If you have nonsegmental vitiligo, approval also requires:

- You are 12 years of age or older
- You have depigmented (lightening of the skin) areas covering 10 percent or less of your total body surface area (BSA)
- You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
- You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
  - Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
  - Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
  - Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
  - Potent immunosuppressants (such as azathioprine, cyclosporine)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
   The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, continue to #2.
   If no, continue to #3.

2. Will Opzelura be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   Other non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

3. Does the patient have a diagnosis of nonsegmental vitiligo (ICD-10 L80) **AND** meet the following criterion?
   The patient has experienced or maintained clinically meaningful repigmentation

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Will Opzelura be used concurrently with **ANY** of the following?
   Other non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Mild to moderate atopic dermatitis (a type of skin condition)
- Nonsegmental vitiligo (a type of skin condition)

If you have mild to moderate atopic dermatitis, renewal also requires:
- You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (symptoms or disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
- You will NOT use Opzelura concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis:
  - Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
  - Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
  - Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
  - Potent immunosuppressants (such as azathioprine, cyclosporine)

If you have nonsegmental vitiligo, renewal also requires:
- You have experienced or maintained clinically meaningful repigmentation (recoloration of the skin after loss in color)
- You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
  - Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
  - Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
  - Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
  - Potent immunosuppressants (such as azathioprine, cyclosporine)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB TOPICAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

REFERENCES

Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corporation; August 2024.

Created: 09/21
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 04/25

SACROSIDASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACROSIDASE	SUCRAID	18554		GPI-10 (5120006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist or medical geneticist
   - The patient's diagnosis is confirmed by ONE of the following:
     - Small bowel biopsy
     - Sucrose breath test
     - Genetic test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:
   A. You have a genetically determined sucrase deficiency , which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or medical geneticist (doctor who treats gene disorders)
   C. Your diagnosis is confirmed by ONE of the following:
      1. Small bowel biopsy (removal of cells or tissue from the body for examination)
      2. Sucrose breath test
      3. Genetic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SACROSIDASE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID) **AND** meet the following criterion?
   - The patient has experienced or maintained improvement on treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for renewal:
   A. You have a genetically determined sucrase deficiency which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
   B. You have experienced or maintained improvement on treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sucraid.

REFERENCES

- Sucraid [Prescriber Information]. Vero Beach, FL: QOL Medical, LLC.; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/12
Client Approval: 05/22
P&T Approval: 04/22

SARGRAMOSTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		GPI-10 (8240205000)	

GUIDELINES FOR USE

1. Therapy is prescribed by or given in consultation with a hematologist or oncologist?

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**
   If no, continue to #2.

2. Is the request for **ONE** of the following indications?
   - To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years of age or older
   - For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years of age or older
   - For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years of age or older
   - For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years of age or older
   - For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years of age or older
   - To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:
   A. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor), **OR** you meet **ONE** of the following:
      1. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer) and are using the requested medication to shorten time to neutrophil (a type of white blood cell) recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND you are 55 years of age or older

   (Denial text continued on next page)

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SARGRAMOSTIM

GUIDELINES FOR USE (CONTINUED)

2. You are undergoing autologous transplantation (your own blood-forming stem cells are collected) and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (to collect blood sample and separate white blood cells in a lab test) AND you are 18 years of age or older
3. You have non-Hodgkin's lymphoma (NHL: type of cancer), acute lymphoblastic leukemia (ALL: type of white blood cell cancer) or Hodgkin's lymphoma (type of cancer) and are using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation (to help your blood and bone marrow recover) AND you are 2 years of age or older
4. The requested medication is being used for the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors (to help your blood and bone marrow recover after using a lab test to match you to the correct donors) AND you are 2 years of age or older
5. The requested medication is being used for the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND you are 2 years of age or older
6. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase your survival

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leukine.

REFERENCES

- Leukine [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 02/03
Client Approval: 04/20

P&T Approval: 04/18

SARILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARILUMAB	KEVZARA	44183		GPI-10 (6650006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polymyalgia rheumatica (PMR) (ICD-10 M35.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had an inadequate response to corticosteroids (e.g., prednisone) or cannot tolerate a corticosteroid taper
   Kevzara will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PMR

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient weighs at least 63 kg (138 lbs)
   Therapy is prescribed by or in consultation with a rheumatologist
   Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g. JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)
- Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have polymyalgia rheumatica, approval also requires:
- You are 18 years of age or older
- You had an inadequate response (drug did not work) to corticosteroids (such as prednisone) or cannot tolerate a corticosteroid taper
- You will NOT use Kevzara concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polymyalgia rheumatica

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

If you have polyarticular juvenile idiopathic arthritis, approval also requires:

- You weigh at least 63 kilograms (138 pounds)
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SARILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica (PMR), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR)
   The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g. JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   NOTE: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   If you have moderate to severe rheumatoid arthritis, renewal also requires:
   You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   (Renewal denial text continued on next page)

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
- You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kevzara.

REFERENCE
Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; June 2024.

Created: 11/16
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SATRALIZUMAB-MWGE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	46781		GPI-10 (9940507040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

2 Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist
- The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
- Enspryng will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

3 Does the patient have at least **ONE** of the following core clinical characteristics?
- Optic neuritis
- Acute myelitis
- Area postrema syndrome
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
- **FIRST APPROVAL: Approve for 1 month with a quantity limit of #2mL per 28 days.**
- **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1mL per 28 days (enter a start date 2 days BEFORE the end date of the first approval).**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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SATRALIZUMAB-MWGE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. You have a positive serologic (blood) test for the anti-aquaporin-4 (AQP4: a type of protein) antibody
E. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
F. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (a type of brain disorder)
    2. Acute myelitis (a type of brain disorder)
    3. Area postrema syndrome (a type of brain disorder)
    4. Acute brainstem syndrome (a type of brain disorder)
    5. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic MRI lesions (affected areas)
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SATRALIZUMAB-MWGE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient had a reduction in relapse frequency from baseline
   - Enspryng will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for renewal:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   B. You have experienced a reduction in relapse frequency from baseline
   C. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES

- Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 08/20
Client Approval: 08/24
P&T Approval: 07/24

SECUKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SECUKINUMAB	COSENTYX	41715		GPI-10 (9025057500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) without psoriatic arthritis involvement and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to FOUR of the preferred agents: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Otezla (apremilast)
   The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
   <u>FIRST APPROVAL</u>: Approve for 1 month with the following quantity limits:
   75mg/0.5mL: #2mL per 28 days.
   150mg/mL: #4mL per 28 days.
   300mg/2mL: #8mL per 28 days.
   <u>SECOND APPROVAL</u>: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
   75mg/0.5mL: #0.5mL per 28 days.
   150mg/mL: #1mL per 28 days.
   300mg/2mL: #2mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #5.
   If no, continue to #8.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   The patient is 2 to 5 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
   <u>FIRST APPROVAL</u>: Approve for 1 month with the following quantity limits:
   75mg/0.5mL: #2mL per 28 days.
   150mg/mL: #4mL per 28 days.
   <u>SECOND APPROVAL</u>: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
   75mg/0.5mL: #0.5mL per 28 days.
   150mg/mL: #1mL per 28 days.

   If no, continue to #6.

6. Is the patient 18 years of age or older **AND** meets the following criterion?
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

   If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve for 1 month with the following quantity limits:
   150mg/mL: #4mL per 28 days.
   300mg/2mL: #8mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
   150mg/mL: #1mL per 28 days.
   300mg/2mL: #2mL per 28 days.

   If no, continue to #9.

8. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #9.
   If no, continue to #13.

9. Is the request for Cosentyx subcutaneous pen or syringe?

   If yes, continue to #10.
   If no, continue to #12.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

10. Is the request for a maintenance dosage of 300mg with or without a loading dose?

    If yes, continue to #11.
    If no, **approve all formulations of the 150mg/mL strength for a total of 6 months by GPID or GPI-14 as follows:**
    Approve for 1 month with a quantity limit of #4mL per 28 days.
    Approve for 5 months with a quantity limit of #1mL per 28 days. (Enter a start date of 3 DAYS BEFORE the END date of the first approval.)

11. Has the patient tried the 150mg maintenance dosing schedule **AND** continues to have active ankylosing spondylitis or active psoriatic arthritis?

    If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
    FIRST APPROVAL: Approve for 1 month with the following quantity limits:
    150mg/mL: #4mL per 28 days.
    300mg/2mL: #2mL per 28 days.
    SECOND APPROVAL: Approve for 5 months with the following quantity limit (enter a start date of 3 DAYS BEFORE the END date of the first approval):
    300mg/2mL: #2mL per 28 days.

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.
    PAC NOTE: Please enter proactive PAs for all formulations of the 150mg/mL strength for a total of 6 months by GPID or GPI-14 as follows:
    Approve for 1 month with a quantity limit of #4mL per 28 days.
    Approve for 5 months with a quantity limit of #1mL per 28 days. (Enter a start date of 3 DAYS BEFORE the END date of the first approval.)

12. Is the request for Cosentyx 125mg/5mL intravenous solution?

    If yes, **approve the 125mg/5mL strength for a total of 6 months by GPID or GPI-14 as follows:**
    Approve for 1 month with a fill count of #1.
    Approve for 5 months with a quantity limit of #15mL per 28 days. (Enter a start date of 3 DAYS BEFORE the END date of the first approval.)

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

13. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Therapy is prescribed by or in consultation with a rheumatologist
    Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
    The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
    The patient had a trial of or contraindication to TWO of the following preferred agents: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, continue to #14.
    If no, continue to #15.

14. Does the patient have **ONE** of the following objective signs of inflammation?
    C-reactive protein (CRP) levels above the upper limit of normal
    Sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
    FIRST APPROVAL:
    150mg/mL: Approve for 1 month with a quantity limit of #4mL per 28 days.
    125mg/5mL: Approve for 1 month with a fill count of #1.
    SECOND APPROVAL: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
    150mg/mL: #1mL per 28 days.
    125mg/5mL: #15mL per 28 days.

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

15. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) (ICD-10 M08.80) and meet **ALL** of the following criteria?
    The patient is 4 years of age or older
    Therapy is prescribed by or in consultation with a rheumatologist
    Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of ERA
    The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

    If yes, **approve all formulations of the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
    <u>FIRST APPROVAL</u>: Approve for 1 month with the following quantity limits:
    75mg/0.5mL: #2mL per 28 days.
    150mg/mL: #4mL per 28 days.
    <u>SECOND APPROVAL</u>: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
    75mg/0.5mL: #0.5mL per 28 days.
    150mg/mL: #1mL per 28 days.

    If no, continue to #16.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

16. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    Therapy is prescribed by or in consultation with a dermatologist
    Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
    The patient had a trial of or contraindication to ONE topical therapy (e.g., clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (e.g., tetracycline, dapsone)
    The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), adalimumab-adaz, Simlandi
    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve all formulations of the requested strength for a total of 4 months by GPID or GPI-14 as follows:**
    <u>FIRST APPROVAL</u>: Approve for 1 month with the following quantity limits:
    150mg/mL: #8mL per 28 days.
    300mg/2mL: #8mL per 28 days.
    <u>SECOND APPROVAL</u>: Approve for 3 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
    150mg/mL: #4mL per 28 days.
    300mg/2mL: #4mL per 28 days.

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Enthesitis-related arthritis (ERA: a type of joint condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are 6 to 17 years of age AND have tried or have a contraindication to FOUR of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Otezla (apremilast)
- You are 18 years of age or older AND have tried or have a contraindication to FOUR of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have psoriatic arthritis, approval also requires:

You are 2 years of age or older

Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)

You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

Requests for the 300mg maintenance dosage in psoriatic arthritis without coexisting plaque psoriasis requires that you have tried the 150mg maintenance dosing schedule AND continue to have active psoriatic arthritis

You meet ONE of the following:
- You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
- You are 6 to 17 years of age AND have tried or have a contraindication to THREE of the preferred medications: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
- You are 18 years of age or older AND have tried or have a contraindication to THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz IR/XR (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
- Requests for the 300mg maintenance dosage requires that you have tried the 150mg maintenance dosage schedule AND continue to have active ankylosing spondylitis
- You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR/XR (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
- You have tried or have a contraindication to TWO of the following preferred medications: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
- You have ONE of the following signs of inflammation:
  - C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - Sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have enthesitis-related arthritis, approval also requires:
- You are 4 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa
- You have tried or have a contraindication to (harmful for you to use) ONE topical therapy (such as clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (such as tetracycline, dapsone)
- You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), adalimumab-adaz, Simlandi

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SECUKINUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient is 6 to 17 years of age AND had a trial of or contraindication to FOUR of the preferred agents: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Otezla (apremilast)
   The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   75mg/0.5mL: #0.5mL per 28 days.
   150mg/mL: #1mL per 28 days.
   300mg/2mL: #2mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #4.
   If no, continue to #5.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient is 2 to 5 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Rinvoq (upadacitinib)
   The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
   The patient is 18 years of age or older AND had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   75mg/0.5mL: #0.5mL per 28 days.
   150mg/mL: #1mL per 28 days.
   300mg/2mL: #2mL per 28 days.
   125mg/5mL: #15mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   150mg/mL: #1mL per 28 days.
   300mg/2mL: #2mL per 28 days.
   125mg/5mL: #15mL per 28 days.

   If no, continue to #6.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   The patient had a trial of or contraindication to TWO of the following preferred agents: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   150mg/mL: #1mL per 28 days.
   125mg/5mL: #15mL per 28 days.

   If no, continue to #7.

7. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) (ICD-10 M08.80) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion
   Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of ERA

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   75mg/0.5mL: #0.5mL per 28 days.
   150mg/mL: #1mL per 28 days.

   If no, continue to #8.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
   The patient has shown improvement in HS symptoms
   Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
   The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), adalimumab-adaz, Simlandi
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   150mg/mL: #4mL per 28 days.
   300mg/2mL: #4mL per 28 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Ankylosing spondylitis (AS: a type of joint condition)
   - Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   - Enthesitis-related arthritis (ERA: a type of joint condition)
   - Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

   (Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Otezla (apremilast)
  - You are 18 years of age or older AND have tried or have a contraindication to FOUR of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You meet ONE of the following:
  - You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
  - You are 6 to 17 years of age AND have tried or have a contraindication to THREE of the preferred medications: Enbrel (etanercept), Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Rinvoq (upadacitinib)
  - You are 18 years of age or older AND have tried or have a contraindication to THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

(Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)

If you have enthesitis-related arthritis, renewal also requires:
- You have experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:

- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), adalimumab-adaz, Simlandi

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosentyx.

REFERENCES

Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.

Created: 02/15
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

SELADELPAR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELADELPAR LYSINE	LIVDELZI	49816		GPI-10 (5278007050)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   The patient has an elevated alkaline phosphatase (ALP) level
   The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
   The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   The patient does NOT have decompensated cirrhosis (Child-Pugh B or C)
   Livdelzi will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Iqirvo [elafibranor])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   Livdelzi will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   Livdelzi will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELADELPAR

INITIAL CRITERIA (CONTINUED)

4. Is alleviation of pruritus a treatment goal?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #5.

5. Has the patient had a trial of or contraindication to ONE of the following preferred agents: Ocaliva (obeticholic acid), Iqirvo (elafibranor)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for approval:
   You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   - You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   - You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   - You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
   You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)
   You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Iqirvo [elafibranor])
   (Initial denial text continued on the next page)

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SELADELPAR

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- Livdelzi will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
- Livdelzi will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

You meet ONE of the following:
- Alleviation of (decreasing) your pruritus (itching) is a goal of treatment with Livdelzi
- You had a trial of or contraindication to (harmful for you to use) ONE of the following preferred medications: Ocaliva (obeticholic acid), Iqirvo (elafibranor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELADELPAR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   The patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Livdelzi
   Livdelzi will NOT be used concurrently with any other second-line PBC treatment (i.e., Ocaliva [obeticholic acid], Iqirvo [elafibranor])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for renewal:
   You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Livdelzi
   You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Iqirvo [elafibranor])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Livdelzi.

REFERENCES
Livdelzi [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/11/24
Created: 08/24
Client Approval: 11/24
P&T Approval: 04/24

SELEXIPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELEXIPAG	UPTRAVI	42922		GPI-10 (4012007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by GPID or GPI-14 as follows (enter both approvals):**
   FIRST APPROVAL: Approve Uptravi 200-800mcg Titration Pack with a quantity limit of #200 per 28 days for 1 fill.
   SECOND APPROVAL: Approve the requested strength as follows:
   200mcg tablet: #8 per day.
   400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.
   1,800mcg vial: #2 per day.
   (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) greater than 2 Wood units
   (Initial denial text continued on next page)

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
- Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
- Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
- Oral cGMP stimulator (such as Adempas [riociguat])
- Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELEXIPAG

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   200mcg tablet: #8 per day.
   400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.
   1,800mcg vial: #2 per day.
   (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uptravi.

REFERENCES

Uptravi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; July 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/16
Client Approval: 06/24
P&T Approval: 01/24

SELINEXOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELINEXOR	XPOVIO	45854		GPI-10 (2156006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with bortezomib (Velcade) **AND** dexamethasone
   - The patient has received at least one prior therapy

   If yes, **approve all of the following for 12 months by GPID or GPI-14:**
   - **40 mg once weekly dose: #4 per 28 days.**
   - **60 mg once weekly dose: #4 per 28 days.**
   - **80 mg once weekly dose: #8 per 28 days.**
   - **100 mg once weekly dose: #8 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (RRMM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least four prior therapies for the treatment of RRMM
   - The patient's RRMM is refractory to **ALL** of the following:
     - Two proteasome inhibitors (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
     - Two immunomodulatory agents (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst])
     - One anti-CD38 monoclonal antibody (e.g., daratumumab [Darzalex])

   If yes, **approve all of the following for 12 months by GPID or GPI-14:**
   - **60 mg once weekly dose: #4 per 28 days.**
   - **80 mg once weekly: #8 per 28 days.**
   - **100 mg once weekly dose: #8 per 28 days.**
   - **80 mg twice weekly (160 mg total per week) dose: #32 per 28 days.**

   If no, continue to #3.

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two lines of systemic therapy

   If yes, **approve all of the following for 12 months by GPID or GPI-14:**
   - **40 mg once weekly dose: #4 per 28 days.**
   - **60 mg once weekly dose: #4 per 28 days.**
   - **40 mg twice weekly (80 mg total per week) dose: #8 per 28 days.**
   - **60 mg twice weekly (120 mg total per week) dose: #24 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (MM: a type of blood cancer)
      2. Relapsed or refractory multiple myeloma (RRMM: a type of blood cancer that returned or did not respond to treatment)
      3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), including DLBCL arising from follicular lymphoma

   B. You are 18 years of age or older
   C. **If you have multiple myeloma, approval also requires:**
      1. The requested medication will be used in combination with bortezomib (Velcade) and dexamethasone
      2. You have received at least one therapy before Xpovio

   D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
      1. The requested medication will be used in combination with dexamethasone
      2. You have received at least four prior therapies for the treatment of RRMM)
      3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
         a. Two proteasome inhibitors (such as bortezomib [Velcade], carfilzomib [Kyprolis])
         b. Two immunomodulatory agents (such as lenalidomide [Revlimid], pomalidomide [Pomalyst])
         c. One anti-CD38 monoclonal antibody (such as daratumumab [Darzalex])

   (Denial text continued on next page)

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

E. **If you have relapsed or refractory diffuse large B-cell lymphoma, approval also requires:**
   1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xpovio.

REFERENCES

- Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; July 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 07/19
Client Approval: 06/23
P&T Approval: 01/21

SELPERCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525		GPI-10 (2153577900)	

GUIDELINES FOR USE

4 Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's cancer has a *RET* (rearranged during transfection) gene fusion, as detected by an FDA-approved test

If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
- **40mg: #3 per day.**
- **80mg, 120mg, 160mg: #2 per day.**

If no, continue to #2.

5 Does the patient have a diagnosis of advanced or metastatic medullary thyroid cancer (MTC) (ICD-10 C73) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient's cancer has a *RET* (rearranged during transfection)-mutation, as detected by an FDA-approved test
- The patient requires systemic therapy

If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
- **40mg: #3 per day.**
- **80mg, 120mg, 160mg: #2 per day.**

If no, continue to #3.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

6 Does the patient have a diagnosis of advanced or metastatic thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient's cancer has a *RET* (rearranged during transfection) gene fusion, as detected by an FDA-approved test
- The patient requires systemic therapy
- The cancer is refractory to radioactive iodine therapy (if radioactive iodine is appropriate)

If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
- **40mg: #3 per day.**
- **80mg, 120mg, 160mg: #2 per day.**

If no, continue to #4.

7 Does the patient have a diagnosis of locally advanced or metastatic solid tumors and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- The patient's tumor has a *RET* (rearranged during transfection) gene fusion, as detected by an FDA-approved test
- The patient's tumor has progressed on or following prior systemic treatment OR the patient has no satisfactory alternative treatment options

If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
- **40mg: #3 per day.**
- **80mg, 120mg, 160mg: #2 per day.**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
   4. Locally advanced or metastatic solid tumors (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)

B. **If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 2 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. You require systemic therapy (treatment that targets the entire body)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 2 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. You require systemic therapy (treatment that targets the entire body)
   4. Your cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate

E. **If you have a locally advanced or metastatic solid tumors, approval also requires:**
   1. You are 2 years of age or older
   2. Your tumor has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. Your tumor has progressed (worsened) on or following prior systemic treatment (treatment that targets the entire body) OR you have no alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELPERCATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

- Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; September 2024.

Created: 07/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

SELUMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELUMETINIB	KOSELUGO	46451		GPI-10 (2153356550)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) and meet **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - The patient has symptomatic, inoperable plexiform neurofibromas (PN)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Koselugo 10mg: #10 per day.**

   Koselugo 25mg: #4 per day.
   -

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
   B. You are 2 to 17 years of age
   C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Koselugo.

REFERENCES

- Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 07/20
Client Approval: 08/20
P&T Approval: 07/20

SETMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SETMELANOTIDE ACETATE	IMCIVREE	47002		GPI-10 (6125386010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of obesity (ICD-10 E66.8, E66.9) **AND** meet the following criterion?
   The patient is 2 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Bardet-Biedl syndrome (BBS) (ICD-10 Q87.83)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, continue to #3.

3. Does the patient have a pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as determined by an FDA-approved test?

   If yes, **approve for 16 weeks by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SETMELANOTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:
You have a diagnosis of obesity (a condition where you have higher than normal body fat)
You are 2 years of age or older
You have ONE of the following:
- Bardet-Biedl syndrome (BBS: a genetic disorder)
- Pro-opiomelanocortin (POMC: type of protein) deficiency (low level), as determined by a Food and Drug Administration (FDA)-approved test
- Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of protein) deficiency, as determined by an FDA-approved test
- Leptin receptor (LEPR: type of protein) deficiency, as determined by an FDA-approved test

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SETMELANOTIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of obesity (ICD-10 E66.8, E66.9)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have Bardet-Biedl syndrome (BBS) (ICD-10 Q87.83) and meet **ONE** of the following criteria?
   The patient is 2 to 17 years of age AND has lost at least 5 percent of baseline body mass index (BMI)
   The patient is 18 years of age or older AND has lost at least 5 percent of baseline body weight

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, continue to #3.

3. Does the patient have a pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as determined by an FDA-approved test, and meet **ONE** of the following criteria?
   The patient is 2 to 17 years of age AND has lost at least 5 percent of baseline body mass index (BMI)
   The patient is 18 years of age or older AND has lost at least 5 percent of baseline body weight

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SETMELANOTIDE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for renewal:
You have a diagnosis of obesity (a condition where you have higher than normal body fat)
You have ONE of the following:
- Bardet-Biedl syndrome (BBS: a genetic disorder)
- Pro-opiomelanocortin (POMC: type of protein) deficiency (low level)
- Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of protein) deficiency
- Leptin receptor (LEPR: type of protein) deficiency

You meet ONE of the following:
- You are 2 to 17 years of age AND have lost at least 5 percent of your baseline body mass index (BMI: a tool for evaluating body fat)
- You are 18 years of age or older AND have lost at least 5 percent of your baseline body weight

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Imcivree.

REFERENCES
Imcivree [Prescribing Information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; December 2024.

Created: 02/21
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/25

SILDENAFIL IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		28273	GPI-14 (40143060102020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #37.5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for approval:

You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

You are 18 years of age or older

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)

Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units

You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)

You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #37.5mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

SILDENAFIL SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, LIQREV, SILDENAFIL CITRATE		33186 54078	GPI-14 (40143060101920, 40143060101825)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 1 to 17 years of age
   The request is for Revatio (sildenafil) suspension
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])
   The patient is unable to swallow pills and has tried crushed sildenafil tablets

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for **Revatio (sildenafil)** suspension **AND** the patient meets the following criterion?
   The patient is unable to swallow pills and has tried crushed sildenafil tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #26.13mL per day.**
   If no, continue to #6.

6. Is the request for **Liqrev** suspension and the patient meets **ALL** of the following criteria?
   The patient is unable to swallow Revatio (sildenafil) tablets
   The patient had a trial of generic sildenafil powder for suspension

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8.13mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for approval:

You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

If you are 1 to 17 years of age, approval also requires:

- You are requesting Revatio (sildenafil) suspension
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
- You are unable to swallow pills AND you have tried crushed sildenafil tablets

If you are 18 years of age or older, approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR) greater than 2 Wood units
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

If you are requesting Revatio (sildenafil) suspension, you are unable to swallow pills AND you have tried crushed sildenafil tablets
If you are requesting Liqrev suspension, you are unable to swallow Revatio (sildenafil) tablets AND you have tried generic sildenafil powder for suspension

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 1 to 17 years of age **AND** meets the following criterion?
   The request is for Revatio (sildenafil) suspension

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes**, approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   Revatio (sildenafil): #26.13mL per day.
   Liqrev (sildenafil): #8.13mL per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for renewal:

You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

If you are 1 to 17 years of age, approval also requires:

- You are requesting Revatio (sildenafil) suspension
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

If you are 18 years of age or older, approval also requires:

- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio and Liqrev.

REFERENCES

Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.
Liqrev [Prescribing Information]. Farmville, NC: CMP Pharma Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

SILDENAFIL TABLET

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		24758	GPI-14 (40143060100320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 1 to 17 years of age
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

SILDENAFIL TABLET

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #12 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   (Initial denial text continued on next page)

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SILDENAFIL TABLET

INITIAL CRITERIA (CONTINUED)

If you are 1 to 17 years of age, approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

If you are 18 years of age or older, approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  Pulmonary vascular resistance (PVR) greater than 2 Wood units
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 1 to 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #12 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You are 1 year of age or older
   You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

SIMVASTATIN 80

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EZETIMIBE/ SIMVASTATIN	VYTORIN		23126	GPI-14 (39994002300350)	
SIMVASTATIN	ZOCOR, SIMVASTATIN		26535	GPI-14 (39400075000360)	

GUIDELINES FOR USE

1. Has the patient been taking the requested medication for at least 12 months?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIMVASTATIN 80 (VYTORIN, ZOCOR)** requires the following rule(s) be met for approval:
   A. You have been taking the medication for at least 12 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vytorin and Zocor.

