



DENVER HEALTH
MEDICAL PLAN INC.™

Elevate

Non-Self-Administered Prior Authorization Approval Criteria

Effective Date: 07/01/2019



**Standard Non-Self-
Administered
Prior Authorization Guidelines**



**STANDARD COMMERCIAL DRUG FORMULARY
NON-SELF-ADMINISTERED
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.



**Standard Non-Self-Administered
Prior Authorization Guidelines**



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

1. Formulary Agents

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- 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 **Medication Request Form** to MedImpact at (858) 790-7100.
- b. Contacting MedImpact at (800) 788-2949 and providing all necessary information requested.

MedImpact will provide an authorization number, specific for the medical need, for all approved requests. Non-approved requests may be appealed. The prescriber must provide information to support the appeal on the basis of medical necessity.



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ABATACEPT/MALTOSE	ORENCIA - IV		26306	

NOTE: For requests for the SQ dosage form of Orencia, please see the Orencia 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) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel Humira, Xeljanz IR/XR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID as follows:**

- **FIRST APPROVAL: Approve for 1 month by GPID with a maximum quantity limit of #4 vials (four 250mg vials) for 3 fills AND**
- **SECOND APPROVAL: Approve for 5 months by GPID with a maximum quantity limit of #4 vials (four 250mg vials) per month (start date is 1 month after the start of the 1st PA).**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis (RA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV (NSA)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 6 years of age or older
- The patient meets **ONE** of the following:
 - The patient had a previous trial of or contraindication to the following formulary preferred immunomodulators: Enbrel **AND** Humira
 - The patient had a previous trial of or contraindication to the following formulary preferred immunomodulator: Actemra

[**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID as follows:**

- **FIRST APPROVAL:** Approve for 1 month by GPID with a maximum quantity limit of #4 vials (four 250mg vials) for 3 fills **AND**
- **SECOND APPROVAL:** Approve for 5 months by GPID with a maximum quantity limit of #4 vials (four 250mg vials) per month (start date is 1 month after the start of the 1st PA).

APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID as follows:**

- **FIRST APPROVAL:** Approve for 1 month by GPID with a maximum quantity limit of #4 vials (four 250mg vials) for 3 fills **AND**
- **SECOND APPROVAL:** Approve for 5 months by GPID with a maximum quantity limit of #4 vials (four 250mg vials) per month (start date is 1 month after the start of the 1st PA).

APPROVAL TEXT: Renewal for psoriatic arthritis (PsA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ABATACEPT - IV (Orencia - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, or psoriatic arthritis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz (IR/XR)

(Initial denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 6 years of age or older
- The patient meets **ONE** of the following:
 - The patient had a previous trial of or contraindication to the following formulary preferred immunomodulators: Enbrel **AND** Humira
 - The patient had a previous trial of or contraindication to the following formulary preferred immunomodulator: Actemra

For patients with psoriatic arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID with a quantity limit of #4 vials (four 250mg vials) per month.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ABATACEPT - IV (ORENCIA - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criterion must be met:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ABATACEPT - IV (NSA)

RATIONALE

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

REFERENCES

- Orencia [Prescribing Information]. Princeton, NJ: E.R. Squibb & Sons, L.L.C.; June 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 05/05

Client Approval: 03/19

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADO-TRASTUZUMAB EMTANSINE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ADO-TRASTUZUMAB EMTANSINE	KADCYLA	40046		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 - The patient's breast cancer is HER2- positive
 - The patient has previously received trastuzumab and a taxane, separately or in combination
 - The patient has received prior therapy for metastatic disease **OR** developed disease recurrence during or within six months of completing adjuvant therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of early breast cancer and meet **ALL** of the following criteria?
 - The patient's breast cancer is HER2- positive
 - The patient has residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires a diagnosis of metastatic breast cancer or early breast cancer. In addition, the following criteria must be met:

For the diagnosis of metastatic breast cancer, approval requires:

- The patient's breast cancer is HER2- positive
- The patient has previously received trastuzumab and a taxane, separately or in combination
- The patient has received prior therapy for metastatic disease **OR** developed disease recurrence during or within six months of completing adjuvant therapy

For the diagnosis of early breast cancer, approval requires:

- The patient's breast cancer is HER2- positive
- The patient has residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ADO-TRASTUZUMAB EMTANSINE (NSA)

RATIONALE

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

REFERENCES

- Kadcyla [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 03/13

Client Approval: 05/19

P&T Approval: 07/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AFLIBERCEPT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AFLIBERCEPT	EYLEA		30919	

GUIDELINES FOR USE

1. Is this medication being prescribed by or given in consultation with an ophthalmologist and/or retina specialist?

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 **ONE** of the following diagnoses?

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

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 receiving treatment in both eyes at this time?

If yes, **approve for 12 months by GPID with a quantity not to exceed 0.10mL (#2 vials) per month.**

If no and one eye is being treated at this time, **approve for 12 months by GPID with a quantity not to exceed 0.05mL (#1 vial) per month.**

DENIAL TEXT: The guideline named **AFLIBERCEPT (Eylea)** requires that the medication is prescribed by or given in consultation with an ophthalmologist and/or retina specialist and the patient has a diagnosis of neovascular (wet) age-related macular degeneration (AMD); macular edema following retinal vein occlusion (RVO); diabetic macular edema (DME); or diabetic retinopathy (DR).

RATIONALE

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

REFERENCES

- Eylea [Prescribing Information]. Tarrytown, NY: Regeneron; May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Created: 04/14

Commercial Effective: 07/01/19

Client Approval: 05/19

P&T Approval: 07/19

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AGALSIDASE BETA	FABRAZYME	24861		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease and meet **ALL** of the following criteria?
 - The patient is 8 years of age or older
 - The requested medication is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
 - The patient is **NOT** concurrently using an alpha-galactosidase A (a-Gal A) pharmacological chaperone (i.e., migalastat)
 - 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 patient who meets the following criterion?
 - Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following 1) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss), 2) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound), OR 3) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy).

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (NSA)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ONE** of the following criteria?

- Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal-A)
- Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following 1) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss), 2) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound), OR 3) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **AGALSIDASE BETA (Fabrazyme)** requires a diagnosis of Fabry disease. In addition, the following criteria must be met:

- The patient is 8 years of age or older
- The requested medication is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
- The patient is **NOT** concurrently using an alpha-galactosidase A (a-Gal A) pharmacological chaperone (i.e., migalastat)
- 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)
- The patient meets **ONE** of the following:
 - Female patients: Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation
 - Male patients: Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal-A), **OR** genetic test documenting galactosidase alpha gene (GLA) mutation

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease **AND** meet the following criterion?
 - The prescribing provider attests that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following:
 - 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.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **AGALSIDASE BETA (Fabrazyme)** requires a diagnosis of Fabry disease for renewal. In addition, the following renewal criteria must be met:

- The prescribing provider attests that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following:
 - 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)

RATIONALE

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

REFERENCES

- Fabrazyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 02/19

Client Approval: 03/19

P&T Approval: 01/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALEMTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ALEMTUZUMAB	LEMTRADA		36182	

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) **AND** meet the following criterion?
 - The patient had a previous trial of at least **TWO** agents that have been FDA approved for the treatment of relapsing forms of multiple sclerosis (MS). (**Please note** that other MS agents may also require prior authorization)

If yes, **approve for 12 months by GPID with a quantity limit of #6mL (five 1.2mL vials) for one fill.**

APPROVAL TEXT: Renewal requires at least 12 months have elapsed since the patient received the most recent course of Lemtrada.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ALEMTUZUMAB (Lemtrada)** requires a diagnosis of a relapsing form of multiple sclerosis. In addition, the following criterion must be met:

- The patient had a previous trial of at least TWO agents that have been FDA approved for the treatment of relapsing forms of multiple sclerosis (**Please note** that other multiple sclerosis agents may also require prior authorization).

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) **AND** meet the following criterion?
 - At least 12 months have elapsed since the patient received the most recent course of Lemtrada

If yes, **approve for 12 months by GPID with a quantity limit of #3.6mL (three 1.2mL vials) for one fill.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ALEMTUZUMAB (Lemtrada)** requires a diagnosis of a relapsing form of multiple sclerosis for renewal. Approval also requires that at least 12 months have elapsed since the patient received the most recent course of Lemtrada.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALEMTUZUMAB (NSA)

RATIONALE

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

REFERENCES

- Lemtrada [Prescribing Information]. Cambridge, MA: Genzyme Corporation.; January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 02/15

Client Approval: 03/19

P&T Approval: 01/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALGLUCOSIDASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ALGLUCOSIDASE ALFA	LUMIZYME MYOZYME	33588		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Pompe's disease (acid alpha-glucosidase [GAA] deficiency)?

If yes, **approve for lifetime by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ALGLUCOSIDASE ALFA** requires a diagnosis of Pompe's disease (acid alpha-glucosidase deficiency).

RATIONALE

Promote appropriate utilization and dosing based on FDA approved indication.

FDA APPROVED INDICATIONS

Lumizyme is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (GAA deficiency).

Myozyme is a lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (GAA deficiency).

DOSAGE AND ADMINISTRATION

20 mg per kg body weight administered every 2 weeks as an intravenous infusion

REFERENCES

- Lumizyme [Prescribing Information]. Cambridge, MA:Genzyme Corporation; August 2014. Myozyme [Prescribing Information] , Cambridge, MA:Genzyme Corporation; May 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 08/14

Client Approval: 11/14

P&T Approval: 11/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASPARAGINASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ASPARAGINASE (ERWINIA CHRYSAN)	ERWINAZE		30918	
PEGASPARGASE	ONCASPAR		24231	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL)?

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 Erwinaze?

If yes, continue to #3.

If no, **approve Oncaspar (GPID 24231) for 12 months for 1 fill per 14 days.**

3. Has the patient developed a hypersensitivity to *E. Coli*-derived asparaginase (e.g., Oncaspar)?

If yes, **approve Erwinaze (GPID 30918) for 12 months with no quantity limit.**

If no, do not approve.

DENIAL TEXT: The guideline named **ASPARAGINASE (Erwinaze, Oncaspar)** requires a diagnosis of acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met:

Request for Erwinaze also requires:

- The patient has developed a hypersensitivity to *E. Coli*-derived asparaginase (e.g., Oncaspar)

RATIONALE

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

REFERENCES

- Erwinaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc., March 2016.
- Oncaspar [Prescribing Information]. Lexington, MA: Baxalta US Inc., January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 12/11

Client Approval: 05/19

P&T Approval: 04/19

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ATEZOLIZUMAB	TECENTRIQ	43408		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma **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 is not eligible to receive cisplatin-containing chemotherapy **AND** has a tumor that expresses PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering 5% or more of the tumor area), as determined by an FDA approved test
- The patient is not eligible to receive any platinum containing chemotherapy regardless of PD-L1 status
- The patient has disease progression during or following treatment with any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with any platinum-containing chemotherapy (e.g. cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by GPID (41377) with a quantity limit of #20mL (1 vial of 1200mg/20mL) per 21 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 a metastatic non-squamous non-small cell lung cancer (NSq NSCLC) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The requested medication will be given in combination with bevacizumab, paclitaxel, and carboplatin as a first-line treatment
- The patient does not have EGFR or ALK genomic tumor aberrations

If yes, **approve for 12 months by GPID (41377) with a quantity limit of #20mL (1 vial of 1200mg/20mL) per 21 days.**

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

4. 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 requested medication will be used as a single-agent

If yes, continue to #5.

If no, continue to #8.

5. Does the patient have NSCLC without an EGFR or ALK mutation **AND** meet the following criterion?

- The patient had disease progression during or following treatment with any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by GPID (41377) with a quantity limit of #20mL (1 vial of 1200mg/20mL) per 21 days.**

If no, continue to #6.

6. Does the patient have NSCLC with an ALK mutation **AND** meet the following criteria?

- The patient had disease progression during or following treatment with **ALL** of the following:
 - Platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - ALK-directed therapy [e.g., Xalkori (crizotinib), Zykadia (ceritinib)]

If yes, **approve for 12 months by GPID (41377) with a quantity limit of #20mL (1 vial of 1200mg/20mL) per 21 days.**

If no, continue to #7.

7. Does the patient have NSCLC with an EGFR mutation **AND** meet the following criteria?

- The patient had disease progression during or following treatment with **ALL** of the following:
 - Platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - EGFR-directed therapy [e.g., Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

If yes, **approve for 12 months by GPID (41377) with a quantity limit of #20mL (1 vial of 1200mg/20mL) per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) 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 paclitaxel protein-bound
 - The patient's tumor expresses PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering 1% or more of the tumor area), as determined by an FDA-approved test

If yes, **approve for 12 months by GPID (46094) with a quantity limit of #28mL (2 vials of 840mg/14mL) per 28 days.**

If no, continue to #9.

9. Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) 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 carboplatin and etoposide as a first-line treatment

If yes, **approve for 12 months by GPID (41377) with a quantity limit of #20mL (1 vial of 1200mg/20ml) per 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ATEZOLIZUMAB (Tecentriq)** requires a diagnosis of locally advanced or metastatic urothelial carcinoma, metastatic non-small cell lung cancer (NSCLC), metastatic non-squamous non-small cell lung cancer (NSq NSCLC), unresectable locally advanced or metastatic triple-negative breast cancer (TNBC), or extensive-stage small cell lung cancer (ES-SCLC). In addition, the following criteria must be met:

For patients with locally advanced or metastatic urothelial carcinoma, approval requires:

- The patient is 18 years of age or older
- The patient must also meet ONE of the following:
 - The patient is not eligible to receive cisplatin-containing chemotherapy **AND** has a tumor that expresses PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering 5% or more of the tumor area), as determined by an FDA approved test
 - The patient is not eligible to receive any platinum containing chemotherapy regardless of PD-L1 status
 - The patient has disease progression during or following treatment with any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with any platinum-containing chemotherapy (e.g. cisplatin, carboplatin, oxaliplatin)

(Denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

For patients with metastatic non-squamous non-small cell lung cancer (NSq NSCLC), approval requires:

- The patient is 18 years of age or older
- The requested medication will be given in combination with bevacizumab, paclitaxel, and carboplatin as a first-line treatment
- The patient does not have EGFR or ALK genomic tumor aberrations

For patients with metastatic non-small cell lung cancer (NSCLC), approval requires:

- The patient is 18 years of age or older
- The requested medication will be used as a single-agent
- The patient must also meet **ONE** of the following:
 - The patient does not have an EGFR or ALK mutation **AND** has disease progression during or following treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient has an ALK mutation with disease progression during or following treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) **AND** ALK-directed therapy [e.g., Xalkori (crizotinib), Zykadia (ceritinib)]
 - The patient has an EGFR mutation with disease progression during or following treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) **AND** EGFR-directed therapy [e.g., Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

For patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC), approval requires:

- The patient is 18 years of age or older
- The requested medication will be used in combination with paclitaxel protein-bound
- The patient's tumor expresses PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering 1% or more of the tumor area), as determined by an FDA-approved test

For patients with extensive-stage small cell lung cancer (ES-SCLC), approval requires:

- The patient is 18 years of age or older
- The requested medication will be used in combination with carboplatin and etoposide as a first-line treatment

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ATEZOLIZUMAB (NSA)

RATIONALE

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

REFERENCES

- Tecentriq [Prescribing Information]. Genentech Inc.: South San Francisco, CA; March 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/08/19

Created: 05/16

Client Approval: 03/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVELUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AVELUMAB	BAVENCIO	44170		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic Merkel cell carcinoma (MCC) and meet the following criterion?

- The patient is 12 years or older

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (UC) and meet **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.**

If no, continue to #3.

3. Does the patient have a diagnosis of advanced renal cell carcinoma and meet ALL of the following criteria?

- The agent is prescribed as a first-line treatment
- The medication will be used in combination with axitinib

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **AVELUMAB (Bavencio)** requires a diagnosis of metastatic Merkel cell carcinoma (MCC), locally advanced urothelial carcinoma, metastatic urothelial carcinoma, or advanced renal cell carcinoma. The following criteria must be met:

For metastatic Merkel cell carcinoma, approval requires the following:

- The patient is 12 years or older

For locally advanced or metastatic urothelial carcinoma, approval requires ONE of the following:

- 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)

For advanced renal cell carcinoma, approval requires the following:

- The medication is prescribed as a first line treatment
- The medication will be used in combination with axitinib

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AVELUMAB (NSA)

RATIONALE

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

REFERENCES

- Bavencio [Prescribing Information]. Darmstadt, Germany. Merck KGaA; May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 04/17

Client Approval: 05/19

P&T Approval: 07/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXICABTAGENE CILOLEUCEL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AXICABTAGENE CILOLEUCEL	YESCARTA	44577		

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?

- Primary Central Nervous System Lymphoma (PCNSL)
- Mantle Cell Lymphoma (MCL)
- Burkitt's Lymphoma

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses?

- Diffuse Large B-Cell Lymphoma (DLBCL) not otherwise specified
- Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
- High grade B-Cell Lymphoma (e.g., double-hit or triple-hit lymphoma)
- Diffuse Large B-Cell Lymphoma (DLBCL) arising from Follicular lymphoma (FL) [i.e., transformed follicular Lymphoma (TFL)]

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
- Treatment is prescribed by a Yescarta-certified hematologist or oncologist
- Yescarta will be administered at a treatment center that is certified to administer Yescarta
- The patient has not received a previous trial of Yescarta

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXICABTAGENE CILOLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the physician attest that the patient meets **ONE** of the following criteria?

- The patient has had disease progression or relapsed after stem cell transplantation (SCT)
- The patient has had disease progression or relapsed after two or more lines of systemic therapy

If yes, **approve 1 fill by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **AXICABTAGENE CILOLEUCEL (Yescarta)** requires that the patient has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma (e.g., double-hit or triple-hit lymphoma), or diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma (FL) [i.e., transformed follicular lymphoma (TFL)]. **AXICABTAGENE CILOLEUCEL (Yescarta)** is not FDA-approved for the treatment of Primary Central Nervous System Lymphoma (PCNSL), Mantle Cell Lymphoma (MCL), or Burkitt's lymphoma. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Treatment is prescribed by a Yescarta-certified hematologist or oncologist
- Yescarta will be administered at a treatment center that is certified to administer Yescarta
- The patient has not had a previous trial of Yescarta
- Physician attestation of **ONE** of the following criteria:
 - The patient has had disease progression or relapsed after stem cell transplantation (SCT)
 - The patient has had disease progression or relapsed after two or more lines of systemic therapy

RATIONALE

Promote appropriate utilization of **YESCARTA** based on FDA approved indication, dosing and clinical trial design.

NOTE: Yescarta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological events. Healthcare facilities that dispense and administer Yescarta must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after Yescarta infusion, if needed for treatment of CRS.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AXICABTAGENE CILOLEUCEL (NSA)

RATIONALE (CONTINUED)

Yescarta is the second gene therapy to be approved by the FDA and was granted Priority Review, Breakthrough Therapy, and Orphan Drug designations. Yescarta is an engineered chimeric antigen receptor (CAR) product that targets CD19, a protein expressed on the surface of B cell leukemia and lymphoma cells. The CAR product is utilized in the process of autologous cell therapy in which a patient's own white blood cells are collected, T cells are isolated, the CAR gene is inserted into the T cells, the T cell colony is expanded, and then the engineered T cells are infused back into the patient. This process results in an expanded number of tumor-specific T cells that circulate throughout the body to target and kill cancer cells.

Diffuse large B-cell lymphoma (DLBCL) is the most common aggressive non-Hodgkin lymphoma (NHL), accounting for three out of every five cases. In the U.S. each year, there are approximately 7,500 patients with refractory DLBCL who are eligible for CAR T therapy. Historically, when treated with the current standard of care, patients with refractory large B-cell lymphoma had a median overall survival of approximately six months, with only 7% attaining a complete response. Currently, patients with large B-cell lymphoma in second or later lines of therapy have poor outcomes and greater unmet need, since nearly half of them either do not respond or relapse shortly after transplant.

FDA APPROVED INDICATIONS

Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitation of Use: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

DOSAGE AND ADMINISTRATION

- Yescarta is supplied as a frozen cell suspension of genetically modified autologous T cells in one infusion bag labeled for the specific recipient. Yescarta is shipped directly to the cell lab associated with the infusion center and is administered in a certified health care facility.
- Yescarta is for autologous use and is administered by intravenous infusion only.
- Prior to infusion:
 - Verify the patient's identity
 - Premedicate with acetaminophen and an H1-antihistamine
 - Confirm availability of tocilizumab
- Yescarta dosing is based on the number of chimeric antigen receptor (CAR) positive viable T cells.
 - The target Yescarta dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AXICABTAGENE CILOLEUCEL (NSA)

AVAILABLE STRENGTHS

Each single infusion bag of Yescarta contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

REFERENCES

- Yescarta [Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc. October 2017.
- ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02348216. A Phase 1-2 Multi-Center Study Evaluating KTE-C19 in Subjects With Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1). Available at: <https://clinicaltrials.gov/ct2/show/NCT02348216>. Accessed October 18, 2017.
- Kite Pharma [Press Release]. Kite's Yescarta (Axicabtagene Ciloleucel) Becomes First CAR T Therapy Approved by the FDA for the Treatment of Adult Patients With Relapsed or Refractory Large B-Cell Lymphoma After Two or More Lines of Systemic Therapy. Available at: http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle_Print&ID=2309672. Accessed October 18, 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 10/17

Client Approval: 12/17

P&T Approval: 10/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BELIMUMAB	BENLYSTA		29633 29634	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of autoantibody-positive systemic lupus erythematosus (SLE) and meets **ALL** of the following criteria?
 - The patient does **NOT** have severe active lupus nephritis or severe active central nervous system lupus
 - The patient is **NOT** taking biologics or intravenous cyclophosphamide
 - The patient is currently using corticosteroids, antimalarials, NSAIDs or immunosuppressives
 - The patient has a positive autoantibody test and a SELENA-SLEDAI score of at least 6
 - The patient is 5 years of age or older

If yes, **approve for 6 months by GPID for all of the following strengths:**

- **Benlysta 120mg vial (GPID 29633).**
- **Benlysta 400mg vial (GPID 29634).**

APPROVAL TEXT: Renewal requires that the patient achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **BELIMUMAB (Benlysta)** requires a diagnosis of autoantibody-positive systemic lupus erythematosus (SLE). In addition, the following criteria must be met:

- The patient does **NOT** have severe active lupus nephritis or severe active central nervous system lupus
- The patient is **NOT** taking biologics or intravenous cyclophosphamide
- The patient is currently using corticosteroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs) or immunosuppressives
- The patient has a positive autoantibody test and an Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of at least 6
- The patient is 5 years of age or older

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autoantibody-positive systemic lupus erythematosus (SLE) and meet the following criterion?
 - The patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline

If yes, approve for 12 months by GPID for all of the following strengths:

- Benlysta 120mg vial (GPID 29633).
- Benlysta 400mg vial (GPID 29634).

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **BELIMUMAB (Benlysta)** requires a diagnosis of autoantibody-positive systemic lupus erythematosus (SLE). In addition, the following criterion must be met:

- The patient achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline

RATIONALE

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

REFERENCES

- Benlysta [Prescribing Information]. Rockville, MD. Human Genome Sciences, Inc., April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 03/11

Client Approval: 05/19

P&T Approval: 07/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELINOSTAT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BELINOSTAT	BELEODAQ	41264		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication being used for the treatment of a patient with relapsed or refractory peripheral T-cell lymphoma (PTCL)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **BELINOSTAT (Belinostat)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL).

RATIONALE

Promote appropriate utilization of Beleodaq based on FDA approved indication.

There is no consensus regarding the preferred induction chemotherapy for peripheral T-cell lymphoma (PTCL), and patients should be encouraged to participate in clinical trials whenever possible. Most of the treatment regimens that have been studied combine an anthracycline with an alkylating agent. Examples of regimens most commonly considered for the treatment of patients with PTCL not enrolled in clinical trials include:

- CHOP ([cyclophosphamide](#), [doxorubicin](#), [vincristine](#), [prednisone](#)) with or without [etoposide](#)
- EPOCH ([etoposide](#), [prednisone](#), [vincristine](#), [cyclophosphamide](#), [doxorubicin](#))

DOSAGE

The recommended dosage of Beleodaq is 1,000 mg/m² administered over 30 minutes by intravenous infusion once daily on Days 1-5 of a 21-day cycle. Cycles can be repeated every 21 days until disease progression or unacceptable toxicity.

FDA APPROVED INDICATION

Beleodaq is a histone deacetylase inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELINOSTAT

REFERENCES

- Beleodaq [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals; July 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 07/14

Client Approval: 09/16

P&T Approval: 08/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BENRALIZUMAB	FASENRA	44635		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe eosinophilic asthma and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - The patient has a documented blood eosinophil level of at least 300 cells/mcL or more within the past 6 months
 - The patient is currently adherent to a maximally tolerated dose of an inhaled corticosteroid **AND** at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
 - The patient has experienced at least 2 or more asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 or more days)
 - The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5 or more
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1 or more
 - Fasenra will be used as add-on maintenance treatment
 - The patient is NOT being concurrently treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (e.g. Nucala, Cinqair)
 - Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

If yes, please enter **TWO** approvals by HICL as follows:

- **FIRST APPROVAL:** approve for 12 weeks (total fill count of 3) with a quantity limit of 1mL (one 30mg/mL pre-filled syringe) per 28 days.
- **SECOND APPROVAL:** approve for 40 weeks (total fill count of 5) with a quantity limit of 1mL (one 30mg/mL pre-filled syringe) per 56 days.