REFERENCES

- Vytorin [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.
- Zocor [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/14/21
Created: 08/11
Client Approval: 05/21
P&T Approval: 08/11

SIMVASTATIN ORAL SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIMVASTATIN	FLOLIPID		41189 41192	GPI-14 (39400075001810, 39400075001820)	

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   The patient had a trial of or contraindication to simvastatin tablets
   The patient has dysphagia (ICD-10 Group R13.1), difficulty swallowing tablets, or has a feeding tube (e.g., G-tube or J-tube)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient also requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #3.
   If no, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of 5mL per day.**

3. Does the patient meet **ALL** of the following criteria?
   The patient is between 40 to 75 years old
   The requested quantity is within the low to moderate intensity daily dosage of 5 to 40 mg
   The patient is not concurrently taking any of the below secondary prevention medications for cardiovascular disease:
   Aspirin/dipyridamole (Aggrenox)
   Clopidogrel (Plavix)
   Dipyridamole
   Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
   Prasugrel (Effient)
   Ticagrelor (Brilinta)
   Ticlopidine
   Vorapaxar (Zontivity)

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of 5mL per day at zero copay.**

   If no, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of 5mL per day (Do NOT enter a zero copay).**

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SIMVASTATIN ORAL SUSPENSION

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:
You have tried or have a contraindication to (harmful for you to use) simvastatin tablets
You have dysphagia (difficulty swallowing), difficulty swallowing tablets, or a feeding tube (such as a G-tube or J-tube)
Requests for zero-dollar cost share also requires the following:
You are between 40 to 75 years old
The requested quantity is within the low to moderate intensity daily dosage of 5 to 40 mg
You are not concurrently (at the same time) taking any of the below secondary prevention medications for cardiovascular disease (heart disease):
Aspirin/dipyridamole (Aggrenox)
Clopidogrel (Plavix)
Dipyridamole
Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
Prasugrel (Effient)
Ticagrelor (Brilinta)
Ticlopidine
Vorapaxar (Zontivity)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Flolipid.

This guideline also applies to plans where the pharmacy benefit allows for coverage of Flolipid at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to Flolipid, which is included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

Flolipid [Prescribing Information]. Brooksville, FL: Salerno Pharmaceuticals LP; June 2020.
U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2023.
U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2023.

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SIMVASTATIN ORAL SUSPENSION

Created: 03/18
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 01/18

SIPONIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIPONIMOD	MAYZENT	45670		GPI-10 (6240707020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
   - **Mayzent 2mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
   - **Mayzent 0.25mg: #4 per day.**
   - **Mayzent 1mg: #1 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype
   (Initial denial text continued on next page)

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SIPONIMOD

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SIPONIMOD

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient has demonstrated a clinical benefit compared to pre-treatment baseline

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
   - **Mayzent 2mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
   - **Mayzent 0.25mg: #4 per day.**
   - **Mayzent 1mg: #1 per day.**

   If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:
A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
B. You have demonstrated a clinical benefit compared to pre-treatment baseline
C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SIPONIMOD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

- Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 04/19
Client Approval: 06/24
P&T Approval: 10/19

SIROLIMUS TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIROLIMUS	HYFTOR		52138	GPI-10 (9078407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for approval:
   A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)
   B. You are 6 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial at the end of the guideline.

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SIROLIMUS TOPICAL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for renewal:

A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyftor.

REFERENCES

- Hyftor [Prescribing Information]. Bethesda, MD: Nobelpharma America, LLC.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 08/22
Client Approval: 08/22
P&T Approval: 07/22

SODIUM/CALCIUM/MAG/POT OXYBATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV	46743		GPI-10 (6245990420)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does not have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial and failure of or contraindication to armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried TWO of the following: venlafaxine, fluoxetine, or a TCA (e.g., amitriptyline, clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography has ruled out non-narcolepsy causes of EDS [**Note to pharmacist**: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals]
   - The patient has low Orexin/Hypocretin levels on CSF assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 months or more and an Epworth Sleepiness Scale (ESS) score greater than 10
   - The patient meets ONE of the following:
     - The patient is 7 to 17 years of age AND had a trial and failure of or contraindication to one generic stimulant indicated for EDS in narcolepsy (e.g., amphetamine, dextroamphetamine, or methylphenidate)
     - The patient is 18 years of age or older AND had a trial and failure of or contraindication to one agent from EACH of the following categories:
       - Generic typical stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)
       - Armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep disorder)
   B. You are not concurrently on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   4. You tried and failed or have a contraindication (harmful for) to armodafinil OR modafinil

D. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. If you are 7 to 17 years old, you tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine, dextroamphetamine, or methylphenidate)
   6. If you are 18 years or older, you tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
      a. Generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.)
      b. Armodafinil OR modafinil

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (uncontrollable daytime sleepiness)
      2. Idiopathic hypersomnia (IH: a type of sleep disorder)
   B. You are not concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]
   C. **If you have narcolepsy, renewal also requires you meet ONE of the following:**
      1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
      2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
      3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

   (Renewal denial text continued on next page)

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA (CONTINUED)

D. **If you have idiopathic hypersomnia, renewal also requires you meet ONE of the following**:
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xywav.

REFERENCES

- Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 11/20
Client Approval: 11/22
P&T Approval: 10/22

SODIUM OXYBATE-LUMRYZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	LUMRYZ	12346		GPI-10 (6245006020)	FORM ≠ SOLUTION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and meet **ALL** of the following criteria?
   The patient is 7 years of age or older
   Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   The patient had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])
   The patient had a trial of generic sodium oxybate
   Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   Lumryz 28-day Starter Pack: #1 per day for 1 fill only.
   4.5gm packet: #1 per day.
   6gm packet: #1 per day.
   7.5gm packet: #1 per day.
   9gm packet: #1 per day.

   If no, continue to #2.

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   The patient is 7 years of age or older
   Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months
   The patient has an Epworth Sleepiness Scale (ESS) score of greater than 10
   The patient had a trial of or contraindication to generic sodium oxybate
   Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient's diagnosis confirmed by **ONE** of the following criteria?
   The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs)
   The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to Pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

4. Is the patient 7 to 17 years of age **AND** meets the following criterion?
   The patient had a trial of or contraindication to a generic typical stimulant (e.g., amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   Lumryz 28-day Starter Pack: #1 per day for 1 fill only.
   4.5gm packet: #1 per day.
   6gm packet: #1 per day.
   7.5gm packet: #1 per day.
   9gm packet: #1 per day.

   If no, continue to #5.

5. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   The patient had a trial of or contraindication to a generic typical stimulant (e.g., amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   The patient had a trial of or contraindication to armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   Lumryz 28-day Starter Pack: #1 per day for 1 fill only.
   4.5gm packet: #1 per day.
   6gm packet: #1 per day.
   7.5gm packet: #1 per day.
   9gm packet: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for approval:
You have ONE of the following:
- Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
- Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

If you have cataplexy with narcolepsy, approval also requires:
- You are 7 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
- You had a trial of generic sodium oxybate
- You had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])
- You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:
- You are 7 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
- You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

You have excessive daytime sleepiness (EDS) persisting for at least 3 months
You have an Epworth Sleepiness Scale (ESS: questionnaire used to assess daytime sleepiness) score of greater than 10
You had a trial of or contraindication to (harmful for you to use) generic sodium oxybate
Your diagnosis is confirmed by ONE of the following:
- You have a Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND at least 2 early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
- You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less AND at least one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
- You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)

If you are 7 to 17 years old, approval also requires:
- You had a trial of or contraindication to (harmful for you to use) a generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

If you are 18 years or older, approval also requires:
- You had a trial of or contraindication to (harmful for you to use) a generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
- You had a trial of or contraindication to (harmful for you to use) armodafinil (Nuvigil) or modafinil (Provigil)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy (ICD-10 Group G47.41) **AND** meet the following criterion?
   Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline
   The patient has demonstrated improvement in sleep latency compared to baseline

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   4.5gm packet: #1 per day.
   6gm packet: #1 per day.
   7.5gm packet: #1 per day.
   9gm packet: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for renewal:
You have narcolepsy (a type of sleep condition)
You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
You meet ONE of the following:
- You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
- You have maintained an improvement in Epworth Sleepiness Scale (ESS: questionnaire used to assess daytime sleepiness) scores by at least 25 percent compared to baseline
- You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep) compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumryz.

REFERENCES
Lumryz [Prescribing Information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 05/23
Client Approval: 10/24
P&T Approval: 10/22

SODIUM OXYBATE-XYREM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	XYREM, SODIUM OXYBATE	12346		GPI-10 (6245006020)	FORM = SOLUTION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does NOT have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient had a trial and failure of or contraindication to armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient has tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   - The patient has low orexin/hypocretin levels on CSF assay

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 or more months
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient 7 to 17 years of age **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to one generic stimulant indicated for excessive daytime sleepiness (EDS) in narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, continue to #8.
   If no, continue to #7.

7. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to one agent from EACH of the following categories:
     - Generic typical stimulant (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
     - Armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the request for generic sodium oxybate?

   If yes, **approve for 6 months for generic only by GPID or GPI-14 with a quantity limit of #18mL per day.**

   If no, continue to #9.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

9. Is the request for brand Xyrem **AND** the patient meets the following criterion?
   - The patient had a trial and failure of or contraindication to generic sodium oxybate

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve. **(NOTE: Please enter a proactive PA for 6 months for generic sodium oxybate by GPID or GPI-14 with a quantity limit of #18mL per day.)**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Idiopathic hypersomnia (IH: a type of sleep disorder)
   2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   3. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), or Restoril (temazepam)

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do NOT have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM (rapid eye movement) sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

4. You have tried and failed or have a contraindication (harmful for) to armodafinil (Nuvigil) OR modafinil (Provigil)
5. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

D. **If you have cataplexy in narcolepsy, approval also requires:**
1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
3. You have tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a tricyclic anti-depressant (such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
3. You have EDS persisting for 3 or more months
4. You have an Epworth Sleepiness Scale (tool to measure sleepiness) score of more than 10
5. Your diagnosis of narcolepsy is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND two or more early-onset rapid eye movement (REM) sleep test periods
   b. A Multiple Sleep Latency Test showing an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
   c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing low levels of a chemical that help with staying awake)
6. If you are 7 to 17 years old, you have tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], or methylphenidate [Ritalin])
7. If you are 18 years or older, you have tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
   a. Generic typical stimulant (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   b. Armodafinil (Nuvigil) OR modafinil (Provigil)
   c. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) **AND** meet the following criterion?
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   5. Narcolepsy (uncontrollable daytime sleepiness)
   6. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], or Restoril [temazepam]

C. **If you have narcolepsy, renewal also requires ONE of the following:**
   a. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   b. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   c. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep)

D. **If you have idiopathic hypersomnia, renewal also requires ONE of the following:**
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyrem.

REFERENCES

- Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/12/23
Created: 11/13
Client Approval: 05/23
P&T Approval: 10/22

SODIUM PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM PHENYLBUTYRATE	BUPHENYL, PHEBURANE, OLPRUVA, SODIUM PHENYLBUTYRATE	11317		GPI-14 (3090806000)	ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) and meet **ALL** of the following criteria?
   The patient's UCD is confirmed by enzymatic, biochemical or genetic testing
   The requested medication will be used as adjunctive therapy along with dietary protein restriction
   The patient's disorder cannot be managed by dietary protein restriction or amino acid supplementation alone

   If yes, continue to #2.
   If no, do not approve.

   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Buphenyl (sodium phenylbutyrate)?

   If yes, **approve the requested formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   Buphenyl tablets: #40 per day.
   Buphenyl powder: #25 grams per day.

   If no, continue to #3.

3. Is the request for Pheburane, and the patient meets **ALL** of the following criteria?
   The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve Pheburane for 12 months by GPID or GPI-14 with a quantity limit of #20 grams per day.**

   If no, continue to #4.

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SODIUM PHENYLBUTYRATE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Olpruva, and the patient meets **ALL** of the following criteria?
   The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
2 grams: #12 per day.
3 grams: #12 per day.
4 grams: #15 per day.
5 grams: #12 per day.
6 grams: #9 per day.
6.67 grams: #9 per day.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for approval:
You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction
Your disorder cannot be managed by dietary protein restriction or amino acid supplementation alone
If your request is for Pheburane or Olpruva, approval also requires:
You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder
You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) **AND** meet the following criterion?
   The patient has experienced a clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, continue to #2.
   If no, do not approve.

   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Buphenyl or Pheburane?

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 as follows:**
   Buphenyl tablets: #40 per day.
   Buphenyl powder: #25 grams per day.
   Pheburane: #20 grams per day.

   If no, continue to #3.

3. Is the request for Olpruva?

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   2 grams: #12 per day.
   3 grams: #12 per day.
   4 grams: #15 per day.
   5 grams: #12 per day.
   6 grams: #9 per day.
   6.67 grams: #9 per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for renewal:
You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
You have experienced a clinical benefit from baseline (for example you have normal fasting glutamine levels, low-normal fasting ammonia levels, mental status clarity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl, Olpruva, or Pheburane.

REFERENCES

Buphenyl [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; April 2023.
Olpruva [Prescribing Information]. Newton, MA: Acer Therapeutics Inc.; December 2022.
Pheburane [Prescribing Information]. Princeton, NJ: Medunik USA, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 08/19
Client Approval: 06/24
P&T Approval: 07/23

SOD PHENYLBUTYRATE-TAURURSODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOD PHENYLBUTYRAT /TAURURSODIOL	RELYVRIO	48081		GPI-10 (7450990270)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   If yes, **approve for a total of 6 months by HICL or GPI-10. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 21 days with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve for the remaining days with a quantity limit of #2 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOD PHENYLBUTYRATE-TAURURSODIOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS: a tool for evaluating functional status])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Relyvrio.

REFERENCES

- Relyvrio [Prescribing Information]. Cambridge, MA: Amylyx Pharmaceuticals, Inc., September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22

SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR	SOVALDI	40795		GPI-10 (1235308000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ONE** of the following criteria?
   The patient has genotype 2 or 3 infection AND is 3 to 17 years of age
   The patient has genotype 1, 2, 3, or 4 infection AND is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #14.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   Sovaldi will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. John's wort, Aptivus [tipranavir]/ritonavir)
   Solvadi will be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

4. Does the patient have genotype 2 infection and meet **ALL** of the following criteria?
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   Sovaldi will be used with ribavirin

   If yes, continue to #5.
   If no, continue to #6.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   The patient is 3 to 17 years of age
   The patient is 18 years of age or older AND had an intolerance or contraindication to the preferred agent: Epclusa

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   400mg tablets: #1 per day.
   200mg tablets: #1 per day.
   200mg pellets: #2 per day.
   150mg pellets: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have genotype 3 infection and meet **ALL** of the following criteria?
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   Sovaldi will be used with ribavirin

   If yes, continue to #7.
   If no, continue to #8.

7. Does the patient meet **ONE** of the following criteria?
   The patient is 3 to 17 years of age
   The patient is 18 years of age or older AND had an intolerance or contraindication to the preferred agent: Epclusa

   If yes, **approve for 24 weeks for the requested strength by GPID or GPI-14 as follows:**
   400mg tablets: #1 per day.
   200mg tablets: #1 per day.
   200mg pellets: #2 per day.
   150mg pellets: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have genotype 1 or 4 infection and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is treatment-naïve
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   Sovaldi will be used with peginterferon alfa and ribavirin

   If yes, continue to #9.
   If no, continue to #10.

9. Does the patient have an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa?

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   400mg tablets: #1 per day.
   200mg tablets: #1 per day.
   200mg pellets: #2 per day.
   150mg pellets: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Does the patient have genotype 1 infection and meet **ALL** of the following criteria?
    The patient is 18 years of age or older
    The patient is treatment-naïve
    The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    Sovaldi will be used with ribavirin
    The patient has a contraindication to interferon (interferon ineligible)

    If yes, continue to #11.
    If no, continue to #12.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

11. Does the patient have an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa?

    If yes, **approve for 24 weeks for the requested strength by GPID or GPI-14 as follows:**
    400mg tablets: #1 per day.
    200mg tablets: #1 per day.
    200mg pellets: #2 per day.
    150mg pellets: #1 per day.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

12. Is the request to prevent post-transplant HCV reinfection and the patient meets **ALL** of the following criteria?
    The patient has hepatocellular carcinoma (ICD-10 C22.0)
    The patient is awaiting liver transplantation
    Sovaldi will be used with ribavirin as pre-transplant treatment

    If yes, **approve for 48 weeks for the requested strength by GPID or GPI-14 as follows:**
    400mg tablets: #1 per day.
    200mg tablets: #1 per day.
    200mg pellets: #2 per day.
    150mg pellets: #1 per day.

    If no, continue to #13.

13. Has the patient previously failed treatment with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir) and meets **ALL** of the following criteria?
    The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

    If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
    400mg tablets: #1 per day.
    200mg tablets: #1 per day.
    200mg pellets: #2 per day.
    150mg pellets: #1 per day.

    If no, continue to #14.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

14. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

If yes, **approve as indicated per guidance in AASLD/IDSA.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:
You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
You have genotype 2 or 3 infection (types of hepatitis C virus) and are 3 to 17 years of age OR you have genotype 1, 2, 3, or 4 infection (types of hepatitis C virus) and are 18 years of age or older
You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
You will NOT use Sovaldi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. John's wort, Aptivus [tipranavir]/ritonavir)
You will NOT use Sovaldi concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
If you have genotype 2 infection, approval also requires:
You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
Sovaldi will be used with ribavirin
You meet ONE of the following:
You are 3 to 17 years of age
You are 18 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa
(Denial text continued on the next page)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

If you have genotype 3 infection, approval also requires:
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
- Sovaldi will be used with ribavirin
- You meet ONE of the following:
  - You are 3 to 17 years of age
  - You are 18 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

If you have genotype 1 infection, approval also requires:
- You are 18 years of age or older
- You are treatment-naïve (no prior treatment)
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
- Sovaldi will be used with peginterferon alfa and ribavirin OR Sovaldi will be used with ribavirin if you have a contraindication to (harmful for you to use) interferon
- You had an intolerance (side effect) or contraindication to ONE of the following preferred medications: Harvoni, Epclusa

If you have genotype 4 infection, approval also requires:
- You are 18 years of age or older
- You are treatment-naïve (no prior treatment)
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
- Sovaldi will be used with peginterferon alfa and ribavirin
- You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa

If Sovaldi will be used to prevent post-transplant HCV reinfection (getting infected again with HCV after transplant), approval also requires:
- You have hepatocellular carcinoma (HCC: a type of liver cancer)

If you had a previous treatment failure with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir), approval also requires:
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage and scarring)
- Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

(Denial text continued on the next page)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

Sovaldi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sovaldi.

REFERENCES

Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.
Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing. Available online at http://www.hcvguidelines.org/full-report-view Accessed October 2023.

Created: 01/14
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

SOFOSBUVIR/VELPATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR	EPCLUSA, SOFOSBUVIR-VELPATASVIR	43561		GPI-10 (1235990265)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
   The patient is 3 years of age or older
   The patient has genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   Epclusa will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. John's wort)
   Epclusa will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient does not have cirrhosis
   The patient has compensated cirrhosis (Child-Pugh A)
   The patient has decompensated cirrhosis (moderate or severe hepatic impairment; Child- Pugh B or C) AND Epclusa will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   400mg-100mg tablets: #1 per day.
   200mg-50mg tablets: #1 per day.
   200mg-50mg pellets: #2 per day.
   150mg-37.5mg pellets: #1 per day.

   If no, continue to #5.

5. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
   The patient has a contraindication to ribavirin (ribavirin ineligible)
   The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin
   The patient has failed prior treatment with an NS5A inhibitor-based regimen (e.g., Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin
   The patient is post-liver transplant, treatment-experienced, AND Epclusa will be used with ribavirin

   If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
   400mg-100mg tablets: #1 per day.
   200mg-50mg tablets: #1 per day.
   200mg-50mg pellets: #2 per day.
   150mg-37.5mg pellets: #1 per day.

   If no, continue to #6.

6. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

- You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
- You are 3 years of age or older
- You have genotype 1, 2, 3, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
- You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
- You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
- You will NOT use Epclusa concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV [human immunodeficiency virus] regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. John's wort)
- You will NOT use Epclusa concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
- You meet ONE of the following:
  - You do not have cirrhosis (liver damage and scarring)
  - You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
  - You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (moderate or severe liver impairment; Child-Pugh B or C [a score that evaluates the severity of liver damage]), and you meet ONE of the following:
    - You will use Epclusa with ribavirin
    - You have a contraindication to (harmful for you to use) ribavirin
    - You have failed prior treatment with a sofosbuvir-based regimen (such as sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin
    - You have failed prior treatment with an NS5A inhibitor-based regimen (such as Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin
    - You received a liver transplant (replaced your liver), are treatment-experienced (failed prior treatment), AND Epclusa will be used with ribavirin

(Denial text continued on next page)

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

Epclusa will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epclusa.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 27, 2023.

Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/22/24
Created: 07/16
Client Approval: 06/24
P&T Approval: 04/24

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		GPI-10 (1235990380)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #8.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   Vosevi will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. John's wort, HIV regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz)
   Vosevi will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naive and meets **ALL** of the following criteria?
   The patient has genotype 3 infection
   The patient has compensated cirrhosis
   The patient has NS5A RAS Y93H polymorphism

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #5.

5. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   The patient has failed prior treatment with a full course of an HCV regimen containing an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a DAA (e.g., Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #7.

7. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   The patient failed prior treatment with Vosevi
   Vosevi will be used with ribavirin

   If yes, **approve for 24 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #8.

8. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
You are 18 years of age or older
You have genotype 1, 2, 3, 4, 5 or 6 infection (types of hepatitis C virus)
You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
You will NOT use Vosevi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. John's wort, HIV (human immunodeficiency virus) regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz)
You will NOT use Vosevi concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)

If you are treatment-naïve (no prior treatment), approval also requires:

You have genotype 3 infection
You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms)
You have NS5A resistance-associated substitution (RAS) Y93H polymorphism (variations in a type of hepatitis C virus protein)

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

If you are treatment-experienced (failed prior treatment), approval also requires:
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
- You meet ONE of the following:
  - You have failed a full course of a regimen containing an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a direct-acting antiviral (such as Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant (replaced your liver or kidney)
  - You have failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])
  - You have failed prior treatment with Vosevi AND Vosevi will be used with ribavirin

Vosevi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 30, 2023.

Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/22/24
Created: 08/17
Client Approval: 06/24
P&T Approval: 04/24

SOFPIRONIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFPIRONIUM BROMIDE	SOFDRA	49707		GPI-10 (9097008320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis (ICD-10 L74.510) and meet **ALL** of the following criteria?
   The patient is 9 years of age or older
   The patient has primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least 6 months duration with all secondary causes ruled out
   The patient had a trial of a prescription strength aluminum chloride product (e.g., Drysol)
   The patient had a trial of the preferred topical anticholinergic agent: Qbrexza (glycopyrronium tosylate)
   Sofdra will NOT be used concurrently with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Qbrexza [glycopyrronium tosylate])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **TWO** of the following criteria?
   Symptoms occur bilaterally
   Symptoms impair daily activities
   The patient has at least one episode per week
   Onset occurred prior to the patient turning 25 years of age
   The patient has a family history of primary axillary hyperhidrosis
   Symptoms do not occur during sleep

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.34mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFPIRONIUM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFPIRONIUM (Sofdra)** requires the following rule(s) be met for approval:
You have primary axillary hyperhidrosis (excessive underarm sweating)
You are 9 years of age or older
You have primary axillary hyperhidrosis as evidenced by focal (limited to a particular area of the body), visible, excessive sweating of at least 6 months duration with all secondary causes (caused by another medical condition) ruled out
You have tried a prescription strength aluminum chloride product (such as Drysol)
You have tried the preferred topical anticholinergic medication: Qbrexza (glycopyrronium tosylate)
You will NOT use Sofdra concurrently (at the same time) with other topical anticholinergics used for primary axillary hyperhidrosis (such as Qbrexza [glycopyrronium tosylate])
You have at least two of the following:
Symptoms occur bilaterally (on both sides of the body)
Symptoms impair daily activities
You have at least one episode per week
Onset occurred before you turn(ed) 25 years old
You have a family history of primary axillary hyperhidrosis
Symptoms do not occur during sleep

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sofdra.

REFERENCES

Sofdra [Prescribing Information]. Wayne, PA: Botanix SB Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 07/24
Client Approval: 07/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLIFENACIN SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLIFENACIN SUCCINATE	VESICARE LS		47476	GPI-14 (54100055201820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurogenic detrusor overactivity and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to TWO of the following:
     - Anticholinergics (e.g., oxybutynin)
     - Beta-3 agonists (e.g., mirabegron)
   - The patient is unable to swallow oral solifenacin tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:
   A. You have neurogenic detrusor overactivity (type of bladder dysfunction)
   B. You are 2 years of age or older
   C. You had a trial of or contraindication (harmful for) to TWO of the following:
      1. Anticholinergics (such as oxybutynin)
      2. Beta-3 agonists (such as mirabegron)
   D. You are unable to swallow oral solifenacin tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vesicare LS.

REFERENCES

- Vesicare LS [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 05/21
Client Approval: 11/21
P&T Approval: 10/21

SOLRIAMFETOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLRIAMFETOL	SUNOSI	45666		GPI-10 (6137007020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** the narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) **AND** that OSA is confirmed by **ONE** of the following criteria?
   - Polysomnography
   - Home sleep apnea testing devices
   - Hospital-based bedside monitoring

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient had a trial of or contraindication to modafinil or armodafinil
   - The patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weight-loss intervention (if BMI > 30)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:
   A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
   (Initial denial text continued on the next page)

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SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
      i. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
      ii. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** one (1) early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** one (1) SOREMP (within about 15 minutes) on a sleep study (polysomnography) the night before the MSLT, with the sleep study ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
      iii. You have low orexin levels on a cerebrospinal fluid (CSF) assay (a test to determine the amount of a type of chemical for wakefulness in your brain)
   2. You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   3. Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   4. You have tried one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval also require:**
   1. Your diagnosis of OSA is confirmed by a sleep study (polysomnography), home sleep apnea testing devices, or hospital-based bedside monitoring
   2. You have had Excessive Daytime Sleepiness (EDS) for at least 3 months and your Epworth Sleepiness Scale (ESS) score is more than 10
   3. You have tried modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)
   4. You have been on a treatment for the obstructive causes of OSA, for at least one month since initiation, and you have been counseled on weight-loss intervention [if your BMI (Body Mass Index: a measure of body fat based on height and weight) is greater than 30]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOLRIAMFETOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA) **AND** meet the following criterion?
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:
   A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
   B. You have sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES

- Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 07/19
Client Approval: 04/20
P&T Approval: 10/19

SOMAPACITAN-BECO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMAPACITAN-BECO	SOGROYA	46831		GPI-10 (3010000720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3) and meet **ALL** of the following criteria?
   The patient is 2.5 to 17 years of age
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity that is less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
      You are 2.5 to 17 years of age
      Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
      Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
      You meet ONE of the following:
         Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
         Your height velocity is less than the 25th percentile for your age
         You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
   (Initial denial text continued on next page)

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

If you have growth hormone deficiency, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMAPACITAN-BECO

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3) and meet **ALL** of the following criteria?
   The patient is 2.5 to 17 years of age
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMAPACITAN-BECO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are 2.5 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
- You meet ONE of the following:
  - Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)

Renewal request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMAPACITAN-BECO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sogroya.