APPROVAL TEXT: Renewal requires the patient to have experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline AND an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline. In addition, if the patient was on maintenance therapy with oral corticosteroids prior to the initiation of Fasenra, then the patient must demonstrate a reduction in the total daily dose of oral corticosteroids for Fasenra renewal.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **BENRALIZUMAB (Fasenra)** requires a diagnosis of severe eosinophilic asthma. In addition, the following criteria must be met:

- The patient is 12 years of age or older
- The patient has a documented blood eosinophil level of at least 300 cells/mcL or more within the past 6 months
- The patient is currently adherent to a maximally tolerated dose of an inhaled corticosteroid **AND** at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least 2 or more asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 or more days)
- The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5 or more
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1 or more
- Fasenra will be used as add-on maintenance treatment
- The patient is NOT being concurrently treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (e.g. Nucala, Cinqair)
- Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma **AND** meet the following criteria?
 - The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline
 - The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), **OR** Asthma Therapy Assessment Questionnaire (ATAQ) score from 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. Was the patient treated with a maintenance therapy regimen of oral corticosteroids prior to initiation of Fasenra?

If yes, continue to #3.

If no, **approve for 12 months by HICL with a quantity limit of 1mL (one 30mg/mL pre-filled syringe) per 56 days.**



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Has the patient decreased their total daily dose of oral corticosteroids from baseline?

If yes, **approve for 12 months by HICL with a quantity limit of 1mL (one 30mg/mL pre-filled syringe) per 56 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **BENRALIZUMAB (Fasenra)** requires a diagnosis of severe asthma for renewal. In addition, the following criteria must also be met:

- The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline
- The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
- The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance therapy with oral corticosteroids prior to initiation of Fasenra

RATIONALE

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

REFERENCES

- Fasenra [Prescribing Information]. Wilmington, DE. AstraZeneca Pharmaceutical LP. November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 02/18

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BEVACIZUMAB	AVASTIN	25963		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) **AND** meet the following criterion?
 - The requested medication is being used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
 - The requested medication is being used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment
 - The patient has progressed on a first-line Avastin-containing regimen

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
 - The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of recurrent glioblastoma (GBM) **AND** is 18 years or older?

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of metastatic renal cell carcinoma (RCC) **AND** meet the following criterion?

- The requested medication is being used in combination with interferon alfa

If yes, **approve for 12 months by HICL.**

If no, continue to #6.

6. Is Avastin being used to treat neovascular (wet) macular degeneration **AND** meet the following criterion?

- The requested medication is prescribed by an ophthalmologist and/or retina specialist

If yes, **approve for 12 months by HICL, up to one vial per affected eye per month.**

If no, continue to #7.

7. Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer **AND** meet the following criterion?

- The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If yes, **approve for 12 months by HICL.**

If no, continue to #8.

8. Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ALL** of the following criteria?

- The requested medication is being used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- The patient has received no more than 2 prior chemotherapy regimens

If yes, **approve for 12 months by HICL.**

If no, continue to #9.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ONE** of the following criteria?

- The requested medication is being used in combination with carboplatin and paclitaxel, **OR**
- The requested medication is being used in combination with carboplatin and gemcitabine, **OR**
- The requested medication is being used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL.**

If no continue to #10.

10. Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?

- The requested medication is being used following initial surgical resection
- The requested medication is being 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.**

If no, do not approve.

DENIAL TEXT: The guideline named **BEVACIZUMAB (Avastin)** requires a diagnosis of **ONE** of the following:

- **Metastatic colorectal cancer (mCRC)** and meet **ONE** of the following:
 - The requested medication is being used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
 - The requested medication is being used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CAPEOX) based chemotherapy as a second-line treatment AND the patient has progressed on a first-line Avastin-containing regimen
- **Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC)** in combination with carboplatin and paclitaxel for first-line treatment
- **Recurrent glioblastoma (GBM)** AND patient is 18 years or older
- **Metastatic renal cell carcinoma (RCC)** in combination with interferon alfa
- **Neovascular (wet) macular degeneration** and treatment is prescribed by an ophthalmologist and/or retina specialist
- **Persistent, recurrent, or metastatic cervical cancer**, in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

(Denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- **Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer**, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan AND patient has received no more than 2 prior chemotherapy regimens
- **Platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer**, in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above
- **Stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection**, in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

RATIONALE

Ensure appropriate utilization of bevacizumab based on its FDA approved indications.

Avastin is a recombinant humanized monoclonal IgG1 antibody administered intravenously that inhibits tumor angiogenesis through inhibition of VEGF similar to Zaltrap. Due to its structural similarity to Lucentis, ophthalmologists use Avastin as an intravitreal injection for the treatment of diabetic macular edema, diabetic retinopathy, and macular degeneration. Randomized, controlled trials such as the Comparison of Age-Related Macular Degeneration Treatment Trial (CATT) and Inhibition of VEGF in Age-related choroidal Neovascularization (IVAN) trial have demonstrated that Lucentis and Avastin are likely to provide similar efficacy when used for treatment of neovascular (wet) age-related macular degeneration.

FDA APPROVED INDICATIONS

Avastin is a vascular endothelial growth factor-specific angiogenesis inhibitor indicated for the treatment of:

- Metastatic colorectal cancer, with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment.
 - Limitation of Use: Avastin is not indicated for adjuvant treatment of colon cancer.
- Metastatic colorectal cancer, with fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line Avastin-containing regimen.
 - Limitation of Use: Avastin is not indicated for adjuvant treatment of colon cancer
- Non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced recurrent or metastatic disease.
- Recurrent glioblastoma in adult patients.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEVACIZUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

- Metastatic renal cell carcinoma in combination with interferon alfa.
- Cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease.
- Epithelial ovarian, fallopian tube or primary peritoneal cancer:
 - In combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for stage III or IV disease following initial surgical resection
 - In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
 - In combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Avastin as a single agent, for platinum sensitive recurrent disease.

DOSAGE AND ADMINISTRATION

Do not administer Avastin until at least 28 days following surgery and the wound is fully healed.

Metastatic Colorectal Cancer (mCRC): The recommended dose when Avastin is administered in combination with intravenous 5-fluorouracil-based chemotherapy is:

- 5 mg/kg every 2 weeks intravenously in combination with bolus-IFL
- 10 mg/kg every 2 weeks intravenously in combination with FOLFOX4
- 5 mg/kg intravenously every 2 weeks or 7.5 mg/kg intravenously every 3 weeks in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy in patients who have progressed on a first-line Avastin-containing regimen

Non-Small Cell Lung Cancer (NSCLC): The recommended dose is 15 mg/kg intravenously every 3 weeks in combination with carboplatin and paclitaxel.

Recurrent Glioblastoma (GBM): The recommended dose is 10 mg/kg intravenously every 2 weeks.

Metastatic Renal Cell Carcinoma (mRCC): The recommended dose is 10 mg/kg intravenously every 2 weeks in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Cervical Cancer: The recommended dose of Avastin is 15 mg/kg intravenously every 3 weeks in combination with paclitaxel and cisplatin or in combination with paclitaxel and topotecan.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer:

- **Treatment of Stage III or IV Disease Following Initial Surgical Resection:**
 - The recommended dose is 15 mg/kg intravenously every 3 weeks in combination with carboplatin and paclitaxel for up to 6 cycles, followed by Avastin 15 mg/kg every 3 weeks as a single agent, for a total of up to 22 cycles or until disease progression, whichever occurs earlier.
- **Platinum Resistant - Recurrent:**
 - When used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan (every week), the recommended dose of Avastin is 10 mg/kg intravenously every 2 weeks.
 - When used in in combination with topotecan (every 3 weeks), the recommended dose of Avastin is 15 mg/kg intravenously every 3 weeks.
- **Platinum Sensitive - Recurrent:**
 - When used in in combination with carboplatin and paclitaxel, the recommended dose of Avastin is 15 mg/kg intravenously every 3 weeks for 6 to 8 cycles, followed by Avastin 15 mg/kg every 3 weeks as a single agent until disease progression.
 - When used in in combination with carboplatin and gemcitabine, the recommended dose of Avastin is 15 mg/kg intravenously every 3 weeks for 6 to 10 cycles, followed by Avastin 15 mg/kg every 3 weeks as a single agent until disease progression.

REFERENCES

- Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2018.
- Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Martin DF, Maguire MG, Fine SL, Ying GS, Jaffe GJ, Grunwald JE, Toth C, Redford M, Ferris FL. Ranibizumab and bevacizumab for treatment of neovascular age-related macular degeneration: two-year results. Ophthalmology. 2012 Jul; 119 (7):1388-98.
- IVAN Study Investigators, Chakravarthy U, Harding SP, et al. Ranibizumab versus bevacizumab to treat neovascular age-related macular degeneration: one-year findings from the IVAN randomized trial. Ophthalmology. 2012 Jul;119(7):1399-411.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/09/18

Created: 02/13

Client Approval: 06/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BLINATUMOMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BLINATUMOMAB	BLINCYTO	41612		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)?

If yes, **approve for 3 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 2.**

APPROVAL TEXT: A prior authorization has been approved for two cycles of Blincyto. For renewal, please document the following:

- Whether the patient has achieved complete remission (CR) or CR with partial hematological recovery of peripheral blood counts (CPh) after two cycles.
- Whether the patient has received stem cell transplant after completion of Blincyto therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
 - The patient is in first or second complete remission
 - The patient has minimal residual disease (MRD) greater than or equal to 0.1%

If yes, **approve for 2 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 1.**

APPROVAL TEXT: A prior authorization has been approved for one cycle of Blincyto. For renewal, please document that the patient has achieved undetectable minimal residual disease (MRD) within one cycle of Blincyto treatment and is relapse-free (i.e., hematological or extramedullary relapse, or secondary leukemia).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **BLINATUMOMAB (Blincyto)** requires a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) or minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met.

For diagnosis of minimal residual disease (MRD) - positive B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

- The patient is in first or second complete remission
- The patient has minimal residual disease (MRD) greater than or equal to 0.1%

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BLINATUMOMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
 - The patient has achieved undetectable minimal residual disease (MRD) within one cycle of Blincyto treatment
 - The patient is relapse-free (i.e., hematological or extramedullary relapse, or secondary leukemia)

If yes, **approve for 5 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 3.**

If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
 - The patient has completed two cycles of induction treatment (cycle 1 and 2) with Blincyto
 - The patient has achieved complete remission (CR) or CR with partial hematological recovery of peripheral blood counts (CPh) after two cycles

If yes, continue to #3.

If no, send to clinical pharmacist for review.

CLINICAL PHARMACIST: Please review initial criteria. If initial criteria were met, an additional cycle may be approved. Please check if initial therapy was interrupted for dose modification, and follow prescribing information regarding dose modification for toxicities due to Blincyto.

3. Has the patient obtained allogeneic hematopoietic stem-cell transplant?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #4.

4. Is the requested medication being used for consolidation therapy of cycles 3 - 5?

If yes, **approve for 5 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 3.**

APPROVAL TEXT: An approval has been entered for 3 cycles of Blincyto to complete 3 cycles of consolidation therapy.

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BLINATUMOMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

5. Is the requested medication being used for continued therapy of cycles 6 - 9?

If yes, **approve for 12 months by HICL with a quantity limit of #28 vials per 84 days with a fill count of 4.**

APPROVAL TEXT: An approval has been entered for 4 cycles of Blincyto for continued therapy to complete 9 cycles of therapy. This medication has been FDA approved for a total of 9 cycles.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline named **BLINATUMOMAB (Blincyto)** requires a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) OR minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met.

For diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

- The patient has achieved complete remission (CR) or CR with partial hematological recovery of peripheral blood counts (CPh) after two cycles of induction treatment (cycle 1 and 2) with Blincyto
- The patient has not received allogeneic hematopoietic stem-cell transplant

For diagnosis of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

- The patient have achieved undetectable minimal residual disease (MRD) within one cycle of Blincyto treatment
- The patient is relapse-free (i.e., hematological or extramedullary relapse, or secondary leukemia)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BLINATUMOMAB (NSA)

RATIONALE

To promote appropriate utilization of Blincyto based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATION

Blincyto is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adults and children with

- B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
 - This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials
- Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

DOSAGE & ADMINISTRATION

MRD-Positive B-cell Precursor ALL

- A treatment course consists of 1 cycle of BLINCYTO for induction followed by up to 3 additional cycles for consolidation
- A single cycle of treatment of Blincyto induction or consolidation consists of 28 days of continuous intravenous infusion, followed by a 14- day treatment-free interval (total 42 days)
- The table below shows the recommended dose by patient weight and schedule.

Patient Weight	Induction Cycle 1		Consolidation Cycles 2 - 4	
	Days 1-28	Days 29-42	Days 1-28	Days 29-42
≥45 kg (fixed-dose)	28 mcg/day	14-day treatment-free interval	28 mcg/day	14-day treatment-free interval
<45 kg (BSA-based dose)	15 mcg/m ² /day (not to exceed 28 mcg/day)		15 mcg/m ² /day (not to exceed 28 mcg/day)	

Relapsed or Refractory B-cell Precursor ALL

A treatment course consists of up to 2 cycles for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.

A single cycle of treatment of Blincyto induction or consolidation consists of 28 days of continuous intravenous infusion, followed by a 14-day treatment-free interval (total 42 days).

A single cycle of treatment of Blincyto continued therapy consists of 28 days of continuous intravenous infusion followed by a 56-day treatment-free interval (total 84 days).

See the table below for the recommended dose by patient weight and schedule. Patients greater than or equal to 45 kg receive a fixed-dose, and for patients less than 45 kg, the dose is calculated using the patient's body surface area (BSA).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BLINATUMOMAB (NSA)

FDA APPROVED INDICATION (CONTINUED)

DOSAGE & ADMINISTRATION

Blincyto dosage and schedule for the treatment of Relapsed or Refractory B-cell Precursor ALL

Patient Weight	Induction Cycle 1			Induction Cycle 2	
	Days 1-7	Days 8-28	Days 29-42	Days 1-28	Days 29-42
≥45 kg (fixed-dose)	9 mcg/day	28 mcg/day	14-day treatment-free interval	28 mcg/day	14-day treatment free interval
<45 kg (BSA-based dose)	5 mcg/m ² /day (not to exceed 9 mcg/day)	15 mcg/m ² /day (not to exceed 28 mcg/day)		15 mcg/m ² /day (not to exceed 28 mcg/day)	

Patient Weight	Consolidation Cycle 3 - 5		Continued Therapy Cycle 6 - 9	
	Days 1-28	Days 29-42	Days 1-28	Days 29-84
≥45 kg (fixed-dose)	28 mcg/day	14-day treatment-free interval	28 mcg/day	56-day treatment-free interval
<45 kg (BSA-based dose)	15 mcg/m ² /day (not to exceed 28 mcg/day)		15 mcg/m ² /day (not to exceed 28 mcg/day)	

If the interruption after an adverse event is no longer than 7 days, continue the same cycle to a total of 28 days of infusion inclusive of days before and after the interruption in that cycle. If the interruption after an adverse event is longer than 7 days, start a new cycle.

REFERENCES

- Blincyto [Prescribing Information]. Thousand Oaks, CA: Amgen Inc. March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 02/15

Client Approval: 05/18

P&T Approval: 04/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BORTEZOMIB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BORTEZOMIB	VELCADE, BORTEZOMIB	25202		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma?

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of mantle cell lymphoma?

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 at least one prior therapy for mantle cell lymphoma?

If yes, **approve for 12 months by HICL.**

If no, **approve Velcade for 12 months by NDC 63020-0049-01. (Note: If the request is for bortezomib by Fresenius Kabi, do not approve since this is indicated for mantle cell lymphoma ONLY in patients who have received at least 1 prior therapy)**

DENIAL TEXT: The guideline named **BORTEZOMIB** requires a diagnosis of multiple myeloma or mantle cell lymphoma. In addition, the following criterion must be met:

For bortezomib (manufactured by Fresenius Kabi), approval requires the patient has received at least one prior therapy for mantle cell lymphoma.

RATIONALE

Ensure appropriate utilization of bortezomib based on FDA approved indication.

FDA APPROVED INDICATIONS

Velcade (Millennium) is a proteasome inhibitor indicated for:

- Treatment of patients with multiple myeloma
- Treatment of patients with mantle cell lymphoma

Bortezomib (Fresenius Kabi) is a proteasome inhibitor indicated for:

- Treatment of patients with multiple myeloma
- Treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BORTEZOMIB (NSA)

REFERENCES

- Velcade [Prescribing Information]. Cambridge, MA: Millennium Pharmaceuticals; June 2017.
- Bortezomib [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi; November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/29/18

Created: 11/12

Client Approval: 01/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ONABOTULINUM TOXIN A	BOTOX	04867		BRAND ≠ BOTOX COSMETIC
ABOBOTULINUM TOXIN A	DYSPO	36477		
RIMABOTULINUM TOXIN B	MYOBLOC	21869		
INCOBOTULINUM TOXIN A	XEOMIN	36687		

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

GUIDELINES FOR USE

BOTOX

1. Is the request for the improvement of appearance of glabellar lines in the face (for example wrinkles)?

If yes, do not approve.

BOTOX DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE - BOTOX (CONTINUED)

2. Does the patient have **ONE** of the following conditions **AND** meet the associated criteria?
- For the treatment of overactive bladder (OAB) approval requires:
 - Patient is 18 years of age or older
 - Patient had a trial or is contraindicated to an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, or Sanctura)
 - For the treatment of urinary incontinence approval requires:
 - Patient is 18 years of age or older
 - Detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)]
 - Patient had a trial or is contraindicated to an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, or Sanctura)
 - For the prophylaxis of headaches in patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer) approval requires:
 - Patient is 18 years of age or older
 - The patient has had a previous trial of any **TWO** of the following prophylactic migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
 - For the treatment of upper or lower limb spasticity requires that the patient is 18 years of age or older
 - For the treatment of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) requires that the patient is 18 years of age or older
 - For the treatment of severe axillary hyperhidrosis (excessive underarm sweating) requires that the patient is 18 years of age or older
 - For the treatment of blepharospasm (involuntary forcible closure of the eyelid) requires that the patient is 12 years of age or older
 - For the treatment of strabismus (crossed-eye) requires that the patient is 12 years of age or older

If yes, **approve for 12 months by GPID with the following quantity limits: up to #4 of the 100-unit vials or #1 of the 200-unit vial every 3 months.**

If no, do not approve.

BOTOX DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE - BOTOX (CONTINUED)

BOTOX DENIAL TEXT: The guideline named **BOTULINUM NEUROTOXIN (Botox)** requires one of the following non-cosmetic conditions: treatment of overactive bladder (OAB), treatment of urinary incontinence, prophylaxis of headaches in chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer), treatment of upper or lower limb spasticity, treatment of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), treatment of severe axillary hyperhidrosis (excessive underarm sweating), treatment of blepharospasm (involuntary forcible closure of the eyelid), or treatment of strabismus (crossed-eye). In addition, the following criteria must also be met:

For the treatment of overactive bladder (OAB), approval requires:

- Patient is 18 years of age or older
- A trial or contraindication to an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, or Sanctura)

For the treatment of urinary incontinence, approval requires:

- Patient is 18 years of age or older
- Detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)]
- A trial or contraindication to an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, or Sanctura)

For the prophylaxis of headaches in patients with chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer), approval requires:

- Patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following prophylactic migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

For the treatment of spasticity, cervical dystonia and severe axillary hyperhidrosis, approval requires:

- Patient is 18 years of age or older

For the treatment of blepharospasm and strabismus, approval requires:

- Patient is 12 years of age or older

This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example wrinkles).

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE (CONTINUED)

DYSPOURT

1. Is the request for the improvement of appearance of glabellar lines in the face (for example wrinkles)?

If yes, do not approve.

DYSPOURT DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Is the request for the treatment of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) **AND** the patient is at least 18 years or older?

If yes, **approve for 12 months by GPID with a quantity limit of up to #2 vials every 3 months.**

If no, continue to #3.

3. Is the request for the treatment of upper limb spasticity **AND** the patient is at least 18 years or older?

If yes, **approve for 12 months by GPID with a quantity limit of up to #2 vials every 3 months.**

If no, continue to #4.

4. Is the request for the treatment of lower limb spasticity in a pediatric patient 2 years of age or older?

If yes, **approve for 12 months by GPID with a quantity limit of up to #2 vials every 3 months.**

If no, do not approve.

DYSPOURT DENIAL TEXT: The guideline named **BOTULINUM NEUROTOXIN (Dysport)** requires a non-cosmetic diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) in a patient at least 18 years or older, upper limb spasticity in a patient at least 18 years or older, or lower limb spasticity in a pediatric patient 2 years of age or older. This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example wrinkles).

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE (CONTINUED)

MYOBLOC

1. Is the request for the improvement of appearance of glabellar lines in the face (for example wrinkles)?

If yes, do not approve.

MYOBLOC DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Is the request for the treatment of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) **AND** the patient is at least 18 years or older?

If yes, **approve for 12 months by GPID with the following quantity limits: up to #2 of the 2,500-unit vials, #1 of the 5,000-unit vial, or #1 of the 10,000-unit vial every 3 months.**

If no, do not approve.

MYOBLOC DENIAL TEXT: The guideline named **BOTULINUM NEUROTOXIN (Myobloc)** requires a non-cosmetic diagnosis of cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) and the patient is at least 18 years or older. This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example wrinkles).

XEOMIN

1. Is the request for the improvement of appearance of glabellar lines in the face (for example wrinkles)?

If yes, do not approve.

XEOMIN 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 sialorrhea (hypersalivation) **AND** the patient is at least 18 years or older?

If yes, **approve for 12 months or length of therapy (whichever is less) by GPID with the following quantity limits: up to #2 of the 50-unit vials or #1 of the 100-units vials every 4 months.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE - XEOMIN (CONTINUED)

3. Is the patient at least 18 years old and have **ONE** of the following conditions?
- Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
 - Blepharospasm (involuntary forcible closure of the eyelid)
 - Upper limb spasticity

If yes, **approve for 12 months or length of therapy (whichever is less) by GPID with the following quantity limits: up to #3 of the 50-unit vials or #2 of the 100 or 200-unit vials every 3 months.**

If no, do not approve.

XEOMIN DENIAL TEXT: The guideline named **BOTULINUM NEUROTOXIN (Xeomin)** requires a non-cosmetic diagnosis such as chronic sialorrhea (hypersalivation), cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), blepharospasm (involuntary forcible closure of the eyelid), or upper limb spasticity. In addition, the patient must be 18 years of age or older. This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example wrinkles).

RATIONALE

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

REFERENCES

- Botox [Prescribing Information]. Irvine, CA: Allergan. May 2018.
- Dysport [Prescribing Information]. Basking Ridge, NJ Ispen: Biopharmaceuticals, Inc.; June 2017.
- Myobloc [Prescribing Information] South San Francisco, CA: Solstice Neurosciences, Inc.; January 2012.
- Xeomin [Prescribing Information]. Greensboro, NC: Merz Pharmaceuticals, LLC; May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 01/10

Client Approval: 05/19

P&T Approval: 07/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BRENTUXIMAB VEDOTIN	ADCETRIS	37879		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 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. Does the patient have a diagnosis of classical Hodgkin lymphoma and meet **ONE** of the following criteria?

- Has failed an autologous hematopoietic stem cell transplant (auto-HSCT)
- Has failed at least two multi-agent chemotherapy regimens (potential regimens include but are not limited to: 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 with a quantity limit of #4 vials per 21 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of classical Hodgkin lymphoma and is considered high risk for relapse or disease progression post-auto-HSCT, as defined according to status following frontline therapy: refractory, relapse within 12 months, or relapse \geq 12 months with extranodal disease?

If yes, continue to #4.

If no, continue to #5.

4. Did the patient obtain a complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy?

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of relapsed systemic anaplastic large cell lymphoma (sALCL) and meet the following criterion?

- Has failed at least one multi-agent chemotherapy regimen (potential regimens include but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #6.

6. Does the patient have a diagnosis of systemic anaplastic large cell lymphoma (sALCL) OR other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, and meet ALL of the following criteria?

- The patient has not received treatment for sALCL or other CD30-expressing PTCL
- The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

If yes, **approve for 12 months with a total fill count of 8 and a quantity limit of #4 vials per 21 days.**

If no, continue to #7.

7. Does the patient have a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) **AND** meet the following criterion?

- The patient has received prior systemic therapy

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #8.

8. Does the patient have a diagnosis of Stage III or IV classical Hodgkin lymphoma (cHL) and meet **ALL** of the following criteria?

- The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
- The patient has not received treatment for Stage III or IV classical Hodgkin lymphoma (cHL)

If yes, **approve for 12 months with a total fill count of 12 and a quantity limit of #3 vials per 14 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **BRENTUXIMAB (Adcetris)** requires a diagnosis of classical Hodgkin lymphoma, Stage III or IV classical Hodgkin lymphoma (cHL), systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), primary cutaneous anaplastic large cell lymphoma (pcALCL), or CD30-expressing mycosis fungoides (MF). In addition, the patient must be 18 years of age or older. The following criteria must also be met:

For the diagnosis of classical Hodgkin lymphoma, approval requires ONE of the following:

- The patient has failed autologous hematopoietic stem cell transplant (auto-HSCT)
- The patient has failed at least two multi-agent chemotherapy regimens (potential regimens include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])
- The patient is considered high risk of relapse or disease progression post-auto-HSCT **AND** the patient has obtained complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy

For the diagnosis of relapsed systemic anaplastic large cell lymphoma (sALCL), approval requires:

- The patient has failed at least one multi-agent chemotherapy regimen (potential regimens include but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

For the diagnosis of systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, approval requires:

- The patient has not received treatment for sALCL or other CD30-expressing PTCL
- The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

For the diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), approval requires:

- The patient has received prior systemic therapy

For the diagnosis of Stage III or IV classical Hodgkin lymphoma (cHL), approval requires:

- The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
- The patient has not received treatment for Stage III or IV classical Hodgkin lymphoma (cHL)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BRENTUXIMAB (NSA)

RATIONALE

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

REFERENCES

- Adcetris [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/10/18

Created: 09/11

Client Approval: 11/18

P&T Approval: 01/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE EXTENDED-RELEASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE EXTENDED- RELEASE	SUBLOCADE		44186 44187	

GUIDELINES FOR USE

- Does the patient have a diagnosis of moderate to severe opioid use disorder and meet the following criterion?
 - The patient previously initiated treatment with a transmucosal buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: The guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires a diagnosis of moderate to severe opioid use disorder. In addition, the following must be met:

- The patient previously initiated treatment with a transmucosal buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

- Is the patient new to Sublocade treatment?