REFERENCES

Sogroya [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 05/23
Client Approval: 05/24
P&T Approval: 01/24

SOMATROGON-GHLA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROGON-GHLA	NGENLA	47896		GPI-10 (3010001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3) and meet **ALL** of the following criteria?
   The patient is 3 to 17 years of age
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   The patient had a trial of or contraindication to ONE of the following preferred agents: Skytrofa (lonapegsomatropin-tcgd) or Sogroya (somapacitan-beco)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity that is less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROGON-GHLA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
You are 3 to 17 years of age
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Skytrofa (lonapegsomatropin-tcgd) or Sogroya (somapacitan-beco)
You meet ONE of the following:
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
- Your height velocity is less than the 25th percentile for your age
- You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

Request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROGON-GHLA

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3) and meet **ALL** of the following criteria?
   The patient is 3 to 17 years of age
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROGON-GHLA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for renewal:

- You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- You are 3 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
- You meet ONE of the following:
  - Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
- Renewal request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ngenla.

REFERENCES

Ngenla [Prescribing Information]. Ringaskiddy, Cork, Ireland: Pfizer Ireland Pharmaceuticals; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 08/23
Client Approval: 05/24
P&T Approval: 01/24

SOMATROPIN - GENOTROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	GENOTROPIN	02824		GPI-10 (3010002000)	MEDI-SPAN & FDB: BRAND = GENOTROPIN. MEDI-SPAN: BRAND = GENOTROPIN MINIQUICK.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure associated with Turner syndrome and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome (PWS) and meet **ALL** of the following criteria?
   The patient has a confirmed genetic diagnosis of PWS
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   The patient has no catch-up growth by age 2 years
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure associated with Turner syndrome (TS: a type of gene condition)
- Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
- Growth failure born small for gestational age (SGA)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have growth failure associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth failure due to Prader-Willi syndrome (PWS), approval also requires:
- You have a confirmed genetic diagnosis of Prader-Willi syndrome
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

(Initial denial text continued on next page)

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

If you have growth failure born small for gestational age (SGA), **approval also requires:**
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You had no catch-up growth by age 2 years
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Genotropin will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?
   Short stature associated with Turner syndrome
   Growth failure born small for gestational age (SGA)

   If yes, continue to #5.
   If no, continue to #6.

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome (PWS) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has improvement in body composition

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   - Growth failure associated with Turner syndrome (TS: a type of gene condition)
   - Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
   - Growth failure born small for gestational age (SGA)
   - Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have short stature associated with Turner syndrome or growth failure born small for gestational age, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth failure due to Prader-Willi syndrome, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have experienced improvement in body composition

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Genotropin will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - GENOTROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Genotropin.

REFERENCES

Genotropin [Prescribing Information]. New York, NY: Pharmacia & Upjohn Co.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

SOMATROPIN - HUMATROPE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	HUMATROPE	02824		GPI-10 (3010002000)	BRAND = HUMATROPE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of short stature or growth failure with short stature homeobox-containing (SHOX) gene deficiency and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   The patient has no catch-up growth by age 2 to 4 years
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   Short stature associated with Turner syndrome (TS: a type of gene condition)
   Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   Growth failure born small for gestational age (SGA)
   Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   (Initial denial text continued on next page)

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have short stature associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have short stature or growth failure with SHOX gene deficiency, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

If you have growth failure born small for gestational age, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You had no catch-up growth by age 2 to 4 years
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Humatrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN – HUMATROPE

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet ALL of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?
   Short stature associated with Turner syndrome
   Short stature or growth failure with SHOX deficiency
   Growth failure born small for gestational age (SGA)

   If yes, continue to #5.
   If no, continue to #6.

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SOMATROPIN - HUMATROPE

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   - Short stature associated with Turner syndrome (TS: a type of gene condition)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   - Growth failure born small for gestational age (SGA)
   - Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN - HUMATROPE

RENEWAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have short stature associated with Turner syndrome, short stature or growth failure with SHOX deficiency, or growth failure born small for gestational age, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Humatrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Humatrope.

REFERENCES
Humatrope [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	NORDITROPIN FLEXPRO	02824		GPI-10 (3010002000)	BRAND = NORDITROPIN FLEXPRO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For short stature associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For short stature associated with Noonan syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   (Initial criteria continued on next page)

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SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

For short stature in pediatric patients born small for gestational age (SGA), approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 to 4 years
- The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, Surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

For growth failure due to Prader-Willi syndrome (PWS), approval requires ALL of the following:

- Confirmed genetic diagnosis of PWS
- Therapy is prescribed by or in consultation with an endocrinologist

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   2. Short stature associated with Turner syndrome (TS: a type of gene condition)
   3. Short stature associated with Noonan syndrome (a type of gene condition)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)

This medication will not be approved for treatment of ANY of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

(Initial denial text continued on next page)

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SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you are a child with short stature born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You had no catch-up growth by age 2 to 4 years
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

G. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

   For short stature associated with Noonan syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   (Renewal criteria continued on next page)

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SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

For short stature associated with Turner syndrome, renewal requires ALL of the following:
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For short stature in pediatric patients born small for gestational age (SGA), renewal requires ALL of the following:
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For adult growth hormone deficiency, renewal requires:
- Therapy is prescribed by or in consultation with an endocrinologist

For growth failure due to Prader-Willi syndrome (PWS), renewal requires ALL of the following:
- Therapy is prescribed by or in consultation with an endocrinologist
- Improvement in body composition

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for renewal:
A. You have ONE of the following diagnoses:
1. Pediatric growth hormone deficiency (GHD)
2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
4. Short stature born small for gestational age (SGA) in a pediatric patient
5. Adult growth hormone deficiency
6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:
1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (unknown cause for short height)

(Renewal denial text continued on next page)

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SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you are a child with short stature born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had improvement in body composition

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - NORDITROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Norditropin.

REFERENCES

- Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/21

SOMATROPIN - NUTROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	NUTROPIN AQ NUSPIN	02824		GPI-10 (3010002000)	FDB: BRAND = NUTROPIN AQ NUSPIN. MEDI-SPAN: BRAND = NUTROPIN AQ NUSPIN 5, NUTROPIN AQ NUSPIN 10, NUTROPIN AQ NUSPIN 20.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   The patient has NOT undergone a renal transplantation
   Therapy is prescribed by or in consultation with a nephrologist
   The patient's height or growth velocity is at least 2 standard deviations (SD) below the mean for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SOMATROPIN (Nutropin AQ)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have growth failure secondary to chronic kidney disease, approval also requires:
- You have NOT undergone a renal (kidney) transplantation
- Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
- Your height or growth velocity is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

If you have short stature associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Nutropin AQ will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   The patient has not undergone a renal transplantation
   The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Nutropin AQ)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA (CONTINUED)

If you have growth failure secondary to chronic kidney disease, renewal also requires:
- You have not had a renal (kidney) transplantation
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have short stature associated with Turner syndrome, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Nutropin AQ will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nutropin AQ.

REFERENCES

Nutropin AQ [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 12/23
P&T Approval: 10/23

SOMATROPIN - OMNITROPE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	OMNITROPE	02824		GPI-10 (3010002000)	BRAND = OMNITROPE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome (PWS) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   Therapy is prescribed by or in consultation with an endocrinologist
   There is confirmed genetic diagnosis of PWS
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   The patient has no catch-up growth by age 2 years
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth failure associated with Turner syndrome and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
   Growth failure born small for gestational age (SGA)
   Growth failure associated with Turner syndrome (TS: a type of gene condition)
   Growth hormone deficiency (GH: a type of hormone disorder with low growth hormone)
   (Initial denial text continued on next page)

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have growth failure due to Prader-Willi syndrome, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have a confirmed genetic diagnosis of Prader-Willi Syndrome
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)

If you have growth failure born small for gestational age, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You had no catch-up growth by age 2 years
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

(Initial denial text continued on next page)

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

If you have growth failure associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Omnitrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - OMNITROPE

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   Therapy is prescribed by or in consultation with an endocrinologist
   There is improvement in body composition

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

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SOMATROPIN - OMNITROPE

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have **ONE** of the following diagnoses?
   Growth failure born small for gestational age (SGA)
   Growth failure associated with Turner syndrome

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   - Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
   - Growth failure born small for gestational age (SGA)
   - Growth failure associated with Turner syndrome (TS: a type of gene condition)
   - Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN – OMNITROPE

RENEWAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have growth failure due to Prader-Willi syndrome, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have experienced improvement in body composition

If you have growth failure born small for gestational age or growth failure associated with Turner syndrome, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Omnitrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN – OMNITROPE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omnitrope.

REFERENCES

Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

SOMATROPIN - SAIZEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	SAIZEN, SAIZEN-SAIZENPREP	02824		GPI-10 (3010002010)	FDB: BRAND = SAIZEN, SAIZEN-SAIZENPREP. MEDI-SPAN: BRAND = SAIZEN, SAIZENPREP.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity that is less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - SAIZEN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
      You are a pediatric patient
      Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
      Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
      You meet ONE of the following criteria:
         Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
         Your height velocity is less than the 25th percentile for your age
         You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
   (Initial denial text continued on next page)

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SOMATROPIN - SAIZEN

INITIAL CRITERIA (CONTINUED)

If you have growth hormone deficiency, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)

Request for Saizen will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SAIZEN

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - SAIZEN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Saizen will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Saizen

REFERENCES
Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

SOMATROPIN - SEROSTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	SEROSTIM	02824		GPI-10 (3010002010)	BRAND = SEROSTIM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of HIV wasting/cachexia who meets **ALL** of the following criteria?
   - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   - Therapy is prescribed by or in consultation with ONE of the following specialists: gastroenterologist, nutritional support specialist, or infectious disease specialist
   - The patient is on HIV anti-retroviral therapy
   - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
   - The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
   - Alternative causes of wasting have been ruled out; alternative causes include:
     - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
     - Diarrhea
     - Inadequate energy (caloric) intake
     - Malignancies
     - Opportunistic infections
   - The patient meets **ONE** of the following criteria for weight loss:
     - 10% unintentional weight loss over 12 months
     - 7.5% unintentional weight loss over 6 months
     - 5% body cell mass (BCM) loss within 6 months
     - BCM less than 35% (men) AND a body mass index (BMI) less than 27 kg per meter squared
     - BCM less than 23% (women) of total body weight AND a body mass index (BMI) less than 27 kg per meter squared
     - BMI less than 18.5 kg per meter squared

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

2. Is the patient hypogonadal as defined by **ONE** of the following?
   - Total serum testosterone level of less than 300ng/dL (10.4 nmol/L)
   - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, **approve for 12 weeks by GPID or GPI-14 for all strengths.**

3. For patients who are hypogonadal, does the patient meet the following criterion?
   - The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for approval:
   A. You have HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
   B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist OR infectious disease specialist (doctor who specializes in the treatment of infections)
   D. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
   E. You have had an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
   F. You have had an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)

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SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

G. Alternative causes of wasting have been ruled out. Alternative causes may include:
   1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
   2. Diarrhea
   3. Inadequate energy (caloric) intake
   4. Malignancies (tumors)
   5. Opportunistic infections (an infection that can occur because of a weakened immune system)

H. You meet ONE of the following criteria for weight loss:
   1. 10% unintentional weight loss over 12 months
   2. 7.5% unintentional weight loss over 6 months
   3. 5% body cell mass (BCM) loss within 6 months
   4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
   5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
   6. BMI less than 18.5 kg per meter squared

I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
   1. You meet one of the following criteria for low testosterone:
      a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
      b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
      c. A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SEROSTIM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient received more than 24 weeks of therapy within the plan year?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a patient with HIV wasting/cachexia who meets **ALL** of the following criteria?
   - The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient has shown clinical benefit in muscle mass and weight as indicated by a 10% or greater increase in weight or BCM from baseline (**Note:** Current and baseline weight must be documented including dates of measurement)
   - The patient is on HIV anti-retroviral therapy

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal:
   A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
   B. You have NOT received more than 24 weeks of therapy within the plan year
   C. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   D. You have shown clinical benefit in muscle mass and weight as indicated by at least a 10 percent increase in weight or BCM (body cell mass) from baseline (Note: current and baseline weight must be documented including dates of measurement)
   E. You are on HIV anti-retroviral therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SEROSTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Serostim.

REFERENCES

- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 10/22
Client Approval: 11/22
P&T Approval: 04/21

SOMATROPIN - ZOMACTON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	ZOMACTON	02824		GPI-10 (3010002000)	BRAND = ZOMACTON

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents:
   Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient has a height velocity that is less than the 25th percentile for age
   The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - ZOMACTON

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of short stature born small for gestational age (SGA) and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   The patient has no catch-up growth by age 2 to 4 years
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of short stature or growth failure with short stature homeobox-containing (SHOX) gene deficiency and meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

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SOMATROPIN - ZOMACTON

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   - Short stature associated with Turner syndrome (TS: a type of gene condition)
   - Short stature born small for gestational age (SGA)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   - Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - ZOMACTON

INITIAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have short stature associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have short stature born small for gestational age, **approval also requires:**
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You had no catch-up growth by age 2 to 4 years
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

(Initial denial text continued on next page)

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SOMATROPIN - ZOMACTON

INITIAL CRITERIA (CONTINUED)

If you have short stature or growth failure with SHOX deficiency, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Zomacton will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZOMACTON

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   Athletic enhancement
   Anti-aging purposes
   Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   The request is for a pediatric patient
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?
   Short stature associated with Turner syndrome
   Short stature born small for gestational age (SGA)
   Short stature or growth failure with SHOX deficiency

   If yes, continue to #5.
   If no, continue to #6.

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SOMATROPIN - ZOMACTON

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   Therapy is prescribed by or in consultation with an endocrinologist
   The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   - Short stature associated with Turner syndrome (TS: a type of gene condition)
   - Short stature born small for gestational age (SGA)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   - Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN - ZOMACTON

RENEWAL CRITERIA (CONTINUED)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have short stature associated with Turner syndrome, short stature born small for gestational age, or short stature or growth failure with SHOX deficiency, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Zomacton will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zomacton

REFERENCES
Zomacton [Prescribing Information]. Parisppany, NJ: Ferring Pharmaceuticals Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

SOMATROPIN - ZORBTIVE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	ZORBTIVE		12767	GPI-14 (30100020102132)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of short bowel syndrome who meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)

   If yes, **approve for 4 weeks by GPID or GPI-14 for #1 vial per day (max dose not to exceed 8mg per day).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (digestive system doctor)
   C. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   D. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZORBTIVE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient been on the medication for 4 weeks?

   If yes, do not approve. [**Note**: The patient should only be approved for one 4 weeks fill in a lifetime.]
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve by GPID or GPI-14 for the remainder of therapy with a maximum of 4 weeks of therapy. (Please subtract any previous fills; maximum cumulative approval is for 4 weeks.).**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for renewal:
   A. You have short bowel syndrome (the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. You have not been on the requested medication for 4 weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZORBTIVE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zorbtive.

REFERENCES

- Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/21

SONIDEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SONIDEGIB PHOSPHATE	ODOMZO	42369		GPI-10 (2137006020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) and meet the following criteria?
   - The patient is 18 years of age or older
   - This is a recurrence of BCC after the patient has already had surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at end of the guideline.

2. Has the patient obtained the following tests prior to initiating therapy?
   - Baseline serum creatinine kinase (CK) level
   - Baseline serum creatinine
   - Pregnancy status of females of reproductive potential

   If yes, **approve for 12 months by HICL or GPI 10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:
   A. You have locally advanced basal cell carcinoma (BCC: type of skin cancer).
   B. You are 18 years of age or older
   C. This is a recurrence (disease returns) of basal cell carcinoma after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
   D. Baseline serum creatine kinase (CK: type of lab test) and serum creatinine levels have been obtained before starting therapy
   E. If you are a female of reproductive potential, you must verify your pregnancy status before starting therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SONIDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odomzo.

REFERENCES

- Odomzo [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 10/15
Client Approval: 12/21
P&T Approval: 01/22

SORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SORAFENIB TOSYLATE	NEXAVAR, SORAFENIB TOSYLATE	33400		GPI-10 (2153306040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable hepatocellular carcinoma?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SORAFENIB (Nexavar)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery)
      3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned or spread, is getting worse and is not responding to a type of treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Nexavar.

REFERENCES

- Nexavar [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/18/22
Created: 05/11
Client Approval: 06/22
P&T Approval: 02/14

SOTATERCEPT-CSRK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTATERCEPT-CSRK	WINREVAIR	49475		GPI-10 (4011007020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age and older
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient been on background PAH therapy (for at least 3 months) with at least TWO of the following agents from different drug classes?
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.**
   If no, continue to #4.

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SOTATERCEPT-CSRK

INITIAL CRITERIA (CONTINUED)

4. Is the patient on ONE agent from one of the following drug classes, **AND** has a contraindication or intolerance to ALL of the other drug classes?
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You are 18 years of age and older
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) greater than 2 Wood units
   (Initial denial text continued on next page)

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SOTATERCEPT-CSRK

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have been on background PAH therapy (for at least 3 months) with at least TWO of the following medications from different drug classes:
  - Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
  - Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
  - Oral cGMP stimulator (such as Adempas [riociguat])
  - Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
- You are on ONE medication from one of the following drug classes, AND you have a contraindication to (harmful for you to use) or intolerance (side effect) to ALL of the other drug classes:
  - Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
  - Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
  - Oral cGMP stimulator (such as Adempas [riociguat])
  - Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTATERCEPT-CSRK

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winrevair.

REFERENCES

Winrevair [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 04/24
Client Approval: 06/24
P&T Approval: 04/24

SOTORASIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTORASIB	LUMAKRAS	47400		GPI-10 (2153248000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer has a KRAS G12C-mutation, as determined by an FDA-approved test
   The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   120mg: #8 per day.
   240mg: #4 per day.
   320mg: #3 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Lumakras will be used in combination with Vectibix (panitumumab)
   The patient's cancer has a KRAS G12C-mutation, as determined by an FDA-approved test
   The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   120mg: #8 per day.
   240mg: #4 per day.
   320mg: #3 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

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SOTORASIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes, or has spread to other parts of the body)
- Metastatic colorectal cancer (mCRC: a type of digestive tract cancer that has spread to other parts of the body)

If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
- You have received at least one prior systemic therapy (treatment that targets the entire body)

If you have metastatic colorectal cancer, approval also requires:
- You are 18 years of age or older
- Lumakras will be used in combination with Vectibix (panitumumab)
- Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
- You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (types of cancer treatments)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumakras.

REFERENCES
Lumakras [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; January 2025.

Created: 07/21
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/25

SPARSENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPARSENTAN	FILSPARI	48721		GPI-10 (5648306500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient is at risk of disease progression
   Therapy is prescribed by or in consultation with a nephrologist
   The patient's diagnosis is confirmed by a biopsy
   The patient has proteinuria of at least 1 g/day
   The patient has an eGFR of at least 30 mL/min/1.73m^2
   The patient had a trial of or contraindication to at least 12 weeks of treatment with an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan)
   The patient has tried an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR has a contraindication to an SGLT2 inhibitor
   Filspari will NOT be used concurrently with an ACE-I (e.g., benazepril, lisinopril), an ARB (e.g., losartan, valsartan), an endothelin receptor antagonist (e.g., ambrisentan, bosentan), aliskiren, or Fabhalta (iptacopan)

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for approval:
   You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   You are 18 years of age or older
   You are at risk of disease progression (worsening)
   Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
   You have proteinuria (increased levels of protein in the urine) of at least 1 g/day
   You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73m^2
   (Initial denial text continued on next page)

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SPARSENTAN

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) at least 12 weeks of treatment with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

You have tried a sodium-glucose cotransporter-2 inhibitor (SGLT2 inhibitor: a type of medication used to protect kidneys, such as Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR you have a contraindication to an SGLT2 inhibitor

Filspari will NOT be used concurrently (at the same time) with an ACE-I (such as benazepril, lisinopril), an ARB (such as losartan, valsartan), an endothelin receptor antagonist (such as ambrisentan, bosentan), aliskiren, or Fabhalta (iptacopan)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SPARSENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   The patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria
   Filspari will NOT be used concurrently with an ACE-I (e.g., benazepril, lisinopril), an ARB (e.g., losartan, valsartan), an endothelin receptor antagonist (e.g., ambrisentan, bosentan), aliskiren, or Fabhalta (iptacopan)

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for renewal:
   You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   You have improved or stable kidney function compared to baseline (before starting Filspari) OR you have a reduction in proteinuria (lowered levels of protein in the urine)
   Filspari will NOT be used concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I, such as benazepril, lisinopril), an angiotensin receptor blocker (ARB, such as losartan, valsartan), an endothelin receptor antagonist (such as ambrisentan, bosentan), aliskiren, or Fabhalta (iptacopan)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filspari.

REFERENCES

Filspari [Prescribing Information]. San Diego, CA: Travere Therapeutics, Inc.; September 2024.

Created: 03/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

SPESOLIMAB-SBZO - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPESOLIMAB-SBZO	SPEVIGO		55498	GPI-14 (9025057770E530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized pustular psoriasis (GPP) (ICD-10 L40.1) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient weighs at least 40 kg (88 lbs)
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has a history of GPP as defined by the presence of sterile, macroscopically visible pustules on non-acral skin (per ERASPEN diagnostic criteria)
   Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for a total of 3 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #4mL for 1 fill.
   SECOND APPROVAL: Approve for 2 months with a quantity limit of #2mL per 28 days. (Please enter a START date of 1 week before the END date of the first approval.)

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for approval:
   You have generalized pustular psoriasis (GPP: a type of skin condition)
   You are 12 years of age or older
   You weigh at least 40 kilograms (88 pounds)
   Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   You have a history of GPP as defined by the presence of sterile, macroscopically visible pustules (blisters with non-infectious pus that can be seen with the naked eye) on non-acral skin (skin in areas of the body such as arms and legs) (per ERASPEN [European Rare and Severe Psoriasis Expert Network] diagnostic criteria)
   (Initial denial text continued on next page)

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SPESOLIMAB-SBZO - SQ

INITIAL CRITERIA (CONTINUED)

You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of GPP

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

SPESOLIMAB-SBZO - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized pustular psoriasis (GPP) (ICD-10 L40.1) and meet **ALL** of the following criteria?
   The patient has shown a clinical response to therapy
   Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for renewal:
   You have generalized pustular psoriasis (GPP: a type of skin condition)
   You have shown a clinical response to therapy
   You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of GPP

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spevigo.

REFERENCES

Spevigo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.

Created: 04/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

STIRIPENTOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
STIRIPENTOL	DIACOMIT	35461		GPI-10 (7260007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older AND weighs 7kg or more
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is currently being treated with clobazam
   - The patient had a trial of or contraindication to TWO of the following: valproic acid derivatives, clobazam, topiramate

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **250mg capsule: #12 per day.**
   - **500mg capsule: #6 per day.**
   - **250mg powder packet: #12 per day.**
   - **500mg powder packet: #6 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are 6 months of age or older AND weighs 7kg or more
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You are currently being treated with clobazam (a type of seizure drug)
   E. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivatives, clobazam, topiramate

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STIRIPENTOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient is currently being treated with clobazam

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **250mg capsule: #12 per day.**
   - **500mg capsule: #6 per day.**
   - **250mg powder packet: #12 per day.**
   - **500mg powder packet: #6 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are currently being treated with clobazam (type of seizure drug)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Diacomit.

REFERENCES

- Diacomit [Prescribing Information]. Beauvais, France: Biocodex, July 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 05/19
Client Approval: 08/22
P&T Approval: 10/22

SUNITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUNITINIB MALATE	SUTENT, SUNITINIB MALATE	33445		GPI-10 (2153307030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to imatinib mesylate (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET) (ICD-10 C25.4) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's tumor is progressive and well-differentiated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The requested medication will be used as adjuvant treatment
   The patient is at high risk of recurrent renal cell carcinoma following nephrectomy

   If yes, **approve for 12 months by HICL or GPI-10, with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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SUNITINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)
- Gastrointestinal stromal tumor (GIST: a type of digestive tumor)
- Unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET: a type of tumor in the pancreas that cannot be completely removed by surgery or has spread to other parts of the body)
- Renal cell carcinoma

If you have advanced renal cell carcinoma, approval also requires:
- You are 18 years of age or older

If you have gastrointestinal stromal tumor, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) imatinib mesylate (Gleevec)

If you have unresectable locally advanced or metastatic pancreatic neuroendocrine tumor, approval also requires:
- You are 18 years of age or older
- Your tumor is progressive (getting worse) and well-differentiated (looks like healthy cells)

If you have renal cell carcinoma, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as adjuvant (add-on) treatment
- You are at high risk of recurrent renal cell carcinoma (cancer returning) following nephrectomy (surgical removal of kidney)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sutent.

REFERENCES
Sutent [Prescriber Information]. New York, NY. Pfizer, Inc. August 2021.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUZETRIGINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUZETRIGINE	JOURNAVX	50239		GPI-10 (6417507000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe acute pain (ICD-10 R52, Group G89.1) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #29 for one fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SUZETRIGINE (Journavx)** requires the following rule(s) be met for approval:
   You have moderate to severe acute (short-term) pain
   You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Journavx.

REFERENCES

Journavx [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals, Inc.; January 2025.

Created: 02/25
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 04/25

TADALAFIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	CIALIS		20736 99409	GPI-14 (40304080000305) (40304080000302)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient tried or had a contraindication to at least **TWO** preferred formulary agents, including **ONE** agent from **EACH** of the following classes?
   - 5-alpha-reductase inhibitors: (e.g., finasteride or dutasteride)
   - Alpha blockers: (e.g., doxazosin, terazosin, tamsulosin, or alfuzosin)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Cialis 2.5mg OR 5mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erectile dysfunction?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is erectile dysfunction a covered benefit?

   If yes, continue to #5.
   If no, guideline does not apply.