If yes, please enter **TWO** approvals by GPID as follows:

- FIRST APPROVAL:** approve GPID 44186 for 2 months with a quantity limit of #1.5mL (#1 300mg/1.5mL syringe) per 30 days.
- SECOND APPROVAL:** approve for 10 months, please enter a start date 2 MONTHS AFTER the START date of the first approval for the requested strength with a quantity limit as follows:
 - GPID 44187: #0.5mL (#1 100mg/0.5mL syringe) per 30 days.
 - GPID 44186: #1.5mL (#1 300mg/1.5mL syringe) per 30 days.

If no, approve by GPID for 12 months for the requested strength with the associated quantity limit as follows:

- GPID 44187: 0.5mL (#1 100mg/0.5mL syringe) per 30 days.
- GPID 44186: 1.5mL (#1 300mg/1.5mL syringe) per 30 days.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE EXTENDED-RELEASE (NSA)

RATIONALE

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

REFERENCES

- Sublocade [Prescribing Information]. North Chesterfield, VA: Invidor, Inc. March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/19/18

Created: 05/18

Client Approval: 11/18

P&T Approval: 04/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE IMPLANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE	PROBUPHINE	01762		ROUTE= IMPLANT

GUIDELINES FOR USE

1. Has the patient previously received one Probuphine treatment course in **each** arm (for a maximum of **two** 6-month treatment courses)?

If yes, do not approve.

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 opioid addiction/dependence and meets the following criteria?
 - The patient has achieved and sustained clinical stability on low to moderate doses of transmucosal buprenorphine (defined as 8 mg per day or less of Subutex/Suboxone or its transmucosal buprenorphine product equivalent for a minimum of 3 months without any need for supplemental dosing or adjustments).
 - Examples of acceptable doses of transmucosal buprenorphine include:
 - Subutex (buprenorphine) sublingual tablet (or its generic equivalent): 8mg or less
 - Suboxone (buprenorphine/naloxone) sublingual tablet (or its generic equivalent): 8mg/2 mg or less
 - Bunavail (buprenorphine/naloxone) buccal film: 4.2 mg/0.7 mg or less
 - Zubsolv (buprenorphine/naloxone) sublingual tablets: 5.7 mg/1.4 mg or less
 - Therapy is prescribed by a physician certified with the Probuphine REMS program to prescribe, insert, and remove Probuphine implants as confirmed by checking probuphinerems.com.

If yes, **approve for 6 months by GPID with a quantity limit of #4 implantable rods.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **BUPRENORPHINE IMPLANT (Probuphine)** requires that the following criteria must also be met.

- The patient has not previously received one Probuphine treatment course in each arm (for a maximum of **two** 6-month treatment courses)
- The patient has achieved and sustained clinical stability on low to moderate doses of transmucosal buprenorphine (defined as 8 mg per day or less of Subutex/Suboxone or its transmucosal buprenorphine product equivalent for a minimum of 3 months without any need for supplemental dosing or adjustments)
- Therapy is prescribed by a physician certified with the Probuphine REMS program to prescribe, insert, and remove Probuphine implants as confirmed by checking probuphinerems.com

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE IMPLANT (NSA)

RATIONALE

Under the Drug Addiction Treatment Act (DATA) codified at 21 United States Code (U.S.C.) 823(g), use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe or dispense this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

Probuphine implants should be used only in patients who are opioid tolerant. Each dose consists of four Probuphine implants inserted subdermally in the inner side of the upper arm. Probuphine subdermal implants are intended to be in place for 6 months of treatment. Remove Probuphine implants by the end of the sixth month.

New implants may be inserted subdermally in an area of the inner side of either upper arm that has not been previously used at the time of removal, if continued treatment is desired. If new implants are not inserted on the same day as the removal of implants, maintain patients on their previous dosage of transmucosal buprenorphine (i.e., the dose from which they were transferred to Probuphine treatment) prior to additional Probuphine treatment.

After one insertion in each arm, most patients should be transitioned back to a transmucosal buprenorphine-containing product for continued treatment. There is no experience with inserting additional implants into other sites in the arm to recommend an approach to a second insertion into a previously used arm. Neither re-insertion into previously used administration sites, nor into sites other than the upper arm, has been studied.

FDA APPROVED INDICATIONS

Indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Probuphine should be used as part of a complete treatment program to include counseling and psychosocial support. Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.

DOSING

Four Probuphine implants are inserted subdermally in the upper arm for 6 months of treatment and are removed by the end of the sixth month. Probuphine implants should **not** be used for additional treatment cycles after one insertion in each upper arm. Probuphine implants must be inserted and removed by trained Healthcare Providers only.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE IMPLANT (NSA)

REFERENCES

- Probuphine [Prescribing Information]. Braeburn Pharmaceuticals, Inc. Princeton, NJ. May 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/2016

Created: 06/20/2016

Client Approval: 09/16

P&T Approval: 08/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUROSUMAB-TWZA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BUROSUMAB-TWZA	CRYSVITA	44867		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of X-linked hypophosphatemia (XLH) confirmed by **ONE** of the following criteria?
 - Physician attestation of XLH symptoms (e.g., osteomalacia, excessive fractures, bowed legs, impaired growth) and **ONE** of the following:
 - The patient has a serum phosphate level of < 3.2 mg/dL in pediatric patients or <2.5 mg/dL in adults **with** normal vitamin D levels
 - The patient has shown hyperexpression of FGF23 protein on assay
 - The patient possesses family history of XLH
 - Genotyping confirmation of the *PHEX* mutation causative of XLH

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 1 year of age or older
 - The patient is not on concurrent oral phosphate salt or active vitamin D analog supplementation
 - The medication is prescribed by or in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist

If yes, **approve for 6 months by HICL with a quantity limit of #3 vials per 14 days.**

APPROVAL TEXT: Renewal authorization requires verification of normalized phosphate levels as defined by reference range for age.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUROSUMAB-TWZA (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **BUROSUMAB (Crysvita)** requires a diagnosis of X-linked hypophosphatemia. In addition, the following criteria must be met:

- The diagnosis of XLH is confirmed by **ONE** of the following:
 - Physician attestation of XLH symptoms (e.g., osteomalacia, excessive fractures, bowed legs, impaired growth) and **ONE** of the following:
 - The patient has a serum phosphate level of < 3.2 mg/dL in pediatric patients or <2.5 mg/dL in adults **with** normal vitamin D levels
 - The patient has shown hyperexpression of FGF23 protein on assay
 - The patient possesses family history of XLH
 - Genotyping confirmation of the *PHEX* mutation causative of XLH
- The patient is 1 year of age or older
- The patient is not on concurrent oral phosphate salt or active vitamin D analog supplementation
- The medication is prescribed by or in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist

RENEWAL CRITERIA

1. Does the patient have a diagnosis of X-linked hypophosphatemia (XLH) and has the patient attained normalized blood phosphate levels as defined by reference range for age?

If yes, **approve for 12 months by HICL with a quantity limit of #3 vials per 14 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **BUROSUMAB (Crysvita)** requires the diagnosis of X-linked hypophosphatemia (XLH) and the patient has attained normalized blood phosphate levels as defined by reference range for age for renewal.

RATIONALE

To promote appropriate utilization of CRYSVITA (burosumab) based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Crysvita is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUROSUMAB-TWZA (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE & ADMINISTRATION

Crysvita is administered by subcutaneous injection and should be administered by a healthcare provider. Discontinue oral phosphate and active vitamin D analogs 1 week prior to initiation of treatment. Fasting serum phosphorus concentration should be below the reference range for age prior to initiation of treatment.

Pediatric Patients with X-linked Hypophosphatemia (1 to less than 18 years of age)

The recommended starting dose regimen is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.

After initiation of treatment with Crysvita, measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is above the lower limit of the reference range for age and below 5 mg/dL, continue treatment with the same dose. Follow dose adjustment schedule in package insert to maintain serum phosphorus within the reference range for age.

Adult Patients with X-linked Hypophosphatemia (18 years of age and older)

The recommended dose regimen in adults is 1 mg/kg body weight, rounded to the nearest 10 mg up to a maximum dose of 90 mg, administered every four weeks.

After initiation of treatment with Crysvita, assess fasting serum phosphorus on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is within the normal range, continue with the same dose.

REFERENCES

- Crysvita [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc. April 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CANAKINUMAB/PF	ILARIS	36497		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with a rheumatologist
 - The patient is 2 years of age or older
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to the following formulary preferred immunomodulator: Actemra [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL with a quantity limit of #2 vials (300mg) per 28 days.**
APPROVAL TEXT: Renewal for systemic juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with a rheumatologist
 - The patient is 4 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #1 vial (150mg) per 56 days.**
If no, continue to #3.

3. Does the patient have a diagnosis of **ONE** of the following periodic fever syndromes?
 - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
 - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
 - Familial Mediterranean Fever (FMF)

If yes, **approve for 12 months by HICL with a quantity limit of #2 vials (300mg) 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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **CANAKINUMAB (Ilaris)** requires a diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA), Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory 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). In addition, the following criteria must be met:

For patients with systemic juvenile idiopathic arthritis (SJIA), approval requires:

- Therapy is prescribed by or in consultation with a rheumatologist
- The patient is 2 years of age or older
- The patient had a previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to the following formulary preferred immunomodulator: Actemra
- 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.

For patients with Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval requires:

- Therapy is prescribed by or in consultation with a rheumatologist
- The patient is 4 years of age or older

RENEWAL CRITERIA

1. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of #2 vials (300mg) per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)?

If yes, **approve for 12 months by HICL with a quantity limit of #1 vial (150mg) per 56 days.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of **ONE** of the following periodic fever syndromes?
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
 - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
 - Familial Mediterranean Fever (FMF)

If yes, **approve for 12 months by HICL with a quantity limit of #2 vials (300mg) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **CANAKINUMAB (Ilaris)** requires a diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA), Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory 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). In addition, the following criteria must be met:

For patients with systemic juvenile idiopathic arthritis (SJIA), approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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 Corporation; December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 08/13

Client Approval: 03/19

P&T Approval: 11/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARFILZOMIB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CARFILZOMIB	KYPROLIS	39338		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meets **ONE** of the following criteria?
 - The patient has tried or has a contraindication to at least one prior multiple myeloma therapy and will be using Kyprolis as a single agent
 - The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with Revlimid (lenalidomide) and dexamethasone
 - The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with dexamethasone

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **CARFILZOMIB (Kyprolis)** requires a diagnosis of multiple myeloma and that the patient meets **ONE** of the following criteria:

- The patient has tried or has a contraindication to at least one prior multiple myeloma therapy and will be using Kyprolis as a single agent
- The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with Revlimid (lenalidomide) and dexamethasone
- The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with dexamethasone

RATIONALE

Ensure appropriate utilization of carfilzomib based on FDA approved indication.

FDA APPROVED INDICATIONS

Kyprolis is a proteasome inhibitor that is indicated for:

- **Combination Therapy**
 - In combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy
- **Monotherapy**
 - As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARFILZOMIB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Please note that doses may be modified based on toxicity. See the carfilzomib, lenalidomide, and dexamethasone prescribing Information respectively for dosing adjustment recommendations.

Combination Therapy

Administer Kyprolis intravenously as a 10-minute infusion on two consecutive days, each week for three weeks followed by a 12-day rest period. Each 28-day period is considered one treatment cycle. The recommended starting dose of Kyprolis is 20 mg/m² in Cycle 1 on Days 1 and 2. If tolerated, escalate to a target dose of 27 mg/m² on Day 8 of Cycle 1. From Cycle 13, omit the Day 8 and 9 doses of Kyprolis. Discontinue Kyprolis after Cycle 18. Lenalidomide 25 mg is taken orally on Days 1–21 and dexamethasone 40 mg by mouth or intravenously on Days 1, 8, 15, and 22 of the 28-day cycles. Continue treatment until disease progression or unacceptable toxicity occurs. Refer to the lenalidomide and dexamethasone prescribing information for other concomitant medications, such as the use of anticoagulant and antacid prophylaxis that may be required with those agents.

Table 1: Kyprolis in Combination with Lenalidomide and Dexamethasone

	Cycle 1											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Days 23–28	
Kyprolis (mg/m²):	20	20	-	27	27	-	27	27	-	-	-	
Dexamethasone	40 mg	-	-	40 mg	-	-	40 mg	-	-	40 mg	-	
Lenalidomide	25 mg daily									-	-	
	Cycles 2 to 12											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Days 23–28	
Kyprolis (mg/m²):	27	27	-	27	27	-	27	27	-	-	-	
Dexamethasone	40 mg	-	-	40 mg	-	-	40 mg	-	-	40 mg	-	
Lenalidomide	25 mg daily									-	-	
	Cycles 13 on ^a											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Days 23–28	
Kyprolis (mg/m²):	27	27	-	-	-	-	27	27	-	-	-	
Dexamethasone	40 mg	-	-	40 mg	-	-	40 mg	-	-	40 mg	-	
Lenalidomide	25 mg daily											

^a Kyprolis is administered through Cycle 18, lenalidomide and dexamethasone continue thereafter.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARFILZOMIB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Monotherapy

Administer Kyprolis intravenously as a 10-minute infusion on two consecutive days, each week for three weeks followed by a 12-day rest period. Each 28-day period is considered one treatment cycle. The recommended starting dose of Kyprolis is 20 mg/m² in Cycle 1 on Days 1 and 2. If tolerated, escalate to a target dose of 27 mg/m² on Day 8 of Cycle 1. From Cycle 13, omit the Day 8 and 9 doses of Kyprolis. Continue treatment until disease progression or unacceptable toxicity occurs.