5. Has the patient tried generic sildenafil (Viagra)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Cialis 2.5mg OR 5mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TADALAFIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TADALAFIL (Cialis)** requires the following rule(s) be met for approval:

A. You have benign prostatic hyperplasia (BPH: your prostate is too big causing difficulty urinating) OR erectile dysfunction (difficulty getting/keeping an erection)
B. **If you have benign prostatic hyperplasia (BPH), approval also requires:**
   1. You previously tried at least two preferred formulary alternatives, including one medication from each of the following classes:
      a. 5-alpha-reductase inhibitors: (such as finasteride or dutasteride)
      b. Alpha blockers: (such as doxazosin, terazosin, tamsulosin, or alfuzosin)
C. **If you have erectile dysfunction, approval also requires**:
   1. You have previously tried generic sildenafil (Viagra)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cialis.

REFERENCES

- Cialis [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 11/14
Client Approval: 08/20
P&T Approval: 01/18

TADALAFIL-ADCIRCA, ALYQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL		26587	GPI-14 (40143080000320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   (*Initial denial text continued on the next page)*

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TADALAFIL-ADCIRCA, ALYQ

INITIAL CRITERIA (CONTINUED)

Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units

You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)

You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-ADCIRCA, ALYQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcirca and Alyq.

REFERENCES

Adcirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2020.
Alyq [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

TADALAFIL-TADLIQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	TADLIQ		52585	GPI-14 (40143080001820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   Tadliq will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   Tadliq will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])
   The patient is unable to swallow tadalafil tablets

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-TADLIQ (Tadliq)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   (Initial denial text continued on the next page)

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TADALAFIL-TADLIQ

INITIAL CRITERIA (CONTINUED)

Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units
You will NOT use Tadliq concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
You are unable to swallow tadalafil tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-TADLIQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   Tadliq will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   Tadliq will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-TADLIQ (Tadliq)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   You will NOT use Tadliq concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tadliq.

REFERENCES

Tadliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

TAFAMIDIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		GPI-10 (4055008020)	
TAFAMIDIS	VYNDAMAX	45729		GPI-10 (4055008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cardiomyopathy associated with wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
   - The requested medication will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis [Attruby])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP
     (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
   - A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Vyndaqel: #4 per day.**
   - **Vyndamax: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAFAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:
You have cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
You will NOT use the requested medication concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as acoramidis [Attruby])
Your diagnosis is confirmed by ONE of the following:
- A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
- A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TAFAMIDIS

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis [Attruby])

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Vyndaqel: #4 per day.**
   - **Vyndamax: #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:
   You have cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
   You will NOT use the requested medication concurrently (at the same time) with other ATTR-CM TTR (transthyretin) stabilizers (such as acoramidis [Attruby])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES

- Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; October 2023.
- Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; October 2023.

Created: 05/19
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

TALAZOPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		GPI-10 (2153558040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 C79.81; Group C50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer is human epidermal growth factor receptor 2 (HER2)-negative
   The patient's cancer has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*), as confirmed by an FDA-approved companion diagnostic test for Talzenna
   The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #2**.**
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient does NOT have hormone receptor (HR)-positive breast cancer
   The patient has hormone receptor (HR)-positive breast cancer AND has received prior treatment with endocrine therapy or be considered inappropriate for endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Talzenna will be used in combination with Xtandi (enzalutamide)
   The patient's cancer has a homologous recombination repair (HRR) gene mutation

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUE ON NEXT PAGE

TALAZOPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   The patient had a bilateral orchiectomy
   The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   Talzenna will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron-Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALAZOPARIB (TALZENNA)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Locally advanced or metastatic breast cancer (cancer that has spread to nearby tissue or lymph nodes or other parts of the body)
      Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
   If you have locally advanced or metastatic breast cancer, approval also requires:
      You are 18 years of age or older
      Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
      You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (gBRCAm: a type of abnormal change in a gene), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic test for Talzenna
      You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
      You meet ONE of the following:
         You do not have hormone receptor (HR: a type of protein)-positive breast cancer
         You have hormone receptor (HR)-positive breast cancer, and you have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]), or endocrine therapy is considered inappropriate for you
   (Denial text continued on next page)

CONTINUE ON NEXT PAGE

TALAZOPARIB

GUIDELINES FOR USE (CONTINUED)

If you have prostate cancer, approval also requires:

- You are 18 years of age or older
- Talzenna will be used in combination with Xtandi (enzalutamide)
- Your cancer has a homologous recombination repair (HRR) gene mutation (a type of abnormal change in a gene)
- You meet ONE of the following:
  - You had a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
  - Talzenna will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron-Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talzenna.

REFERENCES

Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/19
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

TAPINAROF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAPINAROF	VTAMA	48031		GPI-10 (9025007500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
   Vtama will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
   Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   Topical retinoid (e.g., tazarotene cream/gel)
   Anthralin

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAPINAROF

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   The patient had a trial of or contraindication to a topical corticosteroid of medium potency or greater (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
   The patient had a trial of or contraindication to ONE of the following topical non-steroidal immunomodulating agents: Eucrisa (crisaborole), Opzelura (ruxolitinib)
   The patient had a trial of or contraindication to ONE of the following topical calcineurin inhibitors: Elidel (pimecrolimus), Protopic (tacrolimus)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Will Vtama be used concurrently with **ANY** of the following for atopic dermatitis?
   Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   If no, **approve for 3 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Plaque psoriasis (a type of skin condition)
      Atopic dermatitis (a type of skin condition)
   (Initial denial text continued on next page)

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TAPINAROF

INITIAL CRITERIA (CONTINUED)

If you have plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
- You will NOT use Vtama concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
- You had a trial of or contraindication to (harmful for you to use) TWO of the following (from different categories):
  - High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
  - Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
  - Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
  - Topical retinoid (such as tazarotene cream/gel)
  - Anthralin

If you have atopic dermatitis, approval also requires:
- You are 2 years of age or older
- You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
- You have tried or have a contraindication to ONE of the following topical non-steroidal immunomodulating medications (a type of medication): Eucrisa (crisaborole), Opzelura (ruxolitinib)
- You have tried or have a contraindication to ONE of the following topical calcineurin inhibitors (a type of medication): Elidel (pimecrolimus), Protopic (tacrolimus)
- You will NOT use Vtama concurrently (at the same time) with ANY of the following for atopic dermatitis:
  - Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)])
  - Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
  - Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
  - Potent immunosuppressants (such as azathioprine, cyclosporine)

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TAPINAROF

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

TAPINAROF

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease
   Vtama will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
   The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Will Vtama be used concurrently with **ANY** of the following for atopic dermatitis?
   Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], JAK inhibitors [e.g., Opzelura (ruxolitinib)])
   Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

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TAPINAROF

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Plaque psoriasis (a type of skin condition)
- Atopic dermatitis (a type of skin condition)

If you have plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease
- You will NOT use Vtama concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

If you have atopic dermatitis, renewal also requires:
- You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
- You will NOT use Vtama concurrently (at the same time) with ANY of the following for atopic dermatitis:
  - Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)])
  - Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
  - Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
  - Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vtama.

REFERENCES

Vtama [Prescribing Information]. Long Beach, CA: Dermavant Sciences, Inc.; December 2024.

Created: 05/22
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 07/24

TASIMELTEON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TASIMELTEON	HETLIOZ, HETLIOZ LQ, TASIMELTEON	40927		GPI-10 (6025007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-24 hour sleep-wake disorder (N24HSWD) (ICD-10 G47.24, G47.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is light-insensitive or has total blindness
   - The patient had a trial and failure of maximally-tolerated melatonin therapy
   - The requested medication is for the Hetlioz (tasimelteon) capsules

   If yes, **approve the capsule for a lifetime by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (ICD-10 Q93.88) and meet the following criterion?
   - The patient had a trial and failure of maximally-tolerated melatonin therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The requested medication is for brand Hetlioz capsules AND the patient is 16 years of age or older
   - The requested medication is for Hetlioz LQ oral suspension AND the patient is 3 years to 15 years of age

   If yes, **approve the requested medication for a lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Brand Hetlioz capsules: #1 per day.**
   - **Hetlioz LQ oral suspension: #5mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TASIMELTEON

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD: a type of sleep condition)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS: a type of developmental disorder that causes sleeping problems)

B. **If you have non-24 hour sleep-wake disorder, approval also requires:**
   1. You are 18 years of age or older
   2. You are light-insensitive (not affected by light) or have total blindness
   3. You have tried and failed maximally-tolerated melatonin therapy
   4. You are requesting the capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting brand Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz LQ oral suspension if you are 3 to 15 years old
   3. You have tried and failed maximally-tolerated melatonin therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Hetlioz/Hetlioz LQ.

REFERENCES

- Hetlioz/Hetlioz LQ [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.
- Tasimelteon [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 03/14
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/21

TAVABOROLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAVABOROLE	KERYDIN, TAVABOROLE	41353		GPI-10 (9015608000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) (ICD-10 B35.1) of the toenails?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of diabetes, peripheral vascular disease (PVD), or immunosuppression?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have pain surrounding the nail or soft tissue involvement?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient tried or have a contraindication to oral terbinafine OR oral itraconazole, **AND** ciclopirox topical solution?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL per 60 days.**

   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL per 30 days.**

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TAVABOROLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:
You have onychomycosis of the toenails (toenail fungus infection)
You meet ONE of the following:
- You have diabetes (a disorder with high blood sugar), peripheral vascular disease (PVD: a type of blood disorder), or a suppressed immune system
- You have pain surrounding the nail or soft tissue

You have tried or have a contraindication to (harmful for you to use) the following medications:
- Oral terbinafine OR oral itraconazole
- Ciclopirox topical solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerydin.

REFERENCES

Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/14
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/18

TAZEMETOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAZEMETOSTAT	TAZVERIK	46312		GPI-10 (2153367520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced epithelioid sarcoma (ICD-10 C49.9) and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient is not eligible for complete resection

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (ICD-10 Group C82) AND meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's tumors are positive for an EZH2 mutation as detected by an FDA-approved test AND the patient has received at least 2 prior systemic therapies
   - The patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TAZEMETOSTAT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic or locally advanced epithelioid sarcoma (a type of soft tissue cancer that has spread to other parts of the body or has spread from where it started to nearby tissue or lymph nodes)
   2. Relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or did not respond to treatment)

B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
   2. You are 16 years of age or older
   3. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years or older
   2. You meet ONE of the following:
      a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (treatment that targets the entire body)
      b. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tazverik.

REFERENCES

- Tazverik [Prescribing Information]. Cambridge, MA: Epizyme, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/20

TBO-FILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TBO-FILGRASTIM	GRANIX	40426		GPI-10 (8240152070)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a non-myeloid malignancy and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nivestym

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TBO-FILGRASTIM (Granix)** requires the following rule(s) be met for approval:
   A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   B. You are 1 month of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor)
   D. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   E. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TBO-FILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Granix.

REFERENCES

- Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDIZOLID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEDIZOLID PHOSPHATE	SIVEXTRO	41209		GPI-10 (1623007020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an acute bacterial skin and skin structure infection (ABSSSI) and meet **ONE** of the following criteria?
   The request is for continuation of therapy (oral or intravenous)
   The patient is being transitioned from intravenous Sivextro to oral Sivextro
   The patient had a trial of, contraindication to, or resistance to generic linezolid tablets

   If yes, **approve for 1 month by HICL with a quantity limit of #6 for 1 fill only.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDIZOLID (Sivextro)** requires the following rule(s) be met for approval:
   You have an acute bacterial skin and skin structure infection (ABSSSI: a type of skin condition)
   You meet ONE of the following:
   - The request is for continuation of therapy of oral or intravenous (IV: injection into the vein) Sivextro
   - You are being transitioned from IV Sivextro to oral Sivextro
   - You had a trial of, contraindication to (harmful for you to use), or resistance to (medication no longer works as well) generic linezolid tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sivextro.

REFERENCES

Sivextro [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2023.

Created: 11/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/25

TEDUGLUTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEDUGLUTIDE	GATTEX	39890		GPI-10 (5253307000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient is dependent on intravenous parenteral nutrition, defined as requiring parenteral nutrition at least three times per week

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   D. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient has achieved at least a 20 percent reduction in parenteral support compared to baseline
   - The patient has NOT achieved enteral autonomy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for renewal:
   You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   You have achieved at least a 20 percent reduction in parenteral support (administration of nutrition through a vein) compared to baseline
   You have NOT achieved enteral autonomy (you still need nutrition through a tube)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gattex.

REFERENCES

- Gattex [Prescribing Information]. Lexington, MA: Shire-NPS Pharmaceutical; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 02/13
Client Approval: 08/24
P&T Approval: 07/24

TELOTRISTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TELOTRISTAT ETIPRATE	XERMELO	44132		GPI-10 (5257007510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea (ICD-10 E34.0 and R19.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Xermelo will be used in combination with a somatostatin analog (e.g., octreotide)
   - Therapy is prescribed by or in consultation with an oncologist or gastroenterologist
   - The patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
   - The patient's diarrhea is inadequately controlled as defined by having at least four bowel movements per day

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:
   A. You have carcinoid syndrome diarrhea (loose stool caused by a type of tumor)
   B. You are 18 years of age or older
   C. Xermelo will be used in combination with a somatostatin analog (such as octreotide)
   D. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor) or gastroenterologist (doctor who treats digestive conditions)
   E. You have been receiving a stable dose of long-acting somatostatin analog therapy (such as Sandostatin LAR [octreotide] or Somatuline Depot [lanreotide]) for a minimum of 3 months, unless you have a contraindication (it is harmful for you to use)
   F. You have diarrhea that is inadequately controlled as defined by having at least four bowel movements per day

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TELOTRISTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xermelo.

REFERENCES

- Xermelo [Prescribing Information]. Deerfield, IL: TerSera Therapeutics, LLC; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/17
Client Approval: 06/24
P&T Approval: 04/17

TEMOZOLOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEMOZOLOMIDE	TEMODAR , TEMOZOLOMIDE	20355		GPI-10 (2110407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   Anaplastic astrocytoma (ICD-10 C71.9)
   Glioblastoma multiforme (ICD-10 C72.9; Group C71)
   Small cell lung cancer (SCLC) (ICD-10 Group C34)

   If yes, **approve for 12 months as follows:**
   If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.
   If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   Temodar will NOT be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma

   If yes, **approve for 12 months as follows:**
   If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.
   If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEMOZOLOMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Anaplastic astrocytoma (a type of brain cancer)
- Glioblastoma multiforme (a type of brain or spine cancer)
- Small cell lung cancer (SCLC: a type of lung cancer)
- Metastatic melanoma (a type of skin cancer that has spread to other parts of the body)

If you have metastatic melanoma, approval also requires:
- Temodar will NOT be used concurrently (at the same time) with an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEMOZOLOMIDE

RENEWAL CRITERIA

NOTE: For the diagnoses of Anaplastic astrocytoma, Glioblastoma multiforme, or Small cell lung cancer (SCLC), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   Temodar will NOT be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma

   If yes, **approve for 12 months as follows:**
   If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.
   If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for renewal:
   You have metastatic melanoma (a type of skin cancer that has spread to other parts of the body)
   Temodar will NOT be used concurrently (at the same time) with an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEMOZOLOMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Temodar.

REFERENCES

Temodar [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Created: 02/12
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

TENAPANOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TENAPANOR HCL	IBSRELA		46915	GPI-10 (5255858010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of irritable bowel syndrome with constipation (IBS-C) (ICD-10 K58.1) and meet **ALL** of the following criteria?
   4. The patient is 18 years of age or older
   5. The patient had a trial of or contraindication to the preferred agents: Linzess (linaclotide) AND Trulance (plecanatide)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TENAPANOR (Ibsrela)** requires the following rule(s) be met for approval:
   A. You have irritable bowel syndrome with constipation (IBS-C: a type of bowel disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) the preferred medications: Linzess (linaclotide) AND Trulance (plecanatide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibsrela.

REFERENCES

- Ibsrela [Prescribing Information]. Waltham, MA: Ardelyx, Inc.; April 2022.

Created: 05/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPOTINIB HCL	TEPMETKO	47095		GPI-10 (2153377310)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have mesenchymal-epithelial transition (MET) exon 14 skipping alterations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:
   You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   You are 18 years of age or older
   Your tumors have mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a type of gene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tepmetko.

REFERENCES

- Tepmetko [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIFLUNOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIFLUNOMIDE	AUBAGIO, TERIFLUNOMIDE	39624		GPI-10 (6240407000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (IC-10 G35),to include clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease, **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:
   You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
   You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Aubagio.

REFERENCES

Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/12
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/20

TERIPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIPARATIDE	FORTEO, TERIPARATIDE	24700		GPI-10 (3004407000)	

GUIDELINES FOR USE

1. Is the medication being used for **ONE** of the following diagnoses?
   Postmenopausal osteoporosis
   Primary or hypogonadal osteoporosis in a male patient
   Glucocorticoid-induced osteoporosis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient is at high risk for fractures defined as **ONE** of the following:
   History of osteoporotic (i.e., fragility, low trauma) fracture(s)
   2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as Synarel [nafarelin])
   No prior treatment for osteoporosis **AND** FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received a total of 24 months cumulative treatment with Forteo (teriparatide)?

   If yes, continue to #4.
   If no, **approve the requested agent for up to 24 months lifetime cumulative treatment duration by GPID or GPI-14 with the following quantity limits:**
   Forteo (teriparatide) 600mcg/2.4mL: #2.4mL per 28 days.
   Teriparatide 620mcg/2.48mL: #2.48mL per 28 days.

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

4. Does the patient remain at or has returned to having a high risk for fracture?

If yes, **approve the requested agent for up to 12 months by GPID or GPI-14 with the following quantity limits:**
Forteo (teriparatide) 600mcg/2.4mL: #2.4mL per 28 days.
Teriparatide 620mcg/2.48mL: #2.48mL per 28 days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TERIPARATIDE (Forteo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition in women after menopause)
- Primary or hypogonadal (low level of sex hormones) osteoporosis (a type of bone condition) in a male patient
- Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)

You meet ONE of the following:
- You are at high risk for fractures defined as ONE of the following:
  - You have a history of osteoporotic (i.e., fragility, low trauma) fracture(s)
  - You have two or more risk factors for a fracture (such as a history of multiple recent low trauma fractures, bone marrow density [BMD: a type of lab test] T-score less than or equal to -2.5, corticosteroid [such as prednisone] use, or use of GnRH analogs [such as Synarel (nafarelin)])
  - You have had no prior treatment for osteoporosis AND you have a FRAX (test for your risk of fractures) score of at least 20 percent for any major fracture OR at least 3 percent for a hip fracture
- 2. You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine
- You had a trial of, intolerance (side effect), or contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

You meet ONE of the following:
- You have received a total of 24 months of cumulative treatment with Forteo (teriparatide) AND remain at or have returned to having a high risk for fracture
- You have received less than 24 months of cumulative treatment with Forteo (teriparatide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forteo and teriparatide.

REFERENCE

Forteo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; September 2021.
Teriparatide [Prescribing Information]. Morristown, NJ: Alvogen, Inc; November 2019.
Teriparatide [Prescribing Information]. Weston, FL: Apotex Corp.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 05/03
Client Approval: 11/23
P&T Approval: 01/22

TESAMORELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESAMORELIN ACETATE	EGRIFTA , EGRIFTA SV	37268		GPI-10 (3015008510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of HIV with lipodystrophy (ICD-10 E88.1 and B20) and meets **ALL** the following criteria?
   The patient is 18 years of age or older
   The requested medication will be used for the reduction of excess abdominal fat
   The patient is currently receiving treatment with a protease inhibitor (PI), PI combination (i.e., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), OR an NRTI combination (i.e., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESAMORELIN (Egrifta, Egrifta SV)** requires the following rule(s) be met for approval:
   You have human immunodeficiency virus (HIV: an immune system disase caused by a virus) with lipodystrophy (abnormal distribution of fat in the body)
   You are 18 years of age or older
   The requested medication will be used for the reduction of excess abdominal fat
   You are currently receiving treatment with a protease inhibitor (PI: a type of drug), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI: a type of drug), OR an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESAMORELIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Egrifta.

REFERENCES

Egrifta SV [Prescribing Information]. Montreal, Québec, Canada: Theratechnologies Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 02/11

TESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO, TESTOSTERONE	01403		GPI-10 (2310003000)	ROUTE ≠ MISCELL., IMPLANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #8.

2. Does the patient have a previously approved prior authorization for testosterone OR has been receiving any form of testosterone replacement therapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #5.
   If no, continue to #6.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for AndroGel 1%, AndroGel 1.62%, Axiron, Testim, or Vogelxo?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   AndroGel (testosterone):
   25mg (1%) gel packet: #5 grams per day.
   50mg (1%) gel packet: #10 grams per day.
   1.25g-1.62% gel packet: #1.25 grams per day.
   2.5g-1.62% gel packet: #5 grams per day.
   20.25/1.25 gel pump: #5 grams per day.
   Axiron (testosterone):
   30mg/1.5mL sol pump: #6 mL per day.
   Testim (testosterone):
   50mg (1%) gel packet: #10 grams per day.
   Vogelxo (testosterone):
   12.5/1.25g gel pump: #10 grams per day.
   50mg (1%) gel tube/packet: #10 grams per day.

   If no, continue to #7.

7. Is the request for Androderm, Fortesta, Natesto, or Striant, **AND** the patient meets the following criterion?
   The patient had a trial of or contraindication to TWO preferred agents: testosterone cypionate and intramuscular testosterone enanthate

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.
   Fortesta (testosterone):
   10mg (2%): #4 grams per day.
   Natesto (5.5/0.122 gel pump): #0.732 grams per day.
   Striant (30mg): #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

8. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following:
  - You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
  - You meet ONE of the following criteria showing you have low testosterone levels:
    - You have at least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
    - You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
  - If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If the request is for Androderm, Fortesta, Natesto, or Striant, you have tried or have a contraindication to (harmful for you to use) TWO preferred medications: testosterone cypionate and intramuscular (injected into the muscle) testosterone enanthate

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   The patient has improved symptoms compared to baseline and tolerance to treatment
   The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   AndroGel (testosterone):
   25mg (1%) gel packet: #5 grams per day.
   50mg (1%) gel packet: #10 grams per day.
   1.25g-1.62% gel packet: #1.25 grams per day.
   2.5g-1.62% gel packet: #5 grams per day.
   20.25/1.25 gel pump: #5 grams per day.
   Axiron (testosterone):
   30mg/1.5mL sol pump: #6 mL per day.
   Testim (testosterone):
   50mg (1%) gel packet: #10 grams per day.
   Vogelxo (testosterone):
   12.5/1.25g gel pump: #10 grams per day.
   50mg (1%) gel tube/packet: #10 grams per day.
   Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.
   Fortesta (testosterone):
   10mg (2%): #4 grams per day.
   Natesto (5.5/0.122 gel pump): #0.732 grams per day.
   Striant (30mg): #2 per day.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   AndroGel (testosterone):
   25mg (1%) gel packet: #5 grams per day.
   50mg (1%) gel packet: #10 grams per day.
   1.25g-1.62% gel packet: #1.25 grams per day.
   2.5g-1.62% gel packet: #5 grams per day.
   20.25/1.25 gel pump: #5 grams per day.
   Axiron (testosterone):
   30mg/1.5mL sol pump: #6 mL per day.
   Testim (testosterone):
   50mg (1%) gel packet: #10 grams per day.
   Vogelxo (testosterone):
   12.5/1.25g gel pump: #10 grams per day.
   50mg (1%) gel tube/packet: #10 grams per day.
   Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.
   Fortesta (testosterone):
   10mg (2%): #4 grams per day.
   Natesto (5.5/0.122 gel pump): #0.732 grams per day.
   Striant (30mg): #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone formulation.

REFERENCES

Androderm [Prescribing Information]. Madison, NJ: Allergan; May 2020.
Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2020.
Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc.; November 2020.
Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.; July 2017.
Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals.; January 2022.
Natesto [Prescribing Information]. Regensburg, Germany: Haupt Pharma Amareg GmbH; December 2021.
Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC.; October 2016.
Testim [Prescribing Information]. San Antonio, TX: DPT Laboratories, Ltd.; August 2021.
Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc.; July 2020.

Created: 02/01
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 07/22

TESTOSTERONE CYPIONATE - AZMIRO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	AZMIRO		56456	GPI-14 (2310003010E530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient have a previously approved prior authorization for testosterone OR has the patient been receiving any form of testosterone replacement therapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

Has the patient had a trial of or contraindication to generic testosterone cypionate?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #6.
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**

5. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - AZMIRO

INITIAL CRITERIA (CONTINUED)

6. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   The patient had a trial of or contraindication to generic testosterone cypionate

   If yes, **approve for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   - Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   If you are a male with primary or secondary hypogonadism, approval also requires:
   - You meet ONE of the following:
     - You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
     - You meet ONE of the following criteria showing you have low testosterone levels:
       - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
       - You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   - You have tried or have a contraindication to (harmful for you to use) generic testosterone cypionate
   - If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   If you have gender dysphoria, approval also requires:
   - You have tried or have a contraindication to (harmful for you to use) generic testosterone cypionate
   - Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE - AZMIRO

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   The patient has improved symptoms compared to baseline and tolerance to treatment
   The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   (Renewal denial text continued on the next page)

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TESTOSTERONE CYPIONATE - AZMIRO

RENEWAL CRITERIA (CONTINUED)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Azmiro.

REFERENCES
Azmiro [Prescribing Information]. Princeton, NJ: Slayback Pharma LLC; February 2024.

Created: 11/24
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/25

TESTOSTERONE CYPIONATE - DEPO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE		10191 10194	GPI-14 (23100030102010, 23100030102015, 23100030102070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient have a previously approved prior authorization for testosterone OR has the patient been receiving any form of testosterone replacement therapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #5.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   100 mg/mL, 200 mg/mL (10 mL vial): #10 mL per 28 days.
   200 mg/mL (1 mL vial): #10 mL per 30 days.

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TESTOSTERONE CYPIONATE - DEPO

INITIAL CRITERIA (CONTINUED)

5. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   100 mg/mL, 200 mg/mL (10 mL vial): #10 mL per 28 days.
   200 mg/mL (1 mL vial): #10 mL per 30 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - DEPO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following:
  - You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
  - You meet ONE of the following showing you have low testosterone levels:
    - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
    - You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - DEPO

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   The patient has improved symptoms compared to baseline and tolerance to treatment
   The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   100 mg/mL, 200 mg/mL (10 mL vial): #10 mL per 28 days.
   200 mg/mL (1 mL vial): #10 mL per 30 days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   100 mg/mL, 200 mg/mL (10 mL vial): #10 mL per 28 days.
   200 mg/mL (1 mL vial): #10 mL per 30 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - DEPO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Depo-Testosterone.

REFERENCES

Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company; August 2020.

Created: 02/23
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 07/22

TESTOSTERONE ENANTHATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED	01401		GPI-10 (2310003020)	FDB: ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #8.

2. Does the patient have a previously approved prior authorization for testosterone OR has been receiving any form of testosterone replacement therapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #5.
   If no, continue to #6.

5. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

6. Is the request for generic intramuscular testosterone enanthate 200 mg/mL?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days**.

   If no, continue to #7.

7. Is the request for Xyosted and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   Xyosted will be used for testosterone replacement therapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #2 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, who meets the following criterion?
   The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**
   If no, continue to #9.

9. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets the following criterion?
   The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient meet **ONE** of the following criteria?
    The patient is postmenopausal
    The patient is premenopausal, benefitted from an oophorectomy, AND is considered to have a hormone-responsive tumor

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

11. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Delayed puberty not due to a pathological disorder (disease) in a male
- Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following:
  - You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
  - You meet ONE of the following criteria showing you have low testosterone levels:
    - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
    - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
- If the request is for Xyosted, approval also requires:
  - You are 18 years of age or older
  - Xyosted will be used for testosterone replacement therapy

If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

(Initial denial text continued on next page)

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

If you are a female with metastatic breast cancer, approval also requires:
- You meet ONE of the following:
  - You are postmenopausal (after menopause)
  - You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   The patient has improved symptoms compared to baseline and tolerance to treatment
   The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.

   If no, **approve all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   generic intramuscular testosterone enanthate: #5 mL per 28 days.
   Xyosted: #2 mL per 28 days.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   generic intramuscular testosterone enanthate: #5 mL per 28 days.
   Xyosted: #2 mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, who meets **ALL** of the following criteria?
   The patient has NOT received more than two 6-month courses of testosterone replacement therapy
   The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**
   If no, continue to #5.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

5. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets the following criterion?
   The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   The patient is postmenopausal
   The patient is premenopausal, benefitted from an oophorectomy, AND is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   Delayed puberty not due to a pathological disorder (not due to a disease) in a male
   Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   (Renewal denial text continued on next page)

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
- You have NOT received more than two 6-month courses of testosterone replacement therapy
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

If you are a female with metastatic breast cancer, renewal also requires:
- You meet ONE of the following:
  - You are postmenopausal (after menopause)
  - You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone enanthate/Xyosted.

REFERENCES

Testosterone Enanthate [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals, Inc.; November 2021.
Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; January 2025.

Created: 02/23
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/24

TESTOSTERONE UNDECANOATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE UNDECANOATE	JATENZO, KYZATREX, TLANDO, UNDECATREX	07304		GPI-10 (2310003080)	BRAND ≠ AVEED

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #8.

2. Does the patient have a previously approved prior authorization for testosterone OR has the patient been receiving any form of testosterone replacement therapy?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #5.
   If no, continue to #6.

5. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

6. Is the request for Kyzatrex?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   100 mg: #2 per day.
   150 mg, 200 mg: #4 per day.

   If no, continue to #7.

7. Is the request for Jatenzo, Tlando, or Undecatrex **AND** the patient meets the following criterion?
   The patient had a trial of or contraindication to TWO preferred agents: intramuscular testosterone cypionate and intramuscular testosterone enanthate

   If yes, **approve all strengths of the requested medication for 12 months by GPID or GPI-14 with the following quantity limits:**
   Jatenzo 158 mg, 198 mg: #4 per day.
   Jatenzo 237 mg: #2 per day.
   Tlando 112.5 mg: #4 per day.
   Undecatrex 200 mg: #4 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have a previously approved prior authorization for testosterone, OR you have been receiving any form of testosterone replacement therapy
  - You meet ONE of the criteria showing you have low testosterone levels:
    - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
    - You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
- If the request is for Jatenzo, Tlando, or Undecatrex, you have tried or have a contraindication to (harmful for you to use) TWO preferred medications: intramuscular (injected into the muscle) testosterone cypionate and intramuscular testosterone enanthate
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient meets **ALL** of the following criteria?
   The patient has improved symptoms compared to baseline and tolerance to treatment
   The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.

   If no, **approve all strengths of the requested medication for 12 months by GPID or GPI-14 with the following quantity limits:**
   Kyzatrex 100 mg: #2 per day.
   Kyzatrex 150 mg, 200 mg: #4 per day.
   Jatenzo 158 mg, 198 mg: #4 per day.
   Jatenzo 237 mg: #2 per day.
   Tlando 112.5 mg: #4 per day.
   Undecatrex 200 mg: #4 per day.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve all strengths of the requested medication for 12 months by GPID or GPI-14 with the following quantity limits:**
   Kyzatrex 100 mg: #2 per day.
   Kyzatrex 150 mg, 200 mg: #4 per day.
   Jatenzo 158 mg, 198 mg: #4 per day.
   Jatenzo 237 mg: #2 per day.
   Tlando 112.5 mg: #4 per day.
   Undecatrex 200 mg: #4 per day.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA (CONTINUED)

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   - Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   If you are a male with primary or secondary hypogonadism, renewal also requires:
   - You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   - Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   - If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   If you have gender dysphoria, renewal also requires:
   - Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE UNDECANOATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jatenzo, Kyzatrex, Tlando, or Undecatrex.

REFERENCES

Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; September 2019.
Kyzatrex [Prescribing Information]. Raleigh, NC: Marius Pharmaceuticals; July 2022.
Tlando [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; March 2022.
Undecatrex [Prescribing Information]. San Antonio, TX: Trifluent Pharma, Inc.; September 2022.

Created: 02/23
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/23

TETRABENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TETRABENAZINE	XENAZINE	07350		GPI-10 (6238007000)	

GUIDELINES FOR USE

1. Is the request for a tetrabenazine dosage that exceeds 50mg?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient has been genotyped for CYP2D6 and is identified as an extensive metabolizer (EM) or intermediate metabolizer (IM) of CYP2D6

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xenazine 12.5mg: #3 per day**
   - **Xenazine 25mg: #4 per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xenazine 12.5mg: #3 per day**
   - **Xenazine 25mg: #2 per day**

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:
   A. You have chorea (involuntary movements) associated with Huntington's disease (type of inherited disease that causes nerve cells in brain to break down over time)
   B. The medication has been prescribed or given in consultation with a neurologist (nerve doctor)
   C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
      1. You have been genotyped for CYP2D6 (type of enzyme) and you are identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

   (Denial text continued on next page)

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TETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenazine.

REFERENCES

- Xenazine [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/09
Effective: 07/01/20 Client Approval: 04/20 P&T Approval: 11/15

TEZACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZACAFTOR/IVACAFTOR	SYMDEKO	44771		GPI-10 (4530990280)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   The patient is homozygous for the F508del mutation OR has a responsive mutation in the CFTR gene

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZACAFTOR-IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:
   You have cystic fibrosis (CF: a type of lung disorder)
   You are 6 years of age or older
   Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   You are homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) OR you have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Symdeko)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR-IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   The patient has experienced an improvement in clinical status
   Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZACAFTOR-IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:
   You have cystic fibrosis (CF: a type of lung disorder)
   You have experienced an improvement in your clinical status
   You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Symdeko.

REFERENCES

Symdeko [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; August 2023.

Created: 02/18
Effective: 01/28/25 Client Approval: 01/25 P&T Approval: 01/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZEPELUMAB-EKKO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZEPELUMAB-EKKO	TEZSPIRE	47740		GPI-10 (4460807525)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   Tezspire will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   Tezspire will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   The patient has experienced at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, continue to #3.

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   Daytime asthma symptoms more than twice per week
   Any night waking due to asthma
   Use of a short-acting inhaled beta2-agonist (SABA) (e.g., albuterol) reliever for symptoms more than twice per week
   Any activity limitation due to asthma

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:
   You have severe asthma (a type of lung condition)
   You are 12 years of age or older
   Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   Tezspire will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   (Initial denial text continued on next page)

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
- You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months
- You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
  - Daytime asthma symptoms more than twice per week
  - Any night waking due to asthma
  - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
  - Any activity limitation due to asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA

1. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   Reduction in asthma exacerbations from baseline
   Decreased utilization of rescue medications (e.g., albuterol)
   Increase in percent predicted FEV1 from pretreatment baseline
   Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   Tezspire will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

You have shown a clinical response as evidenced by ONE of the following:
- You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Tezspire)
- You have decreased your use of rescue medications (such as albuterol)
- You have an increase in the percent predicted FEV1 (a type of lung test) from pretreatment baseline (before starting Tezspire)
- You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline

You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tezspire.

REFERENCES

Tezspire [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; May 2023.

Created: 01/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

THALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
THALIDOMIDE	THALOMID	11465		GPI-10 (9939207000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   Thalomid will be used in combination with dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of erythema nodosum leprosum (ENL) (ICD-10 L52)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of anemia due to myelodysplastic syndrome (ICD-10 D64.9 and Group D46) **AND** meet the following criterion?
   The patient has been treated for anemia due to myelodysplastic syndrome

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of Waldenström's macroglobulinemia (ICD-10 C88.0)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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THALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Multiple myeloma (a type of blood cancer)
- Erythema nodosum leprosum (ENL: a type of immune condition)
- Anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)
- Waldenström's macroglobulinemia (a type of blood cancer)

If you have multiple myeloma, approval also requires:
- Thalomid will be used in combination with dexamethasone

If you have anemia due to myelodysplastic syndrome, approval also requires:
- You have been treated for anemia due to myelodysplastic syndrome

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thalomid.

REFERENCES

Thalomid [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/12
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 08/12

TILDRAKIZUMAB-ASMN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		GPI-10 (9025058010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   Ilumya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (Please enter a start date of 3 days before the end of the first approval.)

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TILDRAKIZUMAB-ASMN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:
You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
You meet ONE of the following:
- You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
- You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TILDRAKIZUMAB-ASMN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Ilumya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:
   You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more
   You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)
   (Renewal denial text continued on next page)

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TILDRAKIZUMAB-ASMN

RENEWAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilumya.

REFERENCES
Ilumya [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.

Created: 08/18
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

TISLELIZUMAB-JSGR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TISLELIZUMAB-JSGR	TEVIMBRA	49457		GPI-10 (2135796700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) and meet **ALL** of following criteria?
   The patient is 18 years of age or older
   Tevimbra will be used after a prior systemic chemotherapy (e.g., paclitaxel, docetaxel, irinotecan) that did NOT include a PD-(L)1 inhibitor (e.g., Opdivo [nivolumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (G/GEJ) (ICD-10 Group C16) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's cancer is HER2-negative
   Tevimbra will be used in combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based chemotherapy (e.g., fluorouracil [5-FU], capecitabine)
   The patient's tumors express programmed death-ligand 1 (PD-L1)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TISLELIZUMAB-JSGR (Tevimbra)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Unresectable or metastatic esophageal squamous cell carcinoma (ESCC: a type of digestive system cancer that cannot be removed by surgery or has spread to other parts of the body)
   - Unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (G/GEJ: a type of digestive system cancer that cannot be removed by surgery or has spread to other parts of the body)

   (Denial text continued on next page)

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TISLELIZUMAB-JSGR

GUIDELINES FOR USE (CONTINUED)

If you have esophageal squamous cell carcinoma, approval also requires:
- You are 18 years of age or older
- Tevimbra will be used after a prior systemic chemotherapy (cancer treatment that targets the entire body such as paclitaxel, docetaxel, irinotecan) that did NOT include a PD-(L)1 inhibitor (a type of medication such as Opdivo [nivolumab])

If you have gastric or gastroesophageal junction adenocarcinoma, approval also requires:
- You are 18 years of age or older
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
- Tevimbra will be used in combination with platinum (such as cisplatin, oxaliplatin) and fluoropyrimidine-based chemotherapy (such as fluorouracil [5-FU], capecitabine)
- Your tumors express programmed death-ligand 1 (PD-L1: a type of protein)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tevimbra.

REFERENCES

Tevimbra [Prescribing Information]. San Mateo, CA: BeiGene; December 2024.

Created: 08/24
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/25

TIVOZANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIVOZANIB HCL	FOTIVDA	45740		GPI-10 (2153307625)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient received two or more prior systemic therapies (e.g., Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:
   You have relapsed or refractory advanced renal cell carcinoma (a type of kidney cancer that returned or did not respond to treatment)
   You are 18 years of age or older
   You have received two or more systemic therapies (such as Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fotivda.

REFERENCES

Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/21

TOBRAMYCIN INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOBRAMYCIN	BETHKIS, TOBRAMYCIN		16122	GPI-14 (07000070002530)	
TOBRAMYCIN IN 0.225% SOD CHLOR	TOBI, TOBRAMYCIN		61551	GPI-14 (07000070002520)	
TOBRAMYCIN	TOBI PODHALER		30025 34461	GPI-14 (07000070000120)	
TOBRAMYCIN/NEBULIZER	KITABIS PAK, TOBRAMYCIN		37569	GPI-14 (07000070002520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis (ICD-10 Group E84) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   The patient has a lung infection with a gram-negative species (e.g., *Pseudomonas aeruginosa*; *Staphylococcus aureus* is not a gram-negative species)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Bethkis (tobramycin), Tobi (tobramycin) inhalation solution, or Kitabis Pak (tobramycin)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 as follows:**
   Tobi inhalation solution: #280mL (#56 of 5mL ampules) per 28 days (fill count = 6).
   Bethkis: #224mL (#56 of 4mL ampules) per 28 days (fill count = 6).
   Kitabis Pak: #280mL per 28 days (fill count = 6).

   If no, continue to #3.

3. Is the request for Tobi Podhaler and the patient meets **ONE** of the following criteria?
   The patient had a trial and failure of or contraindication to ONE generic inhaled tobramycin product
   The patient is not able to tolerate the prolonged administration of nebulizers

   If yes, **Tobi Podhaler for 12 months by GPID or GPI-14 with a quantity limit of #224 capsules per 28 days (fill count = 6).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOBRAMYCIN INHALED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:
You have cystic fibrosis (a type of lung disoder)
You are 6 years of age or older
You have a lung infection with a gram-negative species (a type of bacteria such as Pseudomonas aeruginosa)
If the request is for Tobi Podhaler, approval also requires ONE of the following:
You have tried or have a contraindication to (harmful for you to use) ONE generic inhaled tobramycin product
You are not able to tolerate the prolonged administration of nebulizers

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tobi, Tobi Podhaler, Bethkis or Kitabis.

REFERENCES

Tobi [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2023.
Tobi Podhaler [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2023.
Bethkis [Prescribing Information]. Woodstock, IL: Chiesi USA, Inc.; February 2023.
Kitabis Pak [Prescribing Information]. Midothian, VA: PARI Respiratory Equipment, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/12
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/21

TOCILIZUMAB - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA		27366 27367 27368	GPI-14 (66500070002030, 66500070002035, 66500070002040)	

PAC NOTE: For requests for the SQ dosage form of Actemra, please see the TOCILIZUMAB-SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, do not approve. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #3.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #5.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #6.

6. Does the patient have a diagnosis of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) (ICD-10 Group D89.83; Z92.850) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRS

   If yes, **approve for 1 fill by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #160mL.**
   CLINICAL PHARMACISTS: Patient must also meet all criteria in Kymriah guideline to be approvable for both agents.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - IV (Actemra - intravenous)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Giant cell arteritis (GCA: a type of inflammatory condition)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
- Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: a type of inflammatory response)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You have tried or have a contraindication to THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Tyenne (tocilizumab-aazg)

If you have giant cell arteritis, approval also requires:
- You are 18 years of age or older
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)

If you have systemic juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)

If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:
- You are 2 years of age or older
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome

NOTE: Actemra will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) **AND** meet the following criterion?
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #3.

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #4.

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - IV (Actemra - intravenous)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Giant cell arteritis (GCA: a type of inflammatory condition)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Tyenne (tocilizumab-aazg)

If you have giant cell arteritis, renewal also requires:
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)

(Renewal denial text continued on next page)

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

If you have systemic juvenile idiopathic arthritis, renewal also requires:

- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)
- You meet ONE of the following:
  - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
  - You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE

Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2024.

Created: 02/10
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA		35486 45082	GPI-14 (6650007000E520, (6650007000D520)	

PAC NOTE: For requests for the IV dosage form of Actemra, please see the TOCILIZUMAB - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #2.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   The patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease [MCTD])
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Giant cell arteritis (GCA: a type of inflammatory condition)
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You have tried or have a contraindication to THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Tyenne (tocilizumab-aazg)

If you have giant cell arteritis, approval also requires:
- You are 18 years of age or older
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

If you have systemic sclerosis-associated interstitial lung disease, approval also requires:
- You are 18 years of age or older
- Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
- You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD, acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

If you have systemic juvenile idiopathic arthritis, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) **AND** meet the following criterion?
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline
   Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Giant cell arteritis (GCA: a type of inflammatory condition)
   - Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   - Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   - Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   If you have moderate to severe rheumatoid arthritis, renewal also requires:
   - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   - You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Tyenne (tocilizumab-aazg)

   (Renewal denial text continued on next page)

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

If you have giant cell arteritis, renewal also requires:
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
- You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg)

If you have systemic juvenile idiopathic arthritis, renewal also requires:
- You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)
- You meet ONE of the following:
  - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
  - You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB - SQ

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2024.

Created: 11/13
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

TOCILIZUMAB-AAZG - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55366 55368 55372	GPI-14 (66500070172030, 66500070172035, 66500070172040)	

PAC NOTE: For requests for the SQ dosage form of Tyenne, please see the TOCILIZUMAB-AAZG-SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, do not approve. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #3.

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #5.

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #6.

6. Does the patient have a diagnosis of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) (ICD-10 Group D89.83; Z92.850) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRS

   If yes, **approve for 1 fill by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #160mL.**
   CLINICAL PHARMACISTS: Patient must also meet all criteria in Kymriah guideline to be approvable for both agents.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-AAZG - IV (Tyenne - intravenous)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Giant cell arteritis (GCA: a type of inflammatory condition)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
- Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: a type of inflammatory response)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You have tried or have a contraindication to ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release)

If you have giant cell arteritis, approval also requires:
- You are 18 years of age or older
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib)

If you have systemic juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:
- You are 2 years of age or older
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome

NOTE: Tyenne will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) **AND** meet the following criterion?
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #3.

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA (CONTINUED)

1. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #4.

2. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) **AND** meet the following criterion?
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-AAZG - IV (Tyenne - intravenous)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Giant cell arteritis (GCA: a type of inflammatory condition)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release)

If you have giant cell arteritis, renewal also requires:
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib)

(Renewal denial text continued on next page)

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA (CONTINUED)

If you have systemic juvenile idiopathic arthritis, renewal also requires:

You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

You meet ONE of the following:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne.

REFERENCE

Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; December 2024.
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2024.

Created: 08/24
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

TOCILIZUMAB-AAZG - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55373 55374	GPI-14 (6650007017D520, 6650007017E520)	

PAC NOTE: For requests for the IV dosage form of Tyenne, please see the TOCILIZUMAB-AAZG - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   The patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease [MCTD])
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Giant cell arteritis (GCA: a type of inflammatory condition)
   - Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   - Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   - Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You have tried or have a contraindication to ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release)

If you have giant cell arteritis, approval also requires:
- You are 18 years of age or older
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

If you have systemic sclerosis-associated interstitial lung disease, approval also requires:
- You are 18 years of age or older
- Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
- You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD, acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib)

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

If you have systemic juvenile idiopathic arthritis, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib IR/XR)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) **AND** meet the following criterion?
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline
   Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   The patient had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) **AND** meet the following criterion?
   Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Giant cell arteritis (GCA: a type of inflammatory condition)
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
- Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release)

If you have giant cell arteritis, renewal also requires:
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis

If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
- You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA (CONTINUED)

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate release), Rinvoq (upadacitinib)

If you have systemic juvenile idiopathic arthritis, renewal also requires:
- You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis
- You meet ONE of the following:
  - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
  - You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne.

REFERENCE

Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; December 2024.
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2024.

Created: 08/24
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 01/25

TOFACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR	39768		GPI-10 (6660306510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   11mg: #1 per day.

   If no, continue to #2.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   11mg: #1 per day.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac)
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   11mg: #1 per day.

   If no, continue to #4.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi)

   If yes, **approve for 6 months for ALL strengths by GPID or GPI-14 as follows:**
   5mg and 10mg: #2 per day.
   11mg and 22mg: #1 per day.

   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pcJIA
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   1mg/mL: #10mL per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/ adalimumab-adaz/Simlandi, Enbrel [etanercept])

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam, diclofenac)
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi)

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

If you have polyarticular course juvenile idiopathic arthritis, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   11mg: #1 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   11mg: #1 per day.

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   11mg: #1 per day.

   If no, continue to #4.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months for ALL strengths by GPID or GPI-14 as follows:**
   5mg and 10mg: #2 per day.
   11mg and 22mg: #1 per day.

   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Xeljanz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pcJIA

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   5mg: #2 per day.
   1mg/mL: #10mL per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Ankylosing spondylitis (AS: a type of joint condition)
   - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   - Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

   (Renewal denial text continued on next page)

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have polyarticular course juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFACITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeljanz/Xeljanz XR.

REFERENCES

Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Inc.; September 2024.

Created: 11/12
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

TOLVAPTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOLVAPTAN	JYNARQUE	36348		GPI-10 (3045406000)	BRAND = JYNARQUE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (ICD-10 Q61.2, Q61.3) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist
   The patient does not have end-stage renal disease (ESRD), including no renal transplantation or dialysis

   If yes, **approve for 6 months for all strengths as follows:**
   90mg-30mg (GPID or GPI-14): #56 per 28 days.
   45mg-15mg (GPID or GPI-14): #56 per 28 days.
   60mg-30mg (GPID or GPI-14): #56 per 28 days.
   30-15mg (GPID or GPI-14): #56 per 28 days.
   15-15mg (GPID or GPI-14): #56 per 28 days.
   15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.
   30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:
   You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   You do not have end-stage renal disease (ESRD: advanced kidney disease), including no renal transplantation (kidney transplant) or dialysis (process of removing excess water, toxins from the blood)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOLVAPTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (ICD-10 Q61.2, Q61.3) **AND** meet the following criterion?
   The patient has not progressed to end-stage renal d isease (ESRD)

   If yes, **approve for 12 months for all strengths as follows:**
   90mg-30mg (GPID or GPI-14): #56 per 28 days.
   45mg-15mg (GPID or GPI-14): #56 per 28 days.
   60mg-30mg (GPID or GPI-14): #56 per 28 days.
   30-15mg (GPID or GPI-14): #56 per 28 days.
   15-15mg (GPID or GPI-14): #56 per 28 days.
   15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.
   30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:
   You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
   You have NOT progressed to end stage renal disease (ESRD: advanced kidney disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOLVAPTAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/23

TOPIRAMATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOPIRAMATE	EPRONTIA		51457	GPI-14 (72600075002020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset or primary generalized tonic-clonic seizures and meet **ALL** of the following criteria?
   - Eprontia will be used as initial monotherapy OR adjunctive therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is unable to take oral tablets or capsules
   - The patient meets ONE of the following:
     - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
     - The patient is 6 years of age or older AND had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
   - Eprontia will be used as adjunctive therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is unable to take oral tablets or capsules
   - The patient meets ONE of the following:
     - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
     - The patient is 6 years of age or older AND had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of migraine and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Eprontia will be used as preventative treatment of migraines
   - The patient is unable to take oral tablets or capsules
   - The patient had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOPIRAMATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOPIRAMATE (Eprontia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)
   3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   4. Migraine

B. You are unable to take oral tablets or capsules

C. **If you have partial-onset seizures or primary generalized tonic-clonic seizures, approval also requires:**
   1. Eprontia will be used as initial monotherapy OR adjunctive therapy (drugs taken together with)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication (harmful for) to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
      b. You are 6 years of age or older AND had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

D. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. Eprontia will be used as adjunctive therapy (drugs taken together with)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication (harmful for) to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
      b. You are 6 years of age or older AND had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, or topiramate ER sprinkle

E. **If you have migraines, approval also requires:**
   1. You are 12 years of age or older
   2. Eprontia will be used as preventative treatment of migraines
   3. You had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

(Denial text continued on next page)

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TOPIRAMATE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eprontia.

REFERENCES

- Eprontia [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 02/22
Client Approval: 05/22
P&T Approval: 04/22

TOREMIFENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOREMIFENE CITRATE	FARESTON, TOREMIFENE CITRATE	11632		GPI-10 (2140268510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer (ICD-10 Groups Group C50, C79.81) and meet **ALL** of the following criteria?
   - The patient is a postmenopausal female
   - The patient has an estrogen-receptor positive or unknown tumor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOREMIFENE (Fareston)** requires the following rule(s) be met for approval:
   A. You have metastatic breast cancer (cancer that has spread to other parts of the body)
   B. You are a postmenopausal female (after menopause)
   C. You have an estrogen-receptor positive or unknown tumor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fareston.

REFERENCES

- Fareston [Prescribing Information] Bedminster, NJ: Kyowa Kirin Inc. May 2017.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/13
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 08/13

TORSEMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TORSEMIDE	SOAANZ		52032 52033	GPI-14 (37200080000335 37200080000345)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of edema associated with heart failure or renal disease (ICD-10 Group R60) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO generic loop diuretics (e.g., furosemide, bumetanide)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **40mg: #5 per day.**
   - **60mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TORSEMIDE (Soaanz)** requires the following rule(s) be met for approval:
   You have edema (swelling caused by fluid build-up in the body) associated with heart failure (a type of heart condition) or renal (kidney) disease
   You are 18 years of age or older
   You have tried or have a contraindication to (harmful for you to use) TWO generic loop diuretics (such as furosemide, bumetanide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Soaanz.

REFERENCES

- Soaanz [Prescribing Information]. Vienna, VA: Sarfez Pharmaceuticals, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 05/22

TOVORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOVORAFENIB	OJEMDA	49542		GPI-10 (2153207500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory low-grade glioma (LGG) (ICD-10 D33.2) **AND** meet the following criterion?
   The patient's cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   100mg: #24 per 28 days.
   25mg/mL: #96mL per 28 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOVORAFENIB (Ojemda)** requires the following rule(s) be met for approval:
   You have relapsed or refractory low-grade glioma (LGG) (a type of brain cancer that has returned or did not respond to treatment)
   Your cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation (types of abnormal changes in genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojemda.