Table 2: Kyprolis Monotherapy

	Cycle 1									
	Week 1			Week 2			Week 3			Week 4
	Day 1	Day 2	Days 3-7	Day 8	Day 9	Days 10-14	Day 15	Day 16	Days 17-21	Days 22-28
Kyprolis (mg/m²):	20	20	-	27	27	-	27	27	-	-
	Cycles 2 to 12									
	Week 1			Week 2			Week 3			Week 4
	Day 1	Day 2	Days 3-7	Day 8	Day 9	Days 10-14	Day 15	Day 16	Days 17-21	Days 22-28
Kyprolis (mg/m²):	27	27	-	27	27	-	27	27	-	-
	Cycles 13 on									
	Week 1			Week 2			Week 3			Week 4
	Day 1	Day 2	Days 3-7	Day 8	Day 9	Days 10-14	Day 15	Day 16	Days 17-21	Days 22-28
Kyprolis (mg/m²):	27	27	-	-	-	-	27	27	-	-

REFERENCES

- Kyprolis [Prescribing Information]. Thousand Oaks, CA: Onyx Pharmaceuticals; June 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 09/01/18

Created: 11/12

Client Approval: 08/18

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CEMPIPLIMAB-RWLC (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CEMPIPLIMAB-RWLC	LIBTAYO	45284		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) and meet the following criterion?
 - The patient is not a candidate for curative surgery or curative radiation

If yes, **approve for 12 months by HICL with a quantity limit of 7mL (1 vial) per 21 days.**
If no, do not approve.

DENIAL TEXT: The guideline named **CEMPIPLIMAB-RWLC (Libtayo)** requires a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) in patients who are not candidates for curative surgery or curative radiation.

RATIONALE

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

REFERENCES

- Libtayo [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERLIPONASE ALFA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CERLIPONASE ALFA	BRINEURA	44258		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet **ALL** of the following criteria?
 - A diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
 - The patient is ambulatory and experiencing symptoms (e.g., instability, intermittent falls, requires assistance to walk, or can crawl only)
 - The patient has a documented CLN2 Clinical Rating Scale Score of 3 to 5, with a minimum score of 1 in each of the motor and language domains
 - The patient is 3 years of age or older
 - The medication is prescribed by or given in consultation with a neurologist or pediatric CLN2 specialist

If yes, **approve for 6 months with a quantity limit of #2 kits per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CERLIPONASE ALFA (Brineura)** requires the following criteria must be met:

- A diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
- The patient is ambulatory and experiencing symptoms (e.g., instability, intermittent falls, requires assistance to walk, or can crawl only)
- The patient has a documented CLN2 Clinical Rating Scale Score of 3 to 5, with a minimum score of 1 in each of the motor and language domains
- The patient is 3 years of age or older
- The medication is prescribed by or given in consultation with a neurologist or pediatric CLN2 specialist

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERLIPONASE ALFA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?

- Patient has improved or maintained baseline motor function (e.g., ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (e.g., ambulation, walking or crawling) from baseline
- CLN2 motor score must be at least 1 (e.g., patient is not bedridden or immobile)

If yes, **approve for 12 months with a quantity limit of #2 kits per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CERLIPONASE ALFA (Brineura)** requires for renewal the following criteria to be met:

- Patient has improved or maintained baseline motor function (e.g., ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (e.g., ambulation, walking or crawling) from baseline
- CLN2 motor score must be at least 1 (e.g., patient is not bedridden or immobile)

RATIONALE

Promote appropriate utilization of **CERLIPONASE ALFA** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Brineura is indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

DOSAGE AND ADMINISTRATION

The recommended dosage of Brineura in pediatric patients 3 years of age and older is 300 mg administered once every other week by intraventricular infusion. Administer Brineura first followed by infusion of the Intraventricular Electrolytes each at an infusion rate of 2.5 mL/hr. The complete Brineura infusion, including the required infusion of Intraventricular Electrolytes, is approximately 4.5 hours. Pre-treatment of patients with antihistamines with or without antipyretics or corticosteroids is recommended 30 to 60 minutes prior to the start of infusion.

AVAILABLE STRENGTHS

Injection: Brineura 150 mg/5 mL (30 mg/mL) solution, two single-dose vials per carton co-packaged with Intraventricular Electrolytes Injection 5 mL in a single-dose vial.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CERLIPONASE ALFA (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

CLN2 Disease Clinical Rating Scale

The CLN2 Disease Clinical Rating Scale is a standardized means of quantitatively assessing disease progression and tracks loss of function in 2 main functional domains: motor and language. Each domain is scored from 0 to 3 as described below in table 1. The scores of the two domains sum up to a total score of six, with 0 representing a complete loss of function, while a score of six represents normal function.

Table 1: CLN2 Disease Clinical Rating Scale

Motor function	Language function
3 Normal Grossly normal gait. No prominent ataxia, no pathologic falls.	3 Normal Apparently normal language. Intelligible and grossly age-appropriate. No decline noted yet.
2 Clumsy, falls Independent gait, as defined by ability to walk without support for 10 steps. Will have obvious instability, and may have intermittent falls.	2 Abnormal Language has become recognizably abnormal; some intelligible words; may form short sentences to convey concepts, requests, or needs.
1 No unaided walking Requires assistance to walk, or can crawl only.	1 Minimal Hardly understandable. Few intelligible words.
0 Immobile Can no longer walk or crawl.	0 Unintelligible No intelligible words or vocalizations.

REFERENCES

- Brineura [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical Inc. April 2017.
- CLN2Connection. Natural History: CLN2 disease follows a devastatingly rapid course—symptoms and functional loss compound with age. Available at: <http://www.cln2connection.com/overview/natural-history>. Accessed April 28, 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 08/17

Client Approval: 08/17

P&T Approval: 07/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CETUXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CETUXIMAB	ERBITUX	25947		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
 - Patient's cancer is wild type KRAS (no mutation) as determined by FDA approved tests
 - Patient's cancer is epidermal growth factor receptor (EGFR)-expressing as determined by FDA approved tests

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

2. Does the patient meet **ONE** of the following criteria?
 - The requested medication is being used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment
 - The requested medication is being used in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
 - The requested medication is being used as a single agent AND the patient has failed oxaliplatin-based and irinotecan-based chemotherapy unless patient is intolerant to irinotecan

If yes, **approve for 12 months by HICL.**
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 locally or regionally advanced squamous cell carcinoma of the head and neck **AND** meet the following criterion?
 - The requested medication will be used in combination with radiation therapy

If yes, **approve for 12 months by HICL.**
If no, continue to #4.

4. Does the patient have a diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck **AND** meet the following criterion?
 - The requested medication is being used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

If yes, **approve for 12 months by HICL.**
If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CETUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck and meet **ALL** of the following criteria?
- The requested medication will be used as a single agent
 - The patient has failed prior platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **CETUXIMAB (Erbix)** requires a diagnosis of metastatic colorectal cancer (mCRC), locally or regionally advanced squamous cell carcinoma of the head and neck, recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, OR recurrent or metastatic squamous cell carcinoma of the head and neck. In addition, the following criteria must be met:

For the diagnosis of metastatic colorectal cancer (mCRC), approval requires:

- Patient's cancer is wild type KRAS (no mutation) as determined by FDA approved tests
- Patient's cancer is epidermal growth factor receptor (EGFR)-expressing as determined by FDA approved tests
- In addition, **ONE** of the following must be met:
 - The requested medication is being used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment
 - The requested medication is being used in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
 - The requested medication is being used as a single agent AND the patient has failed oxaliplatin-based and irinotecan-based chemotherapy unless patient is intolerant to irinotecan

For the diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck, approval requires:

- The requested medication will be used in combination with radiation therapy

For the diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval requires:

- The requested medication is being used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

For the diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck, approval requires:

- The requested medication will be used as a single agent
- The patient has failed prior platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CETUXIMAB (NSA)

RATIONALE

To ensure appropriate use of Erbitux consistent with FDA approved indications.

FDA APPROVED INDICATIONS

Erbitux is an epidermal growth factor receptor (EGFR) antagonist indicated for treatment of:

Head and Neck Cancer

- Locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy.
- Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU.
- Recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy.

Colorectal Cancer

K-Ras mutation-negative (wild-type), EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests:

- in combination with FOLFIRI for first-line treatment,
- in combination with irinotecan in patients who are refractory to
- irinotecan-based chemotherapy,
- as a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan.

DOSAGE AND ADMINISTRATION

- Do not administer Erbitux as an intravenous push or bolus
- Administer via infusion pump or syringe pump. Do not exceed an infusion rate of 10 mg/min
- Premedicate with an H1 antagonist
- Administer 400 mg/m² initial dose as a 120-minute intravenous infusion followed by 250 mg/m² weekly infused over 60 minutes
- Initiate Erbitux one week prior to initiation of radiation therapy. Complete Erbitux administration 1 hour prior to platinum-based therapy with 5-FU and FOLFIRI
- Reduce the infusion rate by 50% for NCI CTC Grade 1 or 2 infusion reactions and non-serious NCI CTC Grade 3 infusion reaction
- Permanently discontinue for serious infusion reactions

Withhold infusion for severe, persistent acneiform rash. Reduce dose for recurrent, severe rash

REFERENCES

- Erbitux [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb, November 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CETUXIMAB (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/12/18

Created: 02/13

Client Approval: 02/18

P&T Approval: 02/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COPANLISIB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
COPANLISIB	ALIQOPA	44503		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed follicular lymphoma (FL) and meet the following criteria?

- The patient is 18 years of age or older
- The patient has received at least two prior systemic therapies for follicular lymphoma (FL)

If yes, **approve for 12 months by HICL with a quantity limit of #3 vials per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **COPANLISIB (Aliqopa)** requires that the following criteria be met:

- A diagnosis of relapsed follicular lymphoma (FL)
- The patient is 18 years of age or older
- The patient has received at least two prior systemic therapies for follicular lymphoma (FL)

RATIONALE

Promote appropriate utilization of COPANLISIB based on FDA approved indication and dosing.

FDA APPROVED INDICATION

ALIQOPA is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

DOSAGE AND ADMINISTRATION

ALIQOPA is administered as a 1-hour intravenous infusion of a 60 mg dose, on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (three weeks on and one week off), until disease progression or unacceptable toxicity.

AVAILABLE STRENGTHS

Injection: supplied as a sterile lyophilized solid, white to slightly yellowish in appearance, in a single-dose vial for reconstitution and further dilution. After reconstitution, the solution is colorless to slightly yellowish. Each vial contains 60 mg of ALIQOPA free base.

REFERENCES

- Aliqopa [Prescribing Information]. Bayer HealthCare Pharmaceuticals Inc.: Whippany, NJ. August 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

COPANLISIB (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 09/17

Client Approval: 12/17

P&T Approval: 10/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CORTICOTROPIN	H.P. ACTHAR GEL	02830		ROUTE = INJECTION

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient less than two years old and diagnosed with infantile spasms?

If yes, **approve for 28 days with a maximum of #8 vials (each 5mL vial contains 400 units).**

If no, do not approve.

DENIAL TEXT: The guideline named **CORTICOTROPIN (H.P. Acthar Gel)** requires a diagnosis of infantile spasms in patients less than 2 years of age. For all other FDA indications, consider the use of IV corticosteroids.

FDA approved indications include: infantile spasm, acute multiple sclerosis, psoriatic arthritis, rheumatoid arthritis including juvenile rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus or systemic dermatomyositis (polymyositis), severe erythema multiforme, Stevens-Johnson syndrome, serum sickness, severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation), symptomatic sarcoidosis, or to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type, or that due to lupus erythematosus.

RATIONALE

Ensure appropriate therapeutic use of this long acting corticotropin formulation.

The recommended regimen for use in infantile spasms is a daily dose of 150 units/m² (divided into twice daily intramuscular injections of 75 units/ m²) then a gradual taper over a 2-week period. A suggested taper schedule is 30 units/ m² every morning for 3 days, 15 units/ m² every morning for 3 days, 10 units/ m² every morning for 3 days, and then 10 units/ m² every other morning for 6 days.

8 vials per 28 days supply based on dosage of 150 units/m²/day with an estimate of 0.7m² body surface area, estimated maximum for a child less than 40 pounds (two years old).

The American Academy of Neurology guidelines for treatment of infantile spasms state that response is usually within 2 weeks and current clinical data is insufficient to determine optimum dosage and duration.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CORTICOTROPIN (NSA)

RATIONALE (CONTINUED)

Questcor states that the H.P. Acthar Gel vial expires 28 days after initial puncture, when stored under ideal conditions (per USP standard guidelines).

FDA APPROVED INDICATIONS

Acthar Gel is indicated for the treatment of infantile spasms, for acute exacerbations of multiple sclerosis, and for numerous other diseases and disorders. (See below).