REFERENCES

Ojemda [Prescribing Information]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/10/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

TRALOKINUMAB-LDRM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRALOKINUMAB-LDRM	ADBRY	47741		GPI-10 (9027308045)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   Adbry will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **ONE** of the following?
   High potency topical corticosteroid (e.g., halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   Topical calcineurin inhibitor (e.g., Protopic [tacrolimus], Elidel [pimecrolimus])
   Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole])
   Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   Phototherapy

   If yes, **approve for a total of 6 months and by HICL or GPI-10. Please enter two authorizations as follows:**
   <u>FIRST APPROVAL</u>: Approve for 1 month with a quantity limit of #6mL per 28 days.
   <u>SECOND APPROVAL</u>: Approve for 5 months with a quantity limit of #4mL per 28 days (enter a start date of 2 days BEFORE the END date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRALOKINUMAB-LDRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:
You have moderate to severe atopic dermatitis (AD: a type of skin condition)
You are 12 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
You have tried or have a contraindication to (harmful for you to use) ONE of the following:
- High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
- Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
- Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole])
- Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
- Phototherapy (light therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRALOKINUMAB-LDRM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient has shown improvement while on Adbry
   Adbry will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:
   You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   You have shown improvement while on Adbry
   You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adbry.

REFERENCES

Adbry [Prescribing Information]. Madison, NJ: LEO Pharma Inc.; June 2024.

Created: 01/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

TRAMADOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMADOL HCL	QDOLO, TRAMADOL HCL		48598	GPI-14 (65100095102005)	

GUIDELINES FOR USE

1. Is the request for the management of pain (ICD-10 R52) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's pain is severe enough to require an opioid analgesic
   - Alternative treatments for the patient's pain are inadequate
   - The patient had a trial of or contraindication to generic tramadol IR tablet or a generic tramadol with acetaminophen product
   - The patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen (e.g., difficulty swallowing)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #80mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:
   The request is for the management of pain
   You are 18 years of age or older
   Your pain is severe enough to require an opioid analgesic (type of pain medication)
   Alternative (other) treatments for your pain are inadequate (did not work)
   You have tried or have a contraindication to (harmful for you to use) generic tramadol immediate-release (IR) tablet or a generic tramadol with acetaminophen product
   You are unable to take oral solid formulations (such as a tablet) of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRAMADOL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qdolo.

REFERENCES

- Qdolo [Prescribing Information]. Athens, GA: Athena Bioscience, LLC; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/21

TRAMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		GPI-10 (2153357010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naive patient OR in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (Group C34) and meet **ALL** of the following criteria?
   The patient has a BRAF V600E mutation as detected by an FDA-approved test
   Mekinist will be used in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   Mekinist will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   There is involvement of lymph node(s), following complete resection

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   The patient has a BRAF V600E mutation
   Mekinist will be used in combination with Tafinlar (dabrafenib)
   The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   The patient is 1 year of age or older
   The patient has a BRAF V600E mutation
   Mekinist will be used in combination with Tafinlar (dabrafenib)
   The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   The patient is 1 to 17 years of age
   The patient has a BRAF V600E mutation
   Mekinist will be used in combination with Tafinlar (dabrafenib)
   The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the tablet formulation?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   2mg: #1 per day.
   0.5mg: #3 per day.

   If no, continue to #8.

8. Is the request for the oral solution **AND** the patient meets the following criterion?
   The patient is unable to swallow Mekinist (trametinib) tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #42mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRAMETINIB (Mekinist)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
- Melanoma (a type of skin cancer)
- Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
- Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
- Low-grade glioma (LGG: a type of brain cancer)

If you have unresectable or metastatic melanoma, approval also requires:

- You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
- Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

If you have metastatic non-small cell lung cancer, approval also requires:

- You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
- Mekinist will be used in combination with Tafinlar (dabrafenib)

If you have melanoma, approval also requires:

- You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
- Mekinist will be used as an adjuvant (add-on) therapy in combination with Tafinlar (dabrafenib)
- There is involvement of lymph node(s), following complete resection (surgical removal)

If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:

- You have a BRAF V600E mutation (abnormal change in gene)
- Mekinist will be used in combination with Tafinlar (dabrafenib)
- You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

(Denial text continued on next page)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

If you have an unresectable or metastatic solid tumor, approval also requires:
- You are 1 year of age or older
- You have a BRAF V600E mutation (abnormal change in gene)
- Mekinist will be used in combination with Tafinlar (dabrafenib)
- Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

If you have low-grade glioma, approval also requires:
- You are 1 to 17 years of age
- You have a BRAF V600E mutation (abnormal change in gene)
- Mekinist will be used in combination with Tafinlar (dabrafenib)
- You require systemic therapy (treatment that targets the entire body)

If the request is for the oral solution, approval also requires:
- You are unable to swallow Mekinist (trametinib) tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES

Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 07/13
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB	HERCEPTIN	18801		GPI-10 (2117007000)	
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA	45653		GPI-10 (2199000272)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50; C79.81) and meet **ALL** of the following criteria?
   The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for trastuzumab
   The patient had a trial of or contraindication to ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), or Ogivri (trastuzumab-dkst)

   If yes, continue to #2.
   If no, continue to #4.

2. Will the requested medication be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   The requested medication will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   The requested medication will be used as part of a treatment regimen with docetaxel and carboplatin
   The requested medication will be used as a single medication following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   Herceptin: no quantity limit.
   Herceptin Hylecta: #5mL per 21 days.

   If no, continue to #3.

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's breast cancer metastatic and does the patient meet **ONE** of the following criteria?
   The requested medication will be used in combination with paclitaxel
   The requested medication will be used as a single medication in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   Herceptin: no quantity limit.
   Herceptin Hylecta: #5mL per 21 days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   The request is for Herceptin
   The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for trastuzumab
   Herceptin will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   The patient has not received prior treatment for metastatic disease

   If yes, **approve Herceptin for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Breast cancer
   Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
   (Denial text continued on next page)

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

GUIDELINES FOR USE (CONTINUED)

If you have breast cancer, approval also requires:

- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for trastuzumab
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), or Ogivri (trastuzumab-dkst)
- You meet ONE of the following:
  - The requested medication will be used as adjuvant (additional) treatment, and you meet ONE of the following:
    - The requested medication will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
    - The requested medication will be used as part of a treatment plan with docetaxel and carboplatin
    - The requested medication will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
  - Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
    - The requested medication will be used in combination with paclitaxel
    - The requested medication will be used as a single medication if you have received one or more chemotherapy regimens (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

- The request is for Herceptin
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for trastuzumab
- Herceptin will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
- You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herceptin or Herceptin Hylecta.

REFERENCES

Herceptin [Prescribing Information]. South San Francisco, CA: Genentech, Inc., June 2024.
Herceptin Hylecta [Prescribing Information]. South San Francisco, CA: Genentech, Inc., June 2024.

Created: 08/12
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 04/20

TRASTUZUMAB-STRF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-STRF	HERCESSI	49554		GPI-10 (2117007040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50; C79.81) and meet **ALL** of the following criteria?
   The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   The patient had a trial of or contraindication to ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), or Ogivri (trastuzumab-dkst)

   If yes, continue to #2.
   If no, continue to #4.

2. Will the requested medication be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   Hercessi will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   Hercessi will be used as part of a treatment regimen with docetaxel and carboplatin
   Hercessi will be used as a single medication following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's breast cancer metastatic and does the patient meet **ONE** of the following criteria?
   Hercessi will be used in combination with paclitaxel
   Hercessi will be used as a single medication in a patient who has received one or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-STRF

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   The patient has HER2-overexpressing (HER2-positive) cancer, as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   Hercessi will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
   The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB-STRF (Hercessi)** requires the following rule(s) be met for approval:
   You have ONE of the following:
      Breast cancer
      Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
   If you have breast cancer, approval also requires:
      Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
      You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), or Ogivri (trastuzumab-dkst)
      You meet ONE of the following:
         Hercessi will be used as adjuvant (additional) treatment, and you meet ONE of the following:
            Hercessi will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
            Hercessi will be used as part of a treatment plan with docetaxel and carboplatin
            Hercessi will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
   (Denial text continued on next page)

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TRASTUZUMAB-STRF

GUIDELINES FOR USE (CONTINUED)

Your breast cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
Hercessi will be used in combination with paclitaxel
Hercessi will be used as a single medication if you have received one or more chemotherapy regimens (type of cancer treatment) for metastatic disease (disease that has spread to other parts of the body)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic for a trastuzumab product
Hercessi will be used in combination with cisplatin and Xeloda (capecitabine) or 5-fluorouracil
You have not received prior treatment for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hercessi.

REFERENCES

Hercessi [Prescribing Information]. Raleigh, NC: Accord BioPharma Inc.; September 2024.
Herceptin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2024.

Created: 12/24
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAZODONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAZODONE HCL	RALDESY	01652		GPI-10 (5812008010)	BRAND = RALDESY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) **AND** meet the following criterion?
   The patient has a contraindication to OR is unable to swallow trazodone tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAZODONE (Raldesy)** requires the following rule(s) be met for approval:
   You have major depressive disorder (a type of mental illness)
   You have a contraindication to (harmful for you to use) OR are unable to swallow trazodone tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Raldesy.

REFERENCES
Raldesy [Prescribing Information]. Parsippany, NJ: Validus Pharmaceuticals LLC; February 2025.

Created: 03/25
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

TREPROSTINIL DPI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL	TYVASO DPI	36541		GPI-14 (40170080002960, 40170080002920, 40170080002930, 40170080002950, 40170080002940, 40170080002980, 40170080002970)	BRAND = TYVASO DPI

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Is the PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL DPI

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the requested strength for 1 month for 1 fill as follows:
   16-32mcg Titration Kit
   16-32-48mcg Titration Kit
   SECOND APPROVAL: Approve the requested strength for 11 months as follows (enter a start date of 3 days BEFORE the end date of the first approval):
   16mcg
   32mcg
   48mcg
   64mcg
   32-48mcg

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL DPI

INITIAL CRITERIA (CONTINUED)

5. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the requested strength for 1 month for 1 fill as follows:
   16-32mcg Titration Kit
   16-32-48mcg Titration Kit
   SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 days BEFORE the end date of the first approval):
   16mcg
   32mcg
   48mcg
   64mcg
   32-48mcg

   If not, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)
   (Initial denial text continued on next page)

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TREPROSTINIL DPI

INITIAL CRITERIA (CONTINUED)

If you have PAH (WHO Group 1), approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR) greater than 2 Wood units
- You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
  - Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
  - Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
  - Oral cGMP stimulator (such as Adempas [riociguat])
  - Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

If you have PH-ILD (WHO Group 3), approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL DPI

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   16mcg
   32mcg
   48mcg
   64mcg
   32-48mcg

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL DPI

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso DPI.

REFERENCES

Tyvaso DPI [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/24
Client Approval: 06/24
P&T Approval: 01/24

TREPROSTINIL INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL	TYVASO		27489 27491 27492	GPI-14 (40170080002020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve Tyvaso Starter Kit for 1 month for 1 fill.
   SECOND APPROVAL: Approve Tyvaso or Tyvaso Refill Kit for 11 months (enter a start date of 3 days BEFORE the end date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve Tyvaso Starter Kit for 1 month for 1 fill.
   SECOND APPROVAL: Approve Tyvaso or Tyvaso Refill Kit for 5 months (enter a start date of 3 days BEFORE the end date of the first approval).

   If not, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL INHALED (Tyvaso)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

If you have PAH (WHO Group 1), approval also requires:
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR) greater than 2 Wood units
- You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
  - Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
  - Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
  - Oral cGMP stimulator (such as Adempas [riociguat])
  - Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

If you have PH-ILD (WHO Group 3), approval also requires:

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)

Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:

Mean pulmonary artery pressure (PAP) greater than 20 mmHg

Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL INHALED

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve Tyvaso or Tyvaso Refill Kit for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INHALED (Tyvaso)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso.

REFERENCES

Tyvaso [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/23
Client Approval: 06/24
P&T Approval: 01/24

TREPROSTINIL INJECTABLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL SODIUM	REMODULIN, TREPROSTINIL	23650		GPI-14 (40170080002080, 40170080002070, 40170080002050, 40170080002060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Remodulin (treprostinil) therapy from a hospital discharge?

   If yes, **approve for 12 months by HICL or for all strengths by GPI-14.**
   If no, continue to #4.

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TREPROSTINIL INJECTABLE

INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Remodulin (treprostinil) therapy and the patient meets **ONE** of the following criteria?
   The patient is intermediate or high risk
   The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or for all strengths by GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) greater than 2 Wood units
   For new start requests of Remodulin (treprostinil), approval also requires ONE of the following:
   You are intermediate or high risk
   You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
   Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (such as Adempas [riociguat])
   (Initial denial text continued on next page)

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TREPROSTINIL INJECTABLE

INITIAL CRITERIA (CONTINUED)

If you are continuing current Remodulin (treprostinil) therapy from a hospital discharge, there is no additional requirement for approval.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL INJECTABLE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or for all strengths by GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remodulin.

REFERENCES

Remodulin [Prescribing Information]. Research Triangle Park, NC; United Therapeutics Corp.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/23
Client Approval: 06/24
P&T Approval: 01/24

TREPROSTINIL ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL DIOLAMINE	ORENITRAM ER	40827		GPI-10 (4017008005)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   The patient does NOT have severe hepatic impairment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Orenitram therapy from a hospital discharge?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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TREPROSTINIL ORAL

INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Orenitram therapy and the patient meets **ALL** of the following criteria?
   The patient had a trial of or contraindication to the preferred oral prostanoid: Uptravi (selexipag)
   The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
   Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   Oral cGMP stimulator (e.g., Adempas [riociguat])
   IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for approval:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   Pulmonary vascular resistance (PVR) greater than 2 Wood units
   You do NOT have severe hepatic (liver) impairment
   (Initial denial text continued on next page)

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TREPROSTINIL ORAL

INITIAL CRITERIA (CONTINUED)

For new start requests of Orenitram, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the preferred oral prostanoid: Uptravi (selexipag)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
  - Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
  - Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
  - Oral cGMP stimulator (such as Adempas [riociguat])
  - Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

If you are continuing current Orenitram therapy from a hospital discharge, there is no additional requirement for approval.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL ORAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for renewal:
   You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orenitram.

REFERENCES

Orenitram [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 09/05
Client Approval: 06/24
P&T Approval: 01/24

TRIENTINE CAPSULE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE HCL	SYPRINE, CLOVIQUE, TRIENTINE HCL	01109		GPI-10 (9920002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   The patient has a Leipzig score of 4 or greater
   The patient is willing to follow a diet avoiding high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat)
   The patient has had a trial of or contraindication to penicillamine (Depen, Cuprimine)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit as follows:**
   250 mg: #8 per day.
   500 mg: #4 per day.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rule(s) be met for approval:
   You have Wilson's disease (a type of genetic disorder)
   Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   You have a Leipzig score (a type of diagnostic score) of 4 or higher
   You are willing to follow a diet avoiding high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   You have tried or have a contraindication to (harmful for you to use) penicillamine (Depen, Cuprimine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE CAPSULE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) **AND** meet the following criterion?
   The patient has achieved a free serum copper of less than 10 mcg/dL

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths with a quantity limit as follows:**
   250 mg: #8 per day.
   500 mg: #4 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rules be met for renewal:
   You have Wilson's disease (a type of genetic disorder)
   You have achieved a free serum copper level (amount of copper in your blood) of less than 10 mcg/dL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine, Clovique, or trientine hydrochloride.

REFERENCES

Syprine [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
Clovique [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2019.
Trientine hydrochloride capsules [Prescribing Information]. East Brunswick, NJ: Rising Pharma Holdings, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/16
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE TABLET

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE TETRAHYDROCHLORIDE	CUVRIOR	45888		GPI-10 (9920002020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   The patient has a prior or current Leipzig score of 4 or greater
   The patient has a non-ceruloplasmin copper (NCC) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE) of between 100 to 500 mcg/24 hours
   The patient is willing to maintain a diet that avoids high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat)
   The patient had a trial of penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
   The patient had a trial of trientine hydrochloride (Syprine)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rule(s) be met for approval:
   You have Wilson's disease (a type of genetic disorder)
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   You have a prior or current Leipzig score (a type of diagnostic score) of 4 or higher
   You have a non-ceruloplasmin copper (NCC: a type of test to check copper levels) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE: a type of test to check copper levels) between 100 to 500 mcg per 24 hours
   You are willing to maintain a diet that avoids high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   You have tried penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
   You have tried trientine hydrochloride (Syprine)
   (Initial denial text continued on the next page)

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TRIENTINE TABLET

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIENTINE TABLET

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) **AND** meet the following criterion?
   The patient's copper levels are monitored via non-ceruloplasmin copper (NCC) or 24-hour urinary copper excretion (UCE) laboratory test

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rules be met for renewal:
   You have Wilson's disease (a type of genetic disorder)
   Your body's copper levels are monitored by a non-ceruloplasmin copper (NCC: a type of test to check copper levels) test or 24-hour urinary copper excretion (UCE: a type of test to check copper levels) test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuvrior.

REFERENCES

Cuvrior [Prescribing Information]. Chicago, IL: Orphalan SA; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 04/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/22

TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIFLURIDINE/ TIPIRACIL HCL	LONSURF	42544		GPI-10 (2199000275)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (ICD-10 C19) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]
   Lonsurf will be used as a single agent OR in combination with bevacizumab

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's metastatic colorectal cancer RAS wild-type?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   15/6.14mg: #100 per 28 days.
   20/8.19mg: #80 per 28 days.

3. Has the patient had previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   15/6.14mg: #100 per 28 days.
   20/8.19mg: #80 per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   15/6.14mg: #100 per 28 days.
   20/8.19mg: #80 per 28 days.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Metastatic colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
   - Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

   If you have metastatic colorectal cancer, approval also requires:
   - You are 18 years of age or older
   - Lonsurf will be used as a single agent OR in combination with bevacizumab
   - You had previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) in combination with an anti-VEGF biological therapy such as Zaltrap (ziv-aflibercept) or Cyramza (ramucirumab)
   - If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

   If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
   - You are 18 years of age or older
   - You had previous treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

   (Denial text continued on next page)

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/15
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

TRIHEPTANOIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIHEPTANOIN	DOJOLVI	46676		GPI-10 (8020008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) (ICD-10 Group E71.31)?

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's diagnosis confirmed by **TWO** of the following?
   - Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
   - Low enzyme activity in cultured fibroblasts
   - One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB

   If yes, continue to #3.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is symptomatic (e.g., rhabdomyolysis, cardiomyopathy) for LC-FAOD
   - Therapy is prescribed by or in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
   - The patient had a trial of or contraindication to commercial MCT oil (medical food product)

   If yes, **approve for 4 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRIHEPTANOIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. Your diagnosis is confirmed by TWO of the following:
   1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
   2. Low enzyme activity in cultured fibroblasts (a type of cell found in the body)
   3. One or more known pathogenic mutations (abnormal changes) in CPT2, ACADVL, HADHA, or HADHB (types of genes)
A. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [a type of heart condition])
B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or physician specialist in medical genetics/inherited metabolic disorders
C. You have tried or have a contraindication to (harmful for you to use) commercial MCT oil (a medical food product)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIHEPTANOIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) (ICD-10 Group E71.31) **AND** meet the following criterion?
   - The patient has experienced a positive clinical response (e.g., improved exercise tolerance) or stabilization of clinical status compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. You have experienced a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

- Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/20
Client Approval: 06/24
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TROFINETIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TROFINETIDE	DAYBUE	48773		GPI-10 (7465307500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Rett syndrome (ICD-10 F84.2) **AND** meet the following criterion?
   The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TROFINETIDE (Daybue)** requires the following rule(s) be met for approval:
   A. You have Rett syndrome (a type of nervous system disorder)
   B. You are 2 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daybue.

REFERENCES

Daybue [Prescribing Information]. San Diego, CA, Acadia Pharmaceuticals Inc.; September 2024..

Library	Commercial	NSA
Yes	Yes	No

Created: 04/23
Effective: 01/0125 Client Approval: 11/24 P&T Approval: 04/23

TUCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TUCATINIB	TUKYSA	46459		GPI-10 (2117008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic breast cancer (ICD-10 Groups C50, C79.81) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's breast cancer is human epidermal growth factor receptor 2 (HER2)-positive
   The patient has received one or more prior anti-HER2-based regimens (i.e., trastuzumab or trastuzumab with pertuzumab) in the metastatic setting
   Tukysa will be used in combination with trastuzumab and capecitabine

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   50mg: #10 per day.
   150mg: #4 per day.

   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (ICD-10 C19) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient's colorectal cancer is RAS wild-type, human epidermal growth factor receptor 2 (HER2)-positive
   The patient's cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
   Tukysa will be used in combination with trastuzumab

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   50mg: #10 per day.
   150mg: #4 per day.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TUCATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Advanced unresectable or metastatic breast cancer (cancer that cannot be removed with surgery or has spread to other parts of the body)
- Unresectable or metastatic colorectal cancer (a type of digestive cancer that cannot be removed with surgery or has spread to other parts of the body)

If you have advanced unresectable or metastatic breast cancer, approval also requires:
- You are 18 years of age or older
- Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- You have received one or more prior anti-HER2-based treatment (trastuzumab or trastuzumab with pertuzumab) for metastatic (has spread to other parts of the body) disease
- Tukysa will be used in combination with trastuzumab and capecitabine

If you have unresectable or metastatic colorectal cancer, approval also requires:
- You are 18 years of age or older
- Your colorectal cancer is RAS wild-type (a type of gene), human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- Your cancer has progressed (worsened) following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)
- Tukysa will be used in combination with trastuzumab

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tukysa.

REFERENCES

Tukysa [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

UBROGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UBROGEPANT	UBRELVY	46273		GPI-10 (6770108000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for the acute treatment of migraines
   The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:
   The request is for the acute (quick onset) treatment of migraines (a type of headache)
   You are 18 years of age or older
   You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute treatment of migraines
   You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBROGEPANT

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) **AND** the patient meets the following criterion?
   Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, continue to #3.

3. Has the patient experienced clinical improvement as defined by **ONE** of the following criteria?
   Ability to function normally within 2 hours of dose
   Headache pain disappears within 2 hours of dose
   Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for renewal:
   The request is for the acute (quick onset) treatment of migraines (a type of headache)
   You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute treatment of migraines
   You meet ONE of the following:
   - You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
   - You have experienced clinical improvement as defined by ONE of the following:
     - Ability to function normally within 2 hours of dose
     - Headache pain disappears within 2 hours of dose
     - Treatment works consistently in the majority of migraine attacks

(Renewal denial text continued on the next page)
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UBROGEPANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ubrelvy.

REFERENCES

Ubrelvy [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 01/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

UPADACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UPADACITINIB	RINVOQ	45955		GPI-10 (6660307200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of RA
   The patient had a trial of or contraindication to 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   15mg: #1 per day.
   1mg/mL: #12mL per day.

   If no, continue to #3.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   The patient has at least TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Opzelura (ruxolitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #4.
   If no, continue to #6.

4. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and is switching to Rinvoq
   The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA)
   The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

5. Has the patient had a trial of or contraindication to **ONE** of the following?
   Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
   Topical PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]
   Topical JAK inhibitor [e.g., Opzelura (ruxolitinib)]
   Phototherapy

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   15mg: #1 per day.
   30mg: #1 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi)

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve 45mg for 8 weeks with a quantity limit of #1 per day.
   SECOND APPROVAL: Approve 15mg and 30mg for 4 months with a quantity limit of #1 per day. (Please enter a start date of 2 days BEFORE the END date of the first approval).

   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CD
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi)

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve 45mg for 12 weeks with a quantity limit of #1 per day.
   SECOND APPROVAL: Approve 15mg and 30mg for 3 months with a quantity limit of #1 per day. (Please enter a start date of 2 days BEFORE the END date of the first approval).

   If no, continue to #8.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of AS
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #9.

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of nr-axSpA
   The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Cimzia [certolizumab])
   The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient meet **ONE** of the following criteria?
    The patient was previously stable on another biologic and is switching to Rinvoq
    The patient has C-reactive protein (CRP) levels above the upper limit of normal
    The patient has sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
    The patient is 2 years of age or older
    Therapy is prescribed by or in consultation with a rheumatologist
    Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of PJIA
    The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

    If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
    15mg: #1 per day.
    1mg/mL: #12mL per day.

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:
    You have ONE of the following:
        Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        Psoriatic arthritis (PsA: a type of skin and joint condition)
        Moderate to severe atopic dermatitis (AD: a type of skin condition)
        Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
        Moderate to severe Crohn's disease (CD: a type of bowel disorder)
        Ankylosing spondylitis (AS: a type of joint condition)
        Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
        Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
    (Initial denial text continued on next page)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

If you have psoriatic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

(Initial denial text continued on next page)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe atopic dermatitis, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- You have at least TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
- You meet ONE of the following:
  - You were previously stable on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to Rinvoq
  - You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
  - You have atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
- You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Cimzia [certolizumab])
- You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Rinvoq
  - You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
- You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab]/adalimumab-adaz/Simlandi, Enbrel [etanercept])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UPADACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   15mg: #1 per day.
   1mg/mL: #12mL per day.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   The patient has shown improvement while on therapy
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Opzelura (ruxolitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   15mg: #1 per day.
   30mg: #1 per day.

   If no, continue to #4.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   15mg: #1 per day.
   30mg: #1 per day.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   15mg: #1 per day.
   30mg: #1 per day.

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #7.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #8.

8. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   15mg: #1 per day.
   1mg/mL: #12mL per day.
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Moderate to severe atopic dermatitis (AD: a type of skin condition)
   - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   - Ankylosing spondylitis (AS: a type of joint condition)
   - Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   - Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

   (Renewal denial text continued on next page)

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have moderate to severe atopic dermatitis, renewal also requires:
- You have shown improvement while on therapy
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES

Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2024.

Created: 08/19
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

URIDINE TRIACETATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URIDINE TRIACETATE	XURIDEN		39481	GPI-10 (3090387520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary orotic aciduria (HOA) (ICD-10 E79.89) **AND** meet the following criterion?
   Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at end of the guideline.

2. Is the patient's HOA diagnosis confirmed by **ALL** of the following criteria?
   The patient has a genetic mutation in the uridine monophosphate synthase (UMPS) gene
   The patient has an elevated urine orotic acid level according to an age-specific reference range

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:
   You have hereditary orotic aciduria (HOA a type of rare genetic disorder)
   Therapy is prescribed by or in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)
   Your HOA diagnosis is confirmed by ALL of the following:
   - You have a genetic mutation (abnormal change in gene) in the uridine monophosphate synthase (UMPS) gene
   - You have elevated urine orotic acid levels (high levels of a type of substance in the rune) according to your age-specific reference range

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE TRIACETATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary orotic aciduria (HOA) (ICD-10 E79.89) **AND** meet the following criterion?
   The patient has had improvement from baseline or stabilization of age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) while on treatment with Xuriden

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:
   You have hereditary orotic aciduria (HOA: a type of rare genetic disorder)
   You have had improvement from baseline (before treatment) or stabilization of age dependent hematologic parameters (blood lab tests such as neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) while on treatment with Xuriden

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xuriden.

REFERENCES

Xuriden [Prescribing Information]. Gaithersburg, MD: Wellstat Therapeutics Corporation. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/16
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 05/16

URSODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URSODIOL	RELTONE, URSODIOL		1073 49115	GPI-14 (52100040000112, 52100040000130)	

GUIDELINES FOR USE

1 Does the patient have a diagnosis of radiolucent, noncalcified gallbladder stones and meet **ALL** of the following criteria?

- The patient's gallbladder stones are less than 20 mm in greatest diameter
- Elective cholecystectomy is planned unless the patient is at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia, OR the patient refuses surgery
- The patient had a trial of generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
- The patient is unable to take generic ursodiol formulations (300mg capsule, 250mg tablet, or 500mg tablet)

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength.**
If no, do not approve.
CLINICIAL SPECIALIST NOTE: Use for prevention of gallstone formation in obese patients with rapid weight loss is not covered for this medication.
DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **URSODIOL (Reltone)** requires the following rule(s) be met for approval:

A. You have radiolucent, noncalcified gallbladder stones (hardened deposits of bile, that is barely visible on x-ray, in your gallbladder that do not contain calcium)
B. Your gallbladder stones are less than 20 mm in diameter
C. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic (entire body) disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, OR you refuse surgery
D. You have tried generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
E. You are unable to take generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet) formulations

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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URSODIOL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reltone.

REFERENCES

- Ursodiol 200 mg & 400 mg Capsules [Prescribing Information]. Las Vegas, NV: Intra-Sana Laboratories LLC; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/21
Client Approval: 03/22
P&T Approval: 01/21

USTEKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB	STELARA	36187		GPI-10 (9025058500, 5250407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Stelara
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #5.
   If no, continue to #6.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

   If no, **approve all formulations of the 45mg/0.5mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #0.5mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #0.5mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #7.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the prescriber requesting an intravenous infusion induction dose of **Stelara 130mg/26mL**?

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve 130mg/26mL for 2 months by GPID or GPI-14 with a quantity limit of #104mL per 56 days.
   SECOND APPROVAL: Approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 4 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days (please enter a start date of 7 weeks AFTER the start date of the first approval).

   If no, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   Psoriatic arthritis (PsA: a type of skin and joint condition)
   Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Stelara
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

If you have psoriatic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 84 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 84 days.**

   If no, **approve all formulations of the 45mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5mL per 84 days.**

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, continue to #5.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   If you have moderate to severe plaque psoriasis, renewal also requires:
   - You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   - You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   If you have psoriatic arthritis, renewal also requires:
   - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:
You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Stelara.

REFERENCES
Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.

Created: 10/09
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

USTEKINUMAB-AEKN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-AEKN	SELARSDI	49526		GPI-10 (9025058502)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a dermatologist
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The patient was previously stable on another biologic and is switching to Selarsdi
   The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve the 45mg/0.5mL or 90mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve the 45mg/0.5mL or 90mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

   If no, **approve the 45mg/0.5mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
   FIRST APPROVAL: Approve for 1 month with a quantity limit of #0.5mL per 28 days.
   SECOND APPROVAL: Approve for 5 months with a quantity limit of #0.5mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the prescriber requesting an intravenous infusion induction dose of **Selarsdi 130mg/26mL**?

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   FIRST APPROVAL: Approve 130mg/26mL for 2 months by GPID or GPI-14 with a quantity limit of #104mL per 56 days.
   SECOND APPROVAL: Approve the 45mg/0.5mL or 90mg/mL strength for 4 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days (please enter a start date of 7 weeks AFTER the start date of the first approval).

   If no, **approve the 45mg/0.5mL or 90mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Selarsdi
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB-AEKN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 84 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 84 days.**

   If no, **approve the 45mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5mL per 84 days.**

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, continue to #5.

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USTEKINUMAB-AEKN

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   Selarsdi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for renewal:
   You have ONE of the following:
   - Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   - Psoriatic arthritis (PsA: a type of skin and joint condition)
   - Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   If you have moderate to severe plaque psoriasis, renewal also requires:
   - You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   - You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   If you have psoriatic arthritis, renewal also requires:
   - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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USTEKINUMAB-AEKN

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:
You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
You will NOT use Selarsdi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Selarsdi and Stelara.

REFERENCES
Selarsdi [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; October 2024.
Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.

Created: 02/25
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 01/25

USTEKINUMAB-KFCE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-KFCE	YESINTEK	50041		GPI-10 (5250407079, 9025058578)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #2.
If no, continue to #4.

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to Yesintek
- The patient has psoriasis covering 3 percent or more of body surface area (BSA)
- The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #5.
If no, continue to #6.

Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.
SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

If no, **approve all formulations of the 45mg/0.5mL strength for a total of 6 months by GPID or GPI-14. Please enter two approvals as follows:**
FIRST APPROVAL: Approve for 1 month with a quantity limit of #0.5mL per 28 days.
SECOND APPROVAL: Approve for 5 months with a quantity limit of #0.5mL per 84 days (please enter a start date of 3 weeks AFTER the start date of the first approval).

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, continue to #8.
If no, continue to #7.

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the prescriber requesting an intravenous infusion induction dose of **Yesintek 130mg/26mL**?

If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
FIRST APPROVAL: Approve 130mg/26mL for 2 months by GPID or GPI-14 with a quantity limit of #104mL per 56 days.
SECOND APPROVAL: Approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 4 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days (please enter a start date of 7 weeks AFTER the start date of the first approval).

If no, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Yesintek
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

(Initial denial text continued on next page)

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB-KFCE

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
- Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 84 days.**

If no, continue to #2.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #3.
If no, continue to #4.

Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 84 days.**

If no, **approve all formulations of the 45mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5mL per 84 days.**

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
- Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

If no, continue to #5.

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USTEKINUMAB-KFCE

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?

Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve all formulations of the 45mg/0.5mL or 90mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe plaque psoriasis, renewal also requires:

- You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
- You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

If you have psoriatic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

(Renewal denial text continued on next page)

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USTEKINUMAB-KFCE

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:
You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

If you have moderate to severe ulcerative colitis, renewal also requires:
You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Yesintek and Stelara.

REFERENCES
Yesintek [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.

Created: 02/25
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 01/25

VADADUSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VADADUSTAT	VAFSEO	49335		GPI-10 (8240258000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a nephrologist
   The patient has been receiving dialysis for at least 3 months
   The patient has an eGFR of less than 60 mL/min/1.73m(2) corresponding to stage 3, 4, or 5 chronic kidney disease (CKD)
   The patient has a hemoglobin level of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit), and will discontinue ESA therapy prior to starting Vafseo
   Vafseo will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Jesduvroq [daprodustat])

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with a quantity limit as follows:**
   150mg: #4 per day.
   300mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VADADUSTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VADADUSTAT (Vafseo)** requires the following rule(s) be met for approval:

You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 3 months
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic kidney disease (CKD)
You have a hemoglobin level of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (such as Epogen, Procrit), and you will discontinue ESA therapy before starting Vafseo
You will NOT use Vafseo concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Jesduvroq [daprodustat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VADADUSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ONE** of the following criteria?
   The patient has a hemoglobin level of at least 10 g/dL
   The patient's hemoglobin level has increased by at least 2 g/dL from their baseline level

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   150mg: #4 per day.
   300mg: #2 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VADADUSTAT (Vafseo)** requires the following rule(s) be met for renewal:
   You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
   You meet ONE of the following:
   You have a hemoglobin level (a type of blood test) of at least 10 g/dL
   Your hemoglobin level has increased by at least 2 g/dL from your baseline level

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vafseo.

REFERENCES

Vafseo [Prescribing Information]. Cambridge, MA: Akebia Therapeutics, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/05/24
Created: 07/24
Client Approval: 07/24
P&T Approval: 01/24

VALBENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VALBENAZINE TOSYLATE	INGREZZA	44202		GPI-10 (6238008020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of tardive dyskinesia (TD) (ICD-10 G24.01) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist
   The patient's TD has been present for at least 3 months
   The patient has a history of using antipsychotic medications (e.g., aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if the patient is 60 years of age or older) as documented in the prescription claims history

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   40mg, 60mg, 80mg: #1 per day.
   Initiation pack (40mg-80mg): 1 pack (#28) per fill.

   If no, continue to #2.

2. Does the patient have a diagnosis of chorea associated with Huntington's disease (ICD-10 G10) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   Tardive dyskinesia (TD: uncontrolled body movements)
   Chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
   (Denial text continued on the next page)

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VALBENAZINE

GUIDELINES FOR USE (CONTINUED)

If you have tardive dyskinesia, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), movement disorder specialist, or psychiatrist (a type of mental health doctor)
- Your tardive dyskinesia has been present for at least 3 months
- You have a history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

If you have chorea associated with Huntington's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or movement disorder specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ingrezza.

REFERENCES
Ingrezza [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 04/17
Client Approval: 05/24
P&T Approval: 01/24

VAMOROLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VAMOROLONE	AGAMREE	49283		GPI-10 (2210007500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   The patient is 2 years of age and older
   Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Did the patient experience lack of efficacy with prednisone or prednisolone and meet **ALL** of the following criteria?
   The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   Steroid myopathy has been ruled out
   The patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 6 months by HICL with a quantity limit of #7.69mL per day.**
   If no, continue to #4.

4. Did the patient experience a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes)?

   If yes, **approve for 6 months by HICL with a quantity limit of #7.69mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VAMOROLONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for approval:
You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
You are 2 years of age and older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
Your diagnosis of DMD is confirmed by genetic testing
You have tried prednisone or prednisolone for at least 6 months
You meet ONE of the following:
- Prednisone or prednisolone did not work for you, and you meet ALL of the following:
  - You are not in Stage 1 of the disease (the pre-symptomatic phase)
  - There is no steroid myopathy (muscle disease due to steroid use)
  - You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
- You have experienced a significant adverse effect (side effects such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VAMOROLONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   The patient has shown improvement while on Agamree, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 12 months by HICL with a quantity limit of #7.69mL per day.**
   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength while on Agamree, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

   If yes, **approve for 12 months by HICL with a quantity limit of #7.69mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for renewal:
   You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   If you are currently ambulatory (can walk), approval also requires:
   You have shown improvement while on Agamree as measured by a standard set of ambulatory or functional status measures (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
   If you are currently non-ambulatory (cannot walk), approval also requires:
   You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength while on Agamree as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

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VAMOROLONE

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Agamree.

REFERENCES

Agamree [Prescribing Information]. Burlington, MA: Santhera Pharmaceuticals, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 01/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

VANDETANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANDETANIB	CAPRELSA	37531		GPI-10 (2153308500)	

GUIDELINES FOR USE

1. Is the patient currently stable on the requested medication?

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   100mg: #2 per day.
   300mg: #1 per day.

   If no, continue to #2.

2. Does the patient have diagnosis of symptomatic or progressive medullary thyroid cancer (ICD-10 C73) AND meet the following criterion?
   The patient's cancer is unresectable locally advanced or metastatic disease

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   100mg: #2 per day.
   300mg: #1 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:
   You are currently stable on the requested medication
   You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery and has spread to nearby tissue, lymph nodes, or other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VANDETANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Caprelsa.

REFERENCS

Caprelsa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. March 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 11/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANZACAFTOR/ TEZACAF/ DEUTIVACAF	ALYFTREK	50120		GPI-10 (4530990385)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   The patient is 6 years of age or older
   Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   Alyftrek will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient has at least ONE *F508del* mutation in the CFTR gene
   The patient has a responsive mutation in the CFTR gene

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with the following quantity limits:**
   4-20-50mg: #3 per day.
   10-50-125mg: #2 per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for approval:
You have cystic fibrosis (CF: a type of lung disorder)
You are 6 years of age or older
Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
You meet ONE of the following:
- You have at least ONE *F508del* mutation (abnormal change) in the CFTR gene
- You have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Alyftrek)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet ALL of the following criteria?
   The patient has experienced an improvement in clinical status
   Alyftrek will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve all strengths for lifetime by GPID or GPI-14 with the following quantity limits:**
   4-20-50mg: #3 per day.
   10-50-125mg: #2 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for renewal:
   You have cystic fibrosis (CF: a type of lung disorder)
   You have experienced an improvement in your clinical status
   You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alyftrek.

REFERENCES

Alyftrek [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2024.

Created: 01/25
Effective: 01/17/25 Client Approval: 01/25 P&T Approval: 01/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VARENICLINE TARTRATE	TYRVAYA		51384	GPI-10 (8628008020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) and meet **ALL** of the following criteria?
   2. The patient is 18 years of age or older
   3. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   4. The patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test, etc.)

   If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit of #8.4mL per 30 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:
   A. You have dry eye disease
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   D. You have at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #8.4mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:
   A. You have dry eye disease
   B. You have demonstrated improvement of dry eye disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyrvaya.

REFERENCES

- Tyrvaya [Prescribing Information]. Princeton, NJ: Oyster Point Pharma, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 10/21
Client Approval: 08/24
P&T Approval: 07/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEDOLIZUMAB	ENTYVIO	41146		GPI-10 (5250308000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the 300 mg vial for 1 month with a quantity limit of #2.
   SECOND APPROVAL: Approve for 5 months for the requested strength as follows (enter a start date of ONE WEEK after the last date of the first approval):
   300 mg vial: #1 per 56 days.
   108 mg/0.68 mL pen: #1.36 mL per 28 days.

   If no, continue to #2.

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL: Approve the 300 mg vial for 1 month with a quantity limit of #2.
   SECOND APPROVAL: Approve for 5 months for the requested strength as follows (enter a start date of ONE WEEK after the last date of the first approval):
   300 mg vial: #1 per 56 days.
   108 mg/0.68 mL pen: #1.36 mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VEDOLIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   300 mg vial: #1 per 56 days.
   108 mg/0.68 mL pen: #1.36 mL per 28 days.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)
   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   300 mg vial: #1 per 56 days.
   108 mg/0.68 mL pen: #1.36 mL per 28 days.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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VEDOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab)/Yesintek (ustekinumab-kfce)/Selarsdi (ustekinumab-aekn), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VEDOLIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entyvio.

REFERENCES

Entyvio [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; May 2024.

Created: 05/14
Effective: 04/01/25 Client Approval: 02/25 P&T Approval: 01/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEMURAFENIB	ZELBORAF	37837		GPI-10 (2153208000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   The patient has a BRAF V600E mutation as detected by an FDA-approved test
   Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease (E88.89) **AND** meet the following criterion?
   The patient has a BRAF V600 mutation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:
   You have ONE of the following:
   Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   Erdheim-Chester Disease (a type of multisystem mutation)
   If you have unresectable or metastatic melanoma, approval also requires:
   You have a BRAF V600E mutation (a type of abnormal change in a gene) as detected by a Food and Drug Administration (FDA)-approved test
   Zelboraf will be used alone or in combination with Cotellic (cobimetinib)
   If you have Erdheim-Chester Disease, approval also requires:
   You have a BRAF V600 mutation (a type of abnormal change in a gene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VEMURAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelboraf.

REFERENCES

Zelboraf [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

VENETOCLAX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VENETOCLAX	VENCLEXTA	43284		GPI-10 (2147008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) OR small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   Starting Pack: #42 (1 pack) per 28 days.
   10mg: #2 per day.
   50mg: #1 per day.
   100mg: #4 per day.

   If no, continue to #2.

2. Does the patient have a acute myeloid leukemia (AML) (ICD-10 Group C92.0) **AND** meet the following criterion?
   The patient has newly-diagnosed AML

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   The patient is 75 years of age or older
   The patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Will Venclexta be used in combination with azacitidine or decitabine?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   10mg: #2 per day.
   50mg: #1 per day.
   100mg: #4 per day.

   If no, continue to #5.

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VENETOCLAX

GUIDELINES FOR USE (CONTINUED)

5. Will Venclexta be used in combination with low-dose cytarabine?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   10mg: #2 per day.
   50mg: #1 per day.
   100mg: #6 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VENETOCLAX (Venclexta)** requires that the following rule(s) be met for approval:
   You have ONE of the following:
   - Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   - Small lymphocytic lymphoma (SLL: a type of blood cancer)
   - Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

   If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
   - You are 18 years of age or older

   If you have acute myeloid leukemia, approval also requires:
   - You have newly-diagnosed acute myeloid leukemia
   - You are 75 years of age or older, OR you are 18 years of age or older with comorbidities (additional diseases) that preclude (prevent) the use of intensive induction chemotherapy (a type of therapy to treat cancer)
   - Venclexta will be used in combination with azacitidine or decitabine or low-dose cytarabine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VENETOCLAX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Venclexta.

REFERENCES

Venclexta [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/16
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/19

VERICIGUAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VERICIGUAT	VERQUVO	47075		GPI-10 (4090008500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an ejection fraction of less than 45 percent
   - Verquvo will NOT be used concurrently with long-acting nitrates or nitric oxide donors (e.g. isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), Adempas (riociguat), or PDE-5 inhibitors (e.g. vardenafil, tadalafil)
   - The patient had a trial of or contraindication to ONE of the following preferred SGLT-2 inhibitors: Farxiga (dapagliflozin), Xigduo XR (dapagliflozin-metformin ER), Jardiance (empagliflozin), Synjardy (empagliflozin-metformin)

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a trial of or contraindication to **ONE** agent from EACH of the following classes?
   - ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor [ARNI] (e.g., Entresto [sacubitril/valsartan])
   - Beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate)
   - Aldosterone antagonists (i.e., spironolactone or eplerenone)

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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VERICIGUAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:
You have chronic heart failure (a type of heart condition)
You are 18 years of age or older
You have an ejection fraction (heart function) of less than 45 percent
You will not use Verquvo concurrently (at the same time) with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), Adempas (riociguat), or PDE-5 inhibitors (such as vardenafil, tadalafil)
You have tried or have a contraindication to (harmful for you to use) ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs): Farxiga (dapagliflozin), Xigduo XR (dapagliflozin-metformin extended release), Jardiance (empagliflozin), Synjardy (empagliflozin-metformin)
You have tried or have a contraindication to ONE agent from EACH of the following classes:

i. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as Entresto [sacubitril/valsartan])
ii. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
iii. Aldosterone antagonists (spironolactone or eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VERICIGUAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient has an ejection fraction of less than 45 percent
   - Verquvo will NOT be used concurrently with long-acting nitrates or nitric oxide donors (e.g. isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), Adempas (riociguat), or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VERICIGUAT (Verquvo**) requires the following rule(s) be met for renewal:
   A. You have chronic heart failure (a type of heart condition)
   B. You have an ejection fraction (heart function) of less than 45 percent
   C. You will NOT be taking Verquvo concurrently (at the same time) with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), Adempas (riociguat), or PDE-5 inhibitors (such as vardenafil, tadalafil)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verquvo.

REFERENCES

- Verquvo [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/20

VIGABATRIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	SABRIL, VIGABATRIN, VIGADRONE, VIGPODER		64315 64314	GPI-14 (72170085000320, 72170085003020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) (ICD-10 Group G40.2) and meet **ALL** of the following criteria?
   The patient is 2 years of age or older
   The requested medication will be used as adjunctive therapy
   The potential benefits outweigh the risk of vision loss
   Therapy is prescribed by or in consultation with a neurologist
   The patient had a trial of or contraindication to THREE antiepileptic medications, at least two of which must be generic (e.g., carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam IR/ER, gabapentin, zonisamide, topiramate, lamotrigine)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day for all formulations: tablet and powder packet.**

   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) and meet **ALL** of the following criteria?
   The patient is 1 month to 2 years of age
   The requested medication will be used as monotherapy
   The potential benefits outweigh the potential risk of vision loss
   Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day for the powder packet.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VIGABATRIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Refractory complex partial seizures (a type of seizure)
- Infantile spasms (a type of seizure disorder in infancy and childhood)

If you have refractory complex partial seizures, approval also requires:
- You are 2 years of age or older
- The requested medication will be used as adjunctive (add-on) therapy
- The potential benefits outweigh the risk of vision loss
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have tried or have a contraindication to (harmful for you to use) THREE antiepileptic medications, at least two of which must be generic (drugs used to treat seizures such as carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam immediate-release/extended-release, gabapentin, zonisamide, topiramate, lamotrigine)

If you have infantile spasms, approval also requires:
- You are 1 month to 2 years of age
- The requested medication will be used as monotherapy (one drug treatment)
- The potential benefits outweigh the potential risk of vision loss
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sabril, Vigadrone, and Vigpoder.

REFERENCES

Sabril [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals; October 2021.
Vigadrone [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; March 2023.
Vigpoder [Prescribing Information]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; July 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/24

Created: 05/22
Client Approval: 08/24

P&T Approval: 04/22

VIGABATRIN SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	VIGAFYDE		55889	GPI-14 (72170085002020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) and meet **ALL** of the following criteria?
   The patient is 1 month to 2 years of age
   Vigafyde will be used as monotherapy
   The potential benefits outweigh the potential risk of vision loss
   Therapy is prescribed by or in consultation with a neurologist
   The patient had a trial of or contraindication to generic vigabatrin powder for solution

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN (Vigafyde)** requires the following rule(s) be met for approval:
   You have infantile spasms (a type of seizure disorder in infancy and childhood)
   You are 1 month to 2 years of age
   Vigafyde will be used as monotherapy (one drug treatment)
   The potential benefits outweigh the potential risk of vision loss
   Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   You have tried or have a contraindication to (harmful for you to use) generic vigabatrin powder for solution

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VIGABATRIN SOLUTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vigafyde.

REFERENCES

Vigafyde [Prescribing Information]. Parsippany, NJ: Pyros Pharmaceuticals, Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/19/24
Created: 08/24
Client Approval: 08/24
P&T Approval: 10/24

VIMSELTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIMSELTINIB	ROMVIMZA	50284		GPI-10 (2153178000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (ICD-10 D48.1; Group M12.2) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Surgical resection of the tumor may cause worsening functional limitation or severe morbidity

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIMSELTINIB (Romvimza)** requires the following rule(s) be met for approval:
   You have symptomatic tenosynovial giant cell tumor (TGCT: a type of tumor that affects joints)
   You are 18 years of age or older
   Surgical resection (removal by surgery) of the tumor may cause worsening functional limitation or severe morbidity (illness)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Romvimza.

REFERENCES

Romvimza [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; February 2025.

Created: 02/25
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VISMODEGIB	ERIVEDGE	38455		GPI-10 (2137007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic basal cell carcinoma **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced basal cell carcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has recurred following surgery or the patient is not a candidate for surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VISMODEGIB (Erivedge)** requires the following rule(s) be met for approval:
   A. You have metastatic basal cell carcinoma or locally advanced basal cell carcinoma (type of skin cancer that has spread in the body or is advanced but has not spread)
   B. You are 18 years of age or older
   C. **If you have locally advanced basal cell carcinoma, approval also requires:**
      1. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VISMODEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Erivedge.

REFERENCES

- Erivedge [Prescribing Information]. South San Francisco, CA: Genentech, Inc., July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 02/12
Client Approval: 12/21
P&T Approval: 01/22

VOCLOSPORIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOCLOSPORIN	LUPKYNIS	47077		GPI-10 (9940208000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of active lupus nephritis (LN) (ICD-10 M32.14) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lupkynis will be used in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil, corticosteroids [e.g., prednisone])
   - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:
   You have active lupus nephritis (LN: a type of immune condition that affects the kidneys)
   You are 18 years of age or older
   Lupkynis will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids [such as prednisone])
   Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of active lupus nephritis (LN) (ICD-10 M32.14) **AND** meet the following criterion?
   - The patient has improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:
   A. You have active lupus nephritis (LN: a type of immune condition that affects the kidneys)
   B. You have improvement in renal response from baseline laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, steroid use)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupkynis.

REFERENCES

- Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/20

VONOPRAZAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VONOPRAZAN/AMOXICILLIN	VOQUEZNA DUAL PAK	47981		GPI-10 (4999320220)	
VONOPRAZAN/AMOXICILLIN /CLARITH	VOQUEZNA TRIPLE PAK	47983		GPI-10 (4999320320)	
VONOPRAZAN FUMARATE	VOQUEZNA	48007		GPI-10 (4927508710)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of *Helicobacter pylori (H. pylori)* infection (ICD-10 B96.81) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient had a trial of or contraindication to a bismuth-based quadruple regimen (i.e., bismuth/tetracycline/metronidazole plus PPI [e.g., omeprazole, lansoprazole])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The request is for Voquezna 20mg and will be used in combination with amoxicillin
   The request is for Voquezna 20mg and will be used in combination with amoxicillin and clarithromycin
   The request is for Voquezna Dual Pak
   The request is for Voquezna Triple Pak

   If yes, **approve for 30 days by HICL or GPI-10 for the requested agent as follows:**
   20mg: #28 per 14 days for 1 fill.
   Dual Pak: #112 per 14 days for 1 fill.
   Triple Pak: #112 per 14 days for 1 fill.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of erosive esophagitis (ICD-10 Group K20) and meet **ALL** of the following criteria?
   The request is for Voquezna
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   The patient's diagnosis is confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D)
   The patient had a trial of or contraindication to TWO proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks each

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of non-erosive gastroesophageal reflux disease (ICD-10 Group K21 except for K21.01) and meet **ALL** of the following criteria?
   The request is for Voquezna 10mg
   The patient is 18 years of age or older
   Therapy is prescribed by or in consultation with a gastroenterologist
   The patient's diagnosis is confirmed by endoscopy AND does not have the presence of visible erosion (e.g., does not have Los Angeles Classification of Reflux Esophagitis Grade A-D)
   The patient had no previous treatment failure with Voquezna in the last 12 months
   The patient had a trial of or contraindication to TWO proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks each

   If yes, **approve for 4 weeks by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VONOPRAZAN (Voquezna Dual Pak, Voquezna Triple Pak, Voquezna)** requires the following rule(s) be met for approval:
You have ONE of the following:
Helicobacter pylori (H. pylori: a type of bacteria*)* infection
Erosive esophagitis (a type of digestive disorder)
Non-erosive gastroesophageal reflux disease (a type of digestive disorder)
(Initial denial text continued on the next page)

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VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

If you have a *Helicobacter pylori* infection, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) a bismuth-based quadruple regimen (bismuth/tetracycline/metronidazole plus proton pump inhibitor [PPI] [such as omeprazole, lansoprazole])
- You meet ONE of the following:
  - Your request is for Voquezna 20mg in combination with amoxicillin
  - Your request is for Voquezna 20mg in combination with amoxicillin and clarithromycin
  - Your request is for Voquezna Dual Pak
  - Your request is for Voquezna Triple Pak

If you have erosive esophagitis, approval also requires:
- Your request is for Voquezna
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- Your diagnosis is confirmed by endoscopy (a procedure to look inside your body, such as Los Angeles Classification of Reflux Esophagitis Grade A-D [a tool to rate the severity of the disease])
- You have tried or have a contraindication to (harmful for you to use) TWO proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole) at a maximum dose for 8 weeks each

If you have non-erosive gastroesophageal reflux disease, approval also requires:
- Your request is for Voquezna 10mg
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- Your diagnosis is confirmed by endoscopy (a procedure to look inside your body) AND you do not have the presence of visible (can be seen) erosion (wearing away) (such as not having Los Angeles Classification of Reflux Esophagitis Grade A-D [a tool to rate the severity of the disease])
- You had no previous treatment failure (drug did not work) with Voquezna in the last 12 months
- You have tried or have a contraindication to (harmful for you to use) TWO proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks each

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VONOPRAZAN

RENEWAL CRITERIA

NOTE: For the diagnosis of *Helicobacter pylori* (*H. pylori*) infection or non-erosive gastroesophageal reflux disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of erosive esophagitis (ICD-10 Group K20) **AND** the request is for Voquezna?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for a continuation of treatment (i.e., the patient recently received an initial prior authorization approval for 8 weeks)?