INFANTILE SPASMS: Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

MULTIPLE SCLEROSIS: Treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

RHEUMATIC DISORDERS: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), and ankylosing spondylitis.

COLLAGEN DISEASES: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis).

DERMATOLOGIC DISEASES: Severe erythema multiforme (Stevens-Johnson syndrome).

ALLERGIC STATES: Serum sickness.

OPHTHALMIC DISEASES: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.

RESPIRATORY DISEASES: Symptomatic sarcoidosis.

EDEMATOUS STATE: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN (NSA)

REFERENCES

- Amphastar Pharmaceuticals, Inc. Cortrosyn package insert. Rancho Cucamonga, CA. September 2005.
- Baram TZ, Mitchell WG et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms; a prospective, randomized, blinded study. Pediatrics 1996; 97:375–379.
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- Mackay MT, Weiss, SK, Adams-Webber, T et al. Practice Parameter: Medical Treatment of Infantile Spasms Report of the American Academy of Neurology and the Child Neurology Society. Neurology 2004; 62:1668–1681. Accessible online at <http://www.neurology.org/content/62/10/1668.full.pdf> [Accessed June 28, 2011].
- Questcor Pharmaceuticals, Inc. HP Acthar Gel package insert. Hayward, CA. June 2011.
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- Riikonen R. A long-term follow-up study of 214 children with the syndrome of infantile spasms. Neuropediatrics. 1982; 13:14–23.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 11/07

Client Approval: 08/17

P&T Approval: 07/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DARATUMUMAB	DARZALEX	42814		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
 - The patient has received at least three prior lines of therapy, including agents from **BOTH** of the following drug classes:
 - Proteasome inhibitors (PI): bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)
 - Immunomodulatory agents: lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)
 - The requested medication will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
 - The patient is refractory to both a proteasome inhibitor (PI) (bortezomib (Velcade), carfilzomib (Kyprolis), or ixazomib (Ninlaro)) **AND** an immunomodulatory agent (lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid))
 - The requested medication will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
 - The patient has received at least one prior line of therapy
 - The requested medication will be used in combination with lenalidomide and dexamethasone **OR** in combination with bortezomib and dexamethasone

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
- The patient has received at least two prior lines of therapy, including lenalidomide and a proteasome inhibitor (PI) (bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro))
 - The requested medication will be used in combination with pomalidomide and dexamethasone

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a newly diagnosed multiple myeloma and meet **ALL** of the following criteria?
- The patient is ineligible for autologous stem cell transplant
 - The requested medication will be used in combination with bortezomib (Velcade), melphalan and prednisone [VMP]

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DARATUMUMAB (Darzalex)** requires a diagnosis of multiple myeloma and that the patient meets **ONE** of the following criteria:

- The patient has received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent **AND** will receive daratumumab as monotherapy
- The patient is refractory to both a proteasome inhibitor (PI) and an immunomodulatory agent **AND** will receive daratumumab as monotherapy
- The patient has received at least one prior line of therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone **OR** in combination with bortezomib and dexamethasone
- The patient has received at least two prior lines of therapy, including lenalidomide and a proteasome inhibitor (PI) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone
- The patient is newly diagnosed with multiple myeloma, ineligible for autologous stem cell transplant, **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone

Proteasome inhibitors include: bortezomib, carfilzomib, or ixazomib; immunomodulatory agents include: lenalidomide, pomalidomide, or thalidomide.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

RATIONALE

To ensure appropriate use of daratumumab (Darzalex) consistent with FDA-approved indications.

FDA-APPROVED INDICATIONS

Daratumumab (Darzalex) is a human CD38-directed monoclonal antibody indicated:

- In combination with bortezomib (Velcade), melphalan, and prednisone for the treatment of patients who are newly diagnosed with multiple myeloma who are ineligible for autologous stem cell transplant.
- In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.
- In combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- As monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

DOSAGE AND ADMINISTRATION

Pre-medicate with corticosteroids, antipyretics and antihistamines.

Dilute and administer as an intravenous infusion. See prescribing information for dilution volume and rate titration.

Darzalex should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion reactions if they occur.

The recommended dose is 16mg/kg actual body weight.

Table 1. Darzalex dosing schedule for monotherapy and in combination with lenalidomide or pomalidomide and low-dose dexamethasone (4-week cycle dosing regimen)

Schedule	Weeks
Weekly	Weeks 1 to 8 (total of 8 doses)
Every two weeks	Weeks 9 to 24 (total of 8 doses)
Every four weeks	Week 25 onwards until disease progression

Table 2. Darzalex dosing schedule in combination with bortezomib and dexamethasone (3-week cycle dosing regimen)

Schedule	Weeks
Weekly	Weeks 1 to 9 (total of 9 doses)
Every three weeks	Weeks 10 to 24 (total of 5 doses)
Every four weeks	Week 25 onwards until disease progression

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DARATUMUMAB (NSA)

FDA-APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Table 3. Darzalex dosing schedule in combination with bortezomib (Velcade), melphalan and prednisone ([VMP], 6-week cycle dosing regimen)

Schedule	Weeks
Weekly	Weeks 1 to 6 (total of 6 doses)
Every three weeks	Weeks 7 to 54 (total of 16 doses)
Every four weeks	Week 55 onwards until disease progression

Administer post-infusion medication as follows to reduce the risk of delayed infusion reactions for patients receiving daratumumab as monotherapy. Consider in other patients.

- Oral corticosteroid (20mg methylprednisolone or equivalent dose of a corticosteroid in accordance with local standards) on the first and second day after all infusions.

REFERENCES

- Darzalex [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; May 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 06/15/18

Created: 12/15

Client Approval: 05/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DAUNORUBICIN/ CYTARABINE LIPOSOME	VYXEOS	44461		ROUTE = INTRAVEN.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
 - The patient has newly diagnosed therapy-related acute myeloid leukemia (t-AML) **OR** AML with myelodysplasia-related changes (AML-MRC)
 - The patient is 18 years of age or older

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires a new diagnosis of therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes in adult patients.

RATIONALE

Promote appropriate utilization of DAUNORUBICIN/CYTARABINE LIPOSOME based on FDA approved indication.

DOSAGE

VYXEOS is a liposome available as a single-dose vial for reconstitution. VYXEOS is administered via intravenous infusion over 90 minutes. A full VYXEOS course consists of 1-2 cycles of Induction and up to 2 cycles of Consolidation:

- First Induction Cycle: (daunorubicin 44 mg/m² and cytarabine 100 mg/m²) liposome days 1, 3, and 5
- Second Induction Cycle: (daunorubicin 44 mg/m² and cytarabine 100 mg/m²) liposome days 1 and 3 [administered 2 to 5 weeks after the first induction cycle, only for those patients failing to achieve a response with the first induction cycle]
- Consolidation Cycle: (daunorubicin 29 mg/m² and cytarabine 65 mg/m²) liposome days 1 and 3

For patients who do not achieve remission with the first induction cycle, a second induction cycle may be administered 2 to 5 weeks after the first if there was no unacceptable toxicity with VYXEOS. Administer the first consolidation cycle 5 to 8 weeks after the start of the last induction.

For hypersensitivity reactions of any grade/severity, interrupt VYXEOS infusion immediately and manage symptoms. Reduce the rate of infusion or discontinue treatment. Discontinue VYXEOS in patients who exhibit impaired cardiac function unless the benefit of continuing treatment outweighs the risk.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

FDA APPROVED INDICATION

VYXEOS is indicated for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes.

REFERENCES

- Vyxeos [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. August 2017.

Library	Commercial	NSA
No	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/17

Client Approval: 12/17

P&T Approval: 10/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-PROLIA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	PROLIA		28656	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and 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, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score \geq 20% for any major fracture OR \geq 3% for hip fracture
 - The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)
 - The patient is unable to use oral therapy (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)

If yes, **approve for 12 months by GPID for 2 fills with a quantity limit of #1mL (#1 pre-filled syringe) per fill.**

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses?
 - Osteoporosis in a male patient
 - Glucocorticoid-induced osteoporosis

If yes, continue to #3.

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-PROLIA (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ALL** 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, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

If yes, **approve for 12 months by GPID for 2 fills with a quantity limit of #1mL (#1 pre-filled syringe) per fill.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?

- Bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer
- Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

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 **ALL** of the following criteria?

- The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

If yes, **approve for 12 months by GPID for 2 fills with a quantity limit of #1mL (#1 pre-filled syringe) per fill.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-PROLIA (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **DENOSUMAB (Prolia)** requires that the patient have a diagnosis of postmenopausal osteoporosis, osteoporosis in a male patient, glucocorticoid-induced osteoporosis, bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, or bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer. In addition, the following criteria must be met:

For the diagnosis of postmenopausal osteoporosis, approval requires ONE of the following:

- 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, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis AND FRAX score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)
- The patient is unable to use oral therapy (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)

For the diagnosis of osteoporosis in a male patient or glucocorticoid-induced osteoporosis, approval requires all of the following:

- 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, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

For diagnosis of bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, or bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer, approval requires all of the following:

- The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DENOSUMAB-PROLIA (NSA)

RATIONALE

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

REFERENCES

- Prolia [Prescribing Information]. Thousand Oaks, CA: Amgen; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 07/10

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-XGEVA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	XGEVA		29261	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma OR bone metastases from a solid tumor **AND** meet the following criterion?

- Xgeva is being used to prevent skeletal-related events (e.g., bone fractures or bone pain requiring radiation)

If yes, **approve for 12 months by GPID for #1 (1.7mL) vial per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity?

If yes, **approve and enter two authorizations as follows:**

- **Approve for 1 month by GPID for #3 (5.1mL) vials per 28 days.**
- **Approve for 11 months by GPID for #1 (1.7mL) vial per 28 days with a start date after the end date of the first authorization.**

If no, continue to #3.

3. Does the patient have a diagnosis of hypercalcemia of malignancy **AND** meet the following criterion?

- The patient is refractory to bisphosphonate therapy (e.g., Fosamax, Actonel, or Boniva)

If yes, **approve and enter two authorizations as follows:**

- **Approve for 1 month by GPID for #3 (5.1mL) vials per 28 days.**
- **Approve for 11 months by GPID for #1 (1.7mL) vial per 28 days with a start date after the end date of the first authorization.**

If no, do not approve.

DENIAL TEXT: The guideline named **DENOSUMAB (Xgeva)** requires that ONE of the following criteria is met:

- Diagnosis of multiple myeloma OR bone metastases from solid tumors AND the requested medication is being used to prevent skeletal-related events (e.g., bone fractures or bone pain requiring radiation)
- Diagnosis of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- Diagnosis of hypercalcemia of malignancy that is refractory to bisphosphonate therapy (e.g., Fosamax, Actonel, or Boniva)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-XGEVA (NSA)

RATIONALE

To ensure appropriate use of denosumab based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Xgeva is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and bone metastases from solid tumors
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

DOSAGE AND ADMINISTRATION

Xgeva is intended for subcutaneous route only and should not be administered intravenously, intramuscularly, or intradermally.

- Multiple Myeloma and Bone Metastasis from Solid Tumors: Administer 120 mg every 4 weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen. Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia
- Giant Cell Tumor of Bone: Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen. Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia
- Hypercalcemia of Malignancy: Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen.

REFERENCES

- Amgen. Xgeva package insert. Thousand Oaks, CA. January, 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/29/18

Created: 11/07

Client Approval: 01/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DINUTUXIMAB

Generic	Brand	HICL	GCN	Exception/Other
DINUTUXIMAB	UNITUXIN	42038		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma and meets all the following criteria?
 - Patient is 17 years of age or younger
 - Patient has received an autologous stem cell transplant
 - Patient achieved at least a partial response to chemotherapy given prior to autologous stem cell transplant
 - Patient has not undergone 5 cycles of dinutuximab in the past

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 patient be receiving dinutuximab concurrently with isotretinoin and either Leukine (GM-CSF) or Proleukin (IL-2)?

If yes, **approve for 12 months by HICL with a fill limit of up to 5 fills.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **DINUTUXIMAB** requires a diagnosis of high-risk neuroblastoma. In addition, the following criteria must be met:

- Patient is 17 years of age or younger
- Patient has received an autologous stem cell transplant
- Patient achieved a partial response to chemotherapy given prior to autologous stem cell transplant
- Patient has not undergone 5 cycles of dinutuximab in the past
- Dinutuximab will be used concurrently with isotretinoin and either Leukine or Proleukin

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DINUTUXIMAB

RATIONALE

Promote appropriate utilization of dinutuximab based on FDA approved indication and dosing.

Unituxin is the first FDA approved medication for the treatment of high-risk neuroblastomas after initial treatment with first-line multi-agent, multimodality therapy, which consists of induction chemotherapy, surgical resection accompanied with radiation, and myeloablative consolidation chemotherapy followed with an autologous stem cell transplant. Following these initial therapies, the prior standard of care was to initiate oral 13-cis-retinoic acid also known as the generic drug isotretinoin, to eradicate residual disease. Unituxin is approved to be given in combination with isotretinoin, IL-2 (marketed as Proleukin [aldesleukin]), and GM-CSF (available as the brand Leukine [sargramostim]) following the initial therapy.