   If yes, continue to #3.
   If no, refer to the Initial Criteria.

3. Has the patient maintained a clinical response while on Voquezna?

   If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VONOPRAZAN (Voquezna)** requires the following rule(s) be met for renewal:
   You have erosive esophagitis (a type of digestive disorder)
   Your request is for Voquezna
   You have maintained a clinical response on Voquezna (the treatment is working)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VONOPRAZAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voquezna TRIPLE PAK, Voquezna DUAL PAK, and Voquezna.

REFERENCES

Voquezna TRIPLE PAK, Voquezna DUAL PAK [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; May 2024.
Voquezna [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/24
Created: 06/22
Client Approval: 08/24
P&T Approval: 04/24

VORASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VORASIDENIB CITRATE	VORANIGO	49796		GPI-10 (2153518000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Grade 2 astrocytoma or oligodendroglioma (ICD-10 C71.9) and meet **ALL** of the following criteria?
   The patient is 12 years of age or older
   The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation
   Voranigo will be used following surgery, including biopsy, sub-total resection, or gross total resection

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   40mg: #1 per day.
   10mg: #2 per day.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VORASIDENIB (Voranigo)** requires the following rule(s) be met for approval:
   You have Grade 2 astrocytoma or oligodendroglioma (types of brain cancer)
   You are 12 years of age or older
   Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation (abnormal changes in types of genes that increase the risk of certain diseases)
   Voranigo will be used following surgery, including biopsy (removal of cells or tissue from the body for examination), sub-total resection (partial removal of tumor), or gross total resection (complete removal of tumor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VORASIDENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voranigo.

REFERENCES

Voranigo [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/24
Created: 08/24
Client Approval: 08/24
P&T Approval: 10/24

VOSORITIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOSORITIDE	VOXZOGO	47677		GPI-10 (3095008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) **AND** meet the following criterion?
   The patient has open epiphyses

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for approval:
   You have achondroplasia (a type of bone condition)
   You have open epiphyses (the end part of a long bone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Voxzogo.

REFERENCES
Voxzogo [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; November 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 01/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/24

ZANUBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZANUBRUTINIB	BRUKINSA	46212		GPI-10 (2153219500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received at least ONE prior therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) (ICD-10 C88.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   The patient has received at least ONE anti-CD20-based regimen (e.g., rituximab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #5.

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   Brukinsa will be used in combination with Gazyva (obinutuzumab)
   Brukinsa will be used after at least TWO lines of systemic therapy (e.g., lenalidomide with rituximab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZANUBRUTINIB (Brukinsa)** requires the following rule(s) be met for approval:
   You have ONE of the following:
   - Mantle cell lymphoma (MCL: a type of blood cancer)
   - Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   - Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer that has returned or did not respond to treatment)
   - Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   - Small lymphocytic lymphoma (SLL: a type of blood cancer)
   - Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or did not respond to treatment)

   If you have mantel cell lymphoma, approval also requires:
   - You are 18 years of age or older
   - You have received at least ONE prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

   If you have Waldenstrom's macroglobulinemia, approval also requires:
   - You are 18 years of age or older

   If you have relapsed or refractory marginal zone lymphoma, approval also requires:
   - You are 18 years of age or older
   - You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan, such as rituximab)

   (Denial text continued on the next page)

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
You are 18 years of age or older

If you have relapsed or refractory follicular lymphoma, approval also requires:
You are 18 years of age or older
Brukinsa will be used in combination with Gazyva (obinutuzumab)
Brukinsa will be used after at least TWO lines of systemic therapy (such as lenalidomide with rituximab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Brukinsa.

REFERENCES
Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/20
Client Approval: 05/24
P&T Approval: 04/24

ZAVEGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZAVEGEPANT HCL	ZAVZPRET	48771		GPI-10 (6770109020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   The patient is 18 years of age or older
   Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines
   The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])
   The patient had a trial of or contraindication to TWO of the following preferred agents: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
   The patient is unable to tolerate oral medications

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per 30 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
   The request is for the acute (quick onset) treatment of migraines (a type of headache)
   You are 18 years of age or older
   You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
   You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])
   You have tried or have a contraindication to TWO of the following medications: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
   You are NOT able to tolerate oral medications

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZAVEGEPANT

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) **AND** the patient meets the following criterion?
   Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 30 days.**
   If no, continue to #3.

3. Has the patient experienced clinical improvement as defined by **ONE** of the following criteria?
   Ability to function normally within 2 hours of dose
   Headache pain disappears within 2 hours of dose
   Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
   The request is for the acute (quick onset) treatment of migraines (a type of headache)
   You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
   You meet ONE of the following:
   - You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
   - You have experienced clinical improvement as defined by ONE of the following:
     - Ability to function normally within 2 hours of dose
     - Headache pain disappears within 2 hours of dose
     - Treatment works consistently in a majority of migraine attacks

(Renewal denial text continued on the next page)
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ZAVEGEPANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavzpret.

REFERENCES

Zavzpret [Prescribing Information]. New York, NY: Pfizer, Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 06/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - ASPIRIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPIRIN	ASPIRIN, ASPIRIN EC, VARIOUS		161 16701 16713 16720	GPI-14 (64100010000315, 64100010000510, 64100010000601, 64100010000605)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for a generic medication?

   If yes, **approve for 12 months by GPID or GPI-14 at zero copay.**
   If no, continue to #3.

3. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification why the generic equivalent cannot be used

   If yes, **approve for 12 months by GPID or GPI-14 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - ASPIRIN** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - Your request is for a generic medication
   - Your request is for a multi-source or single source brand medication (a brand name medication) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - ASPIRIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aspirin medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of aspirin for preventative use at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved aspirin medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

Created: 05/22
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 10/23

ZERO COPAY OVERRIDE - BOWEL PREP

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
SOD PICOSULF/MAG OX/CITRIC AC	CLENPIQ	24291		GPI-10 (4699200345)	
BISAC/NACL/NAHCO3/KCL/PEG 3350	PEG-PREP	33281		GPI-10 (4699200520)	
PEG3350/SOD SULF,BICARB,CL/KCL	GAVILYTE-C, GAVILYTE-G, GOLYTELY COLYTE WITH FLAVOR PACKS, PEG 3350-ELECTROLYTE, PEG 3350 AND ELECTROLYTES	34667 01344		GPI-10 (4699200530)	
SODIUM CHLORIDE/NAHCO3/ KCL/PEG	NULYTELY, NULYTELY WITH FLAVOR PACKS, GAVILYTE-N, PEG 3350-ELECTROLYTE, TRILYTE WITH FLAVOR PACKETS	07981 33276		GPI-10 (4699200430)	
PEG3350/SOD/SUL/NACL /KCL/ASB/C	MOVIPREP, PLENVU, PEG3350/SOD SUL/NACL/KCL/ASB/C	34026		GPI-10 (4699200630)	
PEG 3350/SOD SULF, CHLR/POT/MAG	SUFLAVE	49038		GPI-10 (4699200538)	
SODIUM, POTASSIUM,MAG SULFATES	SUPREP, SODIUM, POTASSIUM,MAG SULFATES	37152		GPI-10 (4699200360)	
SOD SULF/POT CHLORIDE/MAG SULF	SUTAB	46967		GPI-10 (4699200358)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

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ZERO COPAY OVERRIDE - BOWEL PREP

GUIDELINES FOR USE (CONTINUED)

2. Is the patient using the requested medication for colorectal cancer screening **AND** meets the following criterion?

   The patient is between 45 to 75 years of age

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic or SSB medication?

   If yes, **approve the requested medication for 12 months at zero copay with the following fill counts and quantity limits:**
   FILL COUNT
   If no fills in the past 365 days: Approve for 2 fills.
   If 2 or more fills in the past 365 days: Approve for 1 fill.
   QUANTITY LIMIT
   GaviLyte-C, PEG3350/SOD SULF/BICARB/CL/KCL, GaviLyte-N, TriLyte, PEG-PREP: approve by HICL-G or GPI-10-G for #4000mL per fill.
   NuLYTELY: approve by HICL or GPI-10 for #4000mL per fill.
   PEG3350/SOD SUL/NACL/KCL/ASB/C: approve by GPID-G or GPI-14-G for #1 kit per fill.
   SODIUM/POTASSIUM/MAG SULFATES: approve by HICL-G or GPI-10-G for #354mL per fill.
   Plenvu: approve by GPID or GPI-14 for #3 packets per fill.
   Clenpiq: approve by GPID or GPI-14 as follows:
   10mg-3.5g/160mL: #320mL per fill.
   10mg-3.5g/175mL: #350mL per fill.
   Sulfave: approve by HICL or GPI-10 for #2 boxes per fill.
   Sutab: approve by HICL or GPI-10 for #24 tablets per fill.

   If no, continue to #4.

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ZERO COPAY OVERRIDE - BOWEL PREP

GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months at zero copay with the following fill counts and quantity limits:**
   FILL COUNT
   If no fills in the past 365 days: Approve for 2 fills.
   If 2 or more fills in the past 365 days: Approve for 1 fill.
   QUANTITY LIMIT
   GoLYTELY, CoLyte, GaviLyte-G: approve by HICL or GPI-10 for #4000mL per fill.
   MoviPrep: approve by GPID or GPI-14 for #1 kit per fill.
   Suprep: approve by HICL or GPI-10 for #354mL per fill.
   APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZERO COPAY OVERRIDE - BOWEL PREP** requires the following rule(s) be met for approval:
   The requested medication is being used for colorectal cancer screening
   You are between 45 to 75 years of age
   You meet ONE of the following:
   - Your request is for a generic medication or single source brand medication (a brand name medication without a generic available)
   - Your request is for a multi-source medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - BOWEL PREP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for bowel preparation for colonoscopy medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of bowel preparation for colonoscopy medications (used for colorectal cancer screening) at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved bowel preparation for colonoscopy medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

Created: 05/22
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 10/23

ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANASTROZOLE	ARIMIDEX, ANASTROZOLE	10249		GPI-10 (2140281000)	
EXEMESTANE	AROMASIN, EXEMESTANE	20803		GPI-10 (2140283500)	
RALOXIFENE HCL	EVISTA, RALOXIFENE HCL	16917		GPI-10 (3005306010)	
TAMOXIFEN CITRATE	TAMOXIFEN CITRATE		38720 38721	GPI-14 (21402680100310, 21402680100320)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient using the requested medication for prevention (risk reduction) of breast cancer and meets **ALL** of the following criteria?
   The patient is 35 years of age or older
   The request is for a dosing quantity of #1 per day

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months at zero copay with a quantity limit of #1 per day as follows:**
   Anastrozole: Approve by HICL-G or GPI-10-G.
   Exemestane: Approve by HICL-G or GPI-10-G.
   Raloxifene: Approve by HICL-G or GPI-10-G.
   Tamoxifen 10mg and 20mg: Approve <u>both</u> by GPID-G or GPI-14-G.

   If no, continue to #4.

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ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months at zero copay with a quantity limit of #1 per day as follows:**
   Arimidex: Approve by HICL or GPI-10.
   Aromasin: Approve by HICL or GPI-10.
   Evista: Approve by HICL or GPI-10.
   Tamoxifen 10mg and 20mg: Approve both by GPID or GPI-14.
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION** requires the following rule(s) be met for approval:
   The requested medication is being used for prevention (risk reduction) of breast cancer
   You are 35 years of age or older
   You are requesting a quantity of #1 per day
   You meet ONE of the following:
   Your request is for a generic medication
   Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for breast cancer prevention medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of medications for breast cancer prevention at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved medications for breast cancer prevention that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTRACEPTIVES, ORAL				GPI-2 (25)	STC = 0248
CONTRACEPTIVES, TRANSDERMAL					STC = 9495
CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC					STC = 9654
INTRA-UTERINE DEVICES (IUD'S)					STC = 4730
CONTRACEPTIVES, INJECTABLE					STC = 4139
CONTRACEPTIVES, IMPLANTABLE					STC = 3669
CONTRACEPTIVE, INTRAVAGINAL				GPI-10 (5530001000)	STC = 0249
DIAPHRAGMS/CERVICAL CAP				GPI-10 (9740208000) (9740181000) (9740201000)	STC = 3322
CONDOMS, VARIED				GPI-2 (97)	STC = 4650

GUIDELINES FOR USE

1. Does the plan cover the requested contraceptive at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit [EHB] Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for an ORAL contraceptive?

   If yes, continue to #3.
   If no, continue to #7.

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   The request is for a quantity of #1 per day
   The request is for a quantity greater than #1 per day AND the prescriber has provided medical justification as to why the requested quantity is needed for contraception (e.g., continuous therapy, skipping placebo pills, etc.)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a generic medication?

   If yes, **approve the requested medication and quantity for 12 months by HICL-G or GPI-10-G at zero copay.**

   If no, continue to #5.

5. Is the request for a SSB medication?

   If yes, **approve the requested medication and quantity for 12 months by HICL or GPI-10 at zero copay.**

   If no, continue to #6.

6. Is the request for a MSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication and quantity for 12 months by HICL or GPI-10 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand medications only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

GUIDELINES FOR USE (CONTINUED)

7. Is the request for a condom?

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   The request is for a quantity of #60 per fill
   The request is for a quantity greater than #60 per fill AND the prescriber has provided medical justification as to why the requested quantity is needed for contraception

   If yes, **approve the requested quantity for 12 months by HICL or GPI-10 at zero copay.**
   If no, do not approve**.**
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by HICL-G or GPI-10-G at zero copay.**

   If no, continue to #10.

10. Is the request for a SSB medication?

    If yes, **approve the requested medication for 12 months by HICL or GPI-10 at zero copay.**
    If no, continue to #11.

11. Is the request for a MSB medication **AND** the patient meets the following criterion?
    The prescriber has provided medical justification as to why the generic equivalent cannot be used

    If yes, **approve the requested medication for 12 months by HICL or GPI-10 at zero copay.**
    APPROVAL TEXT (applies to multi-source brand medications only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZERO COPAY OVERRIDE - CONTRACEPTIVE** requires that the following rule(s) be met for approval:
You meet ONE of the following:
- Your request is for a generic or a single source brand medication (a brand name medication without a generic available)
- Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

If your request is for an oral contraceptive, approval also requires ONE of the following:
- Your request is for a quantity of #1 per day
- Your request is for a quantity greater than #1 per day AND your doctor has provided medical justification as to why the requested quantity is needed for contraception (such as continuous therapy, skipping placebo pills)

If your request is for a condom, approval also requires ONE of the following:
- Your request is for a quantity of #60 per prescription fill
- Your request is for a quantity greater than #60 per fill AND your doctor has provided medical justification as to why the requested quantity is needed for contraception

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for contraceptive medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of contraceptives at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved contraceptive methods that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024
The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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ZERO COPAY OVERRIDE - FLUORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLUORIDE (SODIUM)	FLURA-DROPS, SOLUVITA, FLUORIDE, SODIUM FLUORIDE, LUDENT FLUORIDE		7472 7473 7510 7511 7512	GPI-14 (79300020000505, 79300020000510, 79300020000515, 79300020002050)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient 6 months to 6 years of age?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #4.

4. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - FLUORIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZERO COPAY OVERRIDE - FLUORIDE** requires the following rule(s) be met for approval:
You are 6 months to 6 years of age
You meet ONE of the following:
- Your request is for a generic medication
- Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for fluoride medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of fluoride at zero copay. The override criteria allow patients access a zero copay by waiving the applicable cost-sharing on FDA-approved fluoride medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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ZERO COPAY OVERRIDE - FOLIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOLIC ACID	FOLIC ACID		94783 94784	GPI-14 (82200010000305, 82200010000310)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #3.

3. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - FOLIC ACID** requires the following rule(s) be met for approval:
   You meet ONE of the following:
   - Your request is for a generic medication
   - Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - FOLIC ACID

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for folic acid medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of folic acid 0.4mg and 0.8mg tablets at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing on FDA-approved folic acid medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA, EMTRICITABINE / TENOFOVIR DISOPROXIL FUMARATE		23152	GPI-14 (12109902300320)	
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY		40953	GPI-14 (12109902290320)	
TENOFOVIR DISOPROXIL FUMARATE	VIREAD, TENOFOVIR DISOPROXIL FUMARATE		14822	GPI-14 (12108570100320)	
EMTRICITABINE	EMTRIVA, EMTRICITABINE		20019	GPI-14 (12106030000120)	
CABOTEGRAVIR	APRETUDE	47270		GPI-10 (1210301000)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet **ALL** of the following criteria?
   The requested medication is FDA-approved for PrEP or recommended by the CDC PrEP Guidelines
   The requested medication will NOT be used concurrently with another HIV medication for the treatment of HIV
   The request is for a dosing quantity of #1 per day for Truvada (emtricitabine/tenofovir disoproxil fumarate), Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), and Descovy (emtricitabine and tenofovir alafenamide)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

GUIDELINES FOR USE (CONTINUED)

3. Is the request for a generic or SSB medication?

   If yes, **approve the requested medication for 12 months as follows:**
   Emtricitabine/tenofovir: Approve by GPID-G or GPI-14-G with a quantity limit of #1 per day. at zero copay.
   Descovy: Approve by GPID or GPI-14 with a quantity limit of #1 per day.
   Tenofovir disoproxil: Approve by GPID-G or GPI-14-G with a quantity limit of #1 per day.
   Emtricitabine: Approve by GPID-G or GPI-14-G with a quantity limit of #1 per day.
   Apretude : Approve by HICL or GPI-10 for 7 fills.

   If no, continue to #4.

4. Is the request for a MSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months at zero copay as follows:**
   Truvada: Approve by GPID or GPI-14 with a quantity limit of #1 per day.
   Viread: Approve by GPID or GPI-14 with a quantity limit of #1 per day.
   Emtriva: Approve by GPID or GPI-14 with a quantity limit of #1 per day.
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS** requires the following rule(s) be met for approval:

- The requested medication is FDA (Food and Drug Administration)-approved for pre-exposure prophylaxis (PrEP) OR recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines
- The requested medication will NOT be used concurrently (at the same time) with another human immunodeficiency virus (HIV) medication for the treatment of HIV
- Your request is for a dosing quantity of #1 per day for Truvada (emtricitabine/tenofovir disoproxil fumarate), Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), and Descovy (emtricitabine and tenofovir alafenamide)
- You meet ONE of the following:
  - Your request is for a generic or a single source brand medication (a brand name medication without a generic available)
  - Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pre-Exposure Prophylaxis (PrEP) medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of medications for Pre-Exposure Prophylaxis (PrEP) at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved medications for breast cancer prevention that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: : https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

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ZERO COPAY OVERRIDE - SMOKING CESSATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUPROPION HCL	ZYBAN, BUROPION HCL SR		27901	GPI-10 (6210000210)	
VARENICLINE TARTRATE	CHANTIX, VARENICLINE TARTRATE		27046 27047 27048	GPI-10 (6210008020)	
NICOTINE	NICOTROL, NICOTROL NS, NICOTINE PATCH, NICODERM CQ, NICOTINE	06249		GPI-10 (6210000500)	
NICOTINE POLACRILEX	NICOTINE GUM, NICOTINE LOZENGE, NICORETTE, VARIOUS	02049		GPI-14 (6210001000)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient 18 years of age or older?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic medication?

   If yes, **approve the requested medication/agent for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #4.

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ZERO COPAY OVERRIDE - SMOKING CESSATION

GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 at zero copay. APPROVAL TEXT (applicable to multi-source brand agents only):** Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - SMOKING CESSATION** requires the following rule(s) be met for approval:
   You are 18 years of age or older
   You meet ONE of the following:
   - Your request is for a generic
   - Your request is for a multi-source medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - SMOKING CESSATION

RATIONALE

This guideline applies to plans where the pharmacy benefit allows for coverage of smoking cessation medication at zero copay. The override criteria allow patient access to all FDA-approved smoking cessation medications at zero copay.

This guideline applies to plans where the pharmacy benefit allows for coverage of medications for smoking cessation at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on smoking cessation agents that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: : https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

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ZERO COPAY OVERRIDE - STATIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROSUVASTATIN CALCIUM	CRESTOR, EZALLOR SPRINKLE, ROSUVASTATIN CALCIUM		19153 20229 39996 38314	GPI-14 (39400060100305, 39400060100310, 39400060106805, 39400060106810)	
PRAVASTATIN SODIUM	PRAVACHOL, PRAVASTATIN SODIUM	06227		GPI-10 (3940006510)	
SIMVASTATIN	ZOCOR, SIMVASTATIN		26531 26532 26533 26534	GPI-14 (39400075000310, 39400075000320, 39400075000330, 39400075000340)	
ATORVASTATIN CALCIUM	LIPITOR, ATORVASTATIN CALCIUM		43720 43721	GPI-14 (39400010100310, 39400010100320)	
LOVASTATIN, LOVASTATIN EXTENDED-RELEASE	ALTOPREV, LOVASTATIN	02793		GPI-10 (3940005000)	
FLUVASTATIN SODIUM , FLUVASTATIN EXTENDED-RELEASE	LESCOL, FLUVASTATIN SODIUM, LESCOL XL, FLUVASTATIN EXTENDED-RELEASE	08946		GPI-10 (3940003010)	
PITAVASTATIN CALCIUM	LIVALO, PITAVASTATIN CALCIUM	36983		GPI-10 (3940005810)	
PITAVASTATIN MAGNESIUM	ZYPITAMAG, PITAVASTATIN MAGNESIUM	44422		GPI-10 (3940005830)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   The patient is between 40 to 75 years old
   The patient is not concurrently taking any of the below secondary prevention medications for cardiovascular disease:
   Aspirin/dipyridamole (Aggrenox)
   Clopidogrel (Plavix)
   Dipyridamole
   Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
   Prasugrel (Effient)
   Ticagrelor (Brilinta)
   Ticlopidine
   Vorapaxar (Zontivity)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the requested quantity within the low to moderate intensity daily dosage as shown below?
   Atorvastatin (Lipitor): 10 - 20 mg
   Fluvastatin (Lescol): 20 - 80 mg (40 mg twice daily)
   Fluvastatin ER (Lescol XL): 80 mg
   Lovastatin: 10 - 40 mg
   Pitavastatin calcium (Livalo): 1 - 4 mg
   Pravastatin (Pravachol): 10 - 80 mg
   Rosuvastatin (Crestor): 5 - 10 mg
   Simvastatin (Zocor): 5 - 40 mg

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #5.

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE (CONTINUED)

5. Is the request for a MSB medication **AND** the patient meets the following criterion?
   The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 at zero copay. APPROVAL TEXT (applicable to multi-source brand agents only):** Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZERO COPAY OVERRIDE - STATIN** requires the following rule(s) be met for approval:
   You are between 40 to 75 years old
   You are not concurrently (at the same time) taking any of the below secondary prevention medications for cardiovascular disease (heart disease):
   Aspirin/dipyridamole (Aggrenox)
   Clopidogrel (Plavix)
   Dipyridamole
   Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
   Prasugrel (Effient)
   Ticagrelor (Brilinta)
   Ticlopidine
   Vorapaxar (Zontivity)
   The requested quantity is within the low to moderate intensity daily dosage as shown below:
   Atorvastatin (Lipitor): 10 - 20 mg
   Fluvastatin (Lescol): 20 - 80 mg (40 mg twice daily)
   Fluvastatin ER (Lescol XL): 80 mg
   Lovastatin: 10 - 40 mg
   Pitavastatin calcium (Livalo): 1 - 4 mg
   Pravastatin (Pravachol): 10 - 80 mg
   Rosuvastatin (Crestor): 5 - 10 mg
   (Denial text continued on next page)

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE (CONTINUED)

You meet ONE of the following:
- Your request is for a generic medication
- Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for statin medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of low-to-moderate intensity statins at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to all FDA-approved low-to-moderate intensity statins that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2023.

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2023.

Created: 12/17
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 10/23

ZILUCOPLAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZILUCOPLAN SODIUM	ZILBRYSQ	49273		GPI-10 (8580509520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   The patient is 18 years of age and older
   Therapy is prescribed by or in consultation with a neurologist
   The patient's diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor (AChR) antibody
   The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with the following quantity limits:**
   16.6mg syringe: #0.416mL per day.
   23mg syringe: #0.574mL per day.
   32.4mg syringe: #0.81mL per day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ZILUCOPLAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for approval:
You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
You are 18 years of age and older
Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
Your diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor (AChR) antibody (a type of blood test that shows you have myasthenia gravis)
You have Myasthenia Gravis Foundation of America class II, III, or IV (indicates severity of disease)
You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as, prednisone)
You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as, azathioprine, cyclophosphamide, methotrexate)
- You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZILUCOPLAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) **AND** meet the following criterion?
   The patient has had clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   16.6mg syringe: #0.416mL per day.
   23mg syringe: #0.574mL per day.
   32.4mg syringe: #0.81mL per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for renewal:
   You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   You have had clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as, the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zilbrysq.

REFERENCES

Zilbrysq [Prescribing Information]. Smyrna, GA: UCB, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 01/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZONISAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZONISAMIDE	ZONISADE	21140		GPI-10 (7260009000)	BRAND = ZONISADE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   The patient is 16 years of age or older
   Zonisade will be used as adjunctive treatment
   The patient is unable to swallow zonisamide capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZONISAMIDE (Zonisade)** requires the following rule(s) be met for approval:
   You have partial-onset seizures (a type of seizure)
   You are 16 years of age or older
   Zonisade will be used as adjunctive (add-on) treatment
   You are unable to swallow zonisamide capsules

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zonisade.

REFERENCES

Zonisade [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; March 2023.

Created: 11/22
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZURANOLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZURANOLONE	ZURZUVAE	49127		GPI-10 (5806009000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postpartum depression (PPD) (ICD-10 F53.0)?

   If yes, **approve for 30 days by GPID or GPI-14 for the requested strength with the following quantity limits:**
   20mg: #28 per 14 days for 1 fill.
   25mg: #28 per 14 days for 1 fill.
   30mg: #14 per 14 days for 1 fill.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZURANOLONE (Zurzuvae)** requires the following rule(s) be met for approval:
   You have postpartum depression (PPD: a type of depression that occurs after giving birth)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zurzuvae.

REFERENCES
Zurzuvae [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
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