Patients at the highest risk for disease progression and mortality (high-risk neuroblastomas) are those who are older than 18 months of age and have disseminated disease or those with localized disease with unfavorable markers such as MYCN amplification.

FDA APPROVED INDICATION

Unituxin is a GD2-binding monoclonal antibody indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

DOSAGE

The recommended daily dose of dinutuximab is 17.5 mg/m²/day as an intravenous infusion over 10 to 20 hours for four consecutive days for a maximum of 5 cycles.

Unituxin is to be used in a regimen containing isotretinoin and either Leukine or Proleukin depending on the cycle. Cycles 1, 3, and 5 are 24 days in duration and Unituxin is given in combination with GM-CSF and RA (see Table 1). Cycles 2 and 4 are 32 days in duration and Unituxin is given in combination with IL-2 and RA (see Table 2).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DINUTUXIMAB

DOSAGE (CONTINUED)

Table 1: Dosing Regimen for Cycles 1, 3, and 5 (from Unituxin Prescribing Information)

Cycle Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15-24
GM-CSF ¹	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Unituxin ²				X	X	X	X								
RA ³											X	X	X	X	X

¹ GM-CSF: 250 µg/m²/day, administered by either subcutaneous injection (recommended) or IV infusion administered over 2 hours.

² Unituxin: 17.5 mg/m²/day, administered by diluted IV infusion over 10–20 hours.

³ RA: for >12 kg body weight, 80 mg/m² orally twice daily for a total dose of 160 mg/m²/day; for ≤12 kg body weight, 2.67 mg/kg orally twice daily for a total daily dose of 5.33 mg/kg/day (round dose up to nearest 10 mg).

Table 2: Dosing Regimen for Cycles 2 and 4 (from Unituxin Prescribing Information)

Cycle Day	1	2	3	4	5	6	7	8	9	10	11	12-14	15-28	29-32
IL-2 ¹	X	X	X	X				X	X	X	X			
Unituxin ²								X	X	X	X			
RA ³													X	

¹ IL-2: 3 MIU/m²/day administered by continuous IV infusion over 96 hours on Days 1-4 and 4.5 MIU/m²/day on Days 8-11.

² Unituxin: 17.5 mg/m²/day, administered by diluted IV infusion over 10-20 hours.

³ RA: for >12 kg body weight, 80 mg/m² orally twice daily for a total dose of 160 mg/m²/day; for ≤12 kg body weight, 2.67 mg/kg orally twice daily for a total daily dose of 5.33 mg/kg/day (round dose up to nearest 10 mg).

HOW SUPPLIED

Dinutuximab is supplied in a carton containing one 17.5 mg/5 mL single use vial (NDC 66302-0014-01)

REFERENCES

- Unituxin [Prescribing Information]. United Therapeutics Corp.: Silver Spring, MD. March 2015.
- National Cancer Institution. Neuroblastoma Treatment. Cancer.gov, Available at http://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdg#section/_214

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/15

Created: 07/15

Client Approval: 08/15

P&T Approval: 08/15



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DURVALUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DURVALUMAB	IMFINZI	44230		ROUTE = INTRAVEN.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma and meet **ONE** of the following criteria?
 - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) **OR**
 - 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.**

If no, continue to #2.

2. Does the patient have a diagnosis of unresectable Stage III non-small cell lung cancer (NSCLC) **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

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DURVALUMAB (Imfinzi)** requires a diagnosis of locally advanced or metastatic urothelial carcinoma **OR** unresectable Stage III non-small cell lung cancer (NSCLC). In addition, the following criteria must be met:

For the diagnosis of locally advanced or metastatic urothelial carcinoma, approval requires ONE of the following:

- The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) **OR**
- The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

For the diagnosis of unresectable Stage III non-small cell lung cancer (NSCLC), approval requires:

- The patient's disease has not progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DURVALUMAB (NSA)

RATIONALE

Promote appropriate utilization of Imfinzi based on FDA approved indication.

FDA APPROVED INDICATIONS

Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with:

- Locally advanced or metastatic urothelial carcinoma who:
 - Have disease progression during or following platinum-containing chemotherapy.
 - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
 - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy

DOSAGE AND ADMINISTRATION

Urothelial Carcinoma: The recommended dose of Imfinzi is 10 mg/kg via intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity occurs.

NSCLC: The recommended dose of Imfinzi is 10 mg/kg via intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity, or a maximum of 12 months.

No dose reductions are recommended for adverse reactions. Withhold or discontinue Imfinzi to manage adverse reactions.

REFERENCES

- Imfinzi [Prescribing Information]. AstraZeneca Pharmaceuticals: Wilmington, DE; February 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/12/18

Created: 08/17

Client Approval: 02/18

P&T Approval: 04/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECALLANTIDE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ECALLANTIDE	KALBITOR	36797		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary angioedema and meet **ALL** of the following criteria?
 - Diagnosis is confirmed via complement testing
 - The medication is being used for treatment of acute attacks of hereditary angioedema
 - The patient is 12 years of age or older
 - The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
 - The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and/or angioedema

If yes, **approve for 12 months (up to 12 fills) by HICL with a quantity limit of 12mL per fill.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: The guideline named **ECALLANTIDE (Kalbitor)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

- Diagnosis is confirmed via complement testing
- The medication is being used for treatment of acute attacks of hereditary angioedema
- The patient is 12 years of age or older
- The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
- The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and/or angioedema

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECALLANTIDE (NSA)

RATIONALE

Ensure appropriate use of Kalbitor (ecallantide) based on FDA-approved indication and dosing/administration.

FDA APPROVED INDICATIONS

Kalbitor (ecallantide) is indicated for treatment of acute attacks of hereditary angioedema in patients 12 years of age and older.

DOSING & ADMINISTRATION

The recommended dose of Kalbitor (ecallantide) is 30mg (3 mL) administered subcutaneously in three 10 mg (1 mL) injections. If the attack persists, an additional dose of 30 mg may be administered within a 24-hour period.

Kalbitor (ecallantide) should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema.

BOXED WARNING FOR ECALLANTIDE:

Anaphylaxis has been reported after administration of Kalbitor (ecallantide). Because of the risk of anaphylaxis, Kalbitor (ecallantide) should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor (ecallantide) to patients with known clinical hypersensitivity to Kalbitor (ecallantide).

REFERENCES

- Kalbitor [Prescribing Information]. Dyax Corp.: Burlington, MA. March 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/18/19

Created: 11/13

Client Approval: 03/19

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ECULIZUMAB	SOLIRIS	34618		

This drug requires a written request for prior authorization.

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)?

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 atypical hemolytic uremic syndrome (aHUS)?

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of generalized Myasthenia gravis (gMG) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient's diagnosis is confirmed by a positive Anti-acetylcholine receptor (AchR) antibody test

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
 - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
 - PNH granulocyte clone size $\geq 10\%$
- The requested medication is prescribed by or in consultation with a hematologist

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?

- The patient is transitioning from an alternative complement inhibitor therapy (i.e., Ultomiris)
- Documentation of evidence of intravascular hemolysis (e.g., lactate dehydrogenase [LDH] level $\geq 1.5 \times$ ULN, hemoglobinuria) **OR** history of major adverse vascular event from thromboembolism

If yes, approve for 6 months by HICL as follows:

Enter both of the following approvals:

- **FIRST APPROVAL:** Approve for 1 month with a quantity limit of #240 mL per 28 days for 1 fill.
- **SECOND APPROVAL:** Approve for 5 months with a quantity limit of #180 mL per 28 days for 5 fills. (Please enter a start date of 1 day after the end date of the first approval)

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ECULIZUMAB (Soliris)** requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), or generalized Myasthenia gravis (gMG). The following criteria must also be met:

- Eculizumab (Soliris) is NOT being used for Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

For patients with generalized Myasthenia gravis (gMG), approval requires:

- The patient is 18 years of age or older
- The patient's diagnosis is confirmed by a positive Anti-acetylcholine receptor (AChR) antibody test

For patients with paroxysmal nocturnal hemoglobinuria (PNH), approval requires:

- The patient is 18 years of age or older
- The patient has confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
 - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
 - PNH granulocyte clone size greater than or equal to 10%
- The requested medication is prescribed by or in consultation with a hematologist
- The patient meets **ONE** of the following:
 - Transitioning from alternative complement inhibitor therapy (i.e., Ultomiris)
 - Documentation of evidence of intravascular hemolysis (e.g., lactate dehydrogenase [LDH] level greater than or equal to $1.5 \times$ ULN, hemoglobinuria) **OR** history of major adverse vascular event from thromboembolism

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND** meet the following criterion?

- Physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

If yes, **approve for 12 months by HICL with a quantity limit of #180 mL per 28 days.**
If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses?

- Atypical hemolytic uremic syndrome (aHUS)
- Generalized myasthenia gravis (gMG)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ECULIZUMAB (Soliris)** requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), or generalized Myasthenia gravis (gMG). In addition, the following criteria must be met:

For patients with paroxysmal nocturnal hemoglobinuria (PNH), approval requires:

- Physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

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.; August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 08/13

Client Approval: 03/19

P&T Approval: 01/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
EDARAVONE	RADICAVA	44252		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
 - The patient is currently taking riluzole (Rilutek) or has previously tried riluzole (Rilutek)
 - Requested medication is prescribed by or given in consultation with a neurologist or ALS specialist at a ALS Specialty Center or Care Clinic
 - Duration of disease (from onset of symptoms) is less than 2 years
 - Normal Respiratory Function defined as a Forced Vital Capacity (FVC) greater than 80%
 - Mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (e.g., speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

If yes, please enter **TWO** approvals by HICL as follows (total approval duration is 6 months):

- FIRST APPROVAL:** approve for 1 month for 1 fill with a quantity limit of #2800mL (twenty-eight 30mg/100mL single-dose bags)
- SECOND APPROVAL:** approve for 5 months with a quantity limit of #2000mL (twenty 30mg/100mL single dose bags) per 28 days (Please enter a start date after the end date of the first approval).

If no, do not approve.

DENIAL TEXT: The guideline named **EDARAVONE (Radicava)** requires a diagnosis of amyotrophic lateral sclerosis (ALS) and the following criteria to be met:

- The patient is currently taking riluzole (Rilutek) or has previously tried riluzole (Rilutek)
- Requested medication is prescribed by or given in consultation with a neurologist or ALS specialist at a ALS Specialty Center or Care Clinic
- Duration of disease (from onset of symptoms) is less than 2 years
- Normal Respiratory Function defined as a Forced Vital Capacity (FVC) greater than 80%
- Mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (e.g., speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?

- Patient has improved or maintained baseline functional ability or demonstrated a less-than-expected decline in functional ability from baseline as measured by functional assessments (e.g., ALSFRS)
- Patient does not require invasive ventilation
- Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

If yes, **approve for 12 months with a quantity limit of #2000mL (twenty 30mg/100mL single dose bags) per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **EDARAVONE (Radicava)** requires a diagnosis of amyotrophic lateral sclerosis (ALS) for renewal and the following criteria to be met:

- Patient has improved or maintained baseline functional ability or demonstrated a less-than-expected decline in functional ability from baseline as measured by functional assessments (e.g., ALSFRS)
- Patient does not require invasive ventilation
- Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

RATIONALE

Promote appropriate utilization of **EDARAVONE** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE AND ADMINISTRATION

The recommended dosage of Radicava is an intravenous infusion of 60 mg administered over a 60-minute period according to the following schedule:

- An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period.
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

AVAILABLE STRENGTHS

Injection: 30 mg/100 mL in a single-dose polypropylene bag; two bags per carton.

The ALSFRS-R is a validated questionnaire-based scale designed to be a clinical rating tool to monitor the progression of patients in clinical practice as well as an outcome measure in clinical trials. The rate of progression of ALS patient population is typically linear, however it is not homogenous, therefore it is difficult to ascertain the general rate of progression for the patient population. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). There are four domains: bulbar, fine motor, gross motor and breathing. Each questionnaire item is scored from 0-4, with higher scores representing greater functional ability; the total possible score is 48 points.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Figure 1: ALSFRS-R Questionnaire

Bulbar	Fine Motor	Gross Motor	Breathing
<p>1. Speech</p> <ul style="list-style-type: none">4. Normal speech processes3. Detectable speech disturbance2. Intelligible with repeating1. Speech combined with nonvocal communication0. Loss of useful speech <p>2. Salivation</p> <ul style="list-style-type: none">4. Normal3. Slight but definite excess of saliva in mouth; may have nighttime drooling2. Moderately excessive saliva; may have minimal drooling1. Marked excess of saliva with some drooling0. Marked drooling; requires constant tissue or handkerchief <p>3. Swallowing</p> <ul style="list-style-type: none">4. Normal eating habits3. Early eating problems-occasional choking2. Dietary consistency changes1. Needs supplemental tube feeding0. NPO (exclusively parenteral or enteral feeding)	<p>4. Handwriting</p> <ul style="list-style-type: none">4. Normal3. Slow or sloppy; all words are legible2. Not all words are legible1. Able to grip pen but unable to write0. Unable to grip pen <p>5a. Cutting Food / Handling Utensils</p> <ul style="list-style-type: none">4. Normal3. Somewhat slow and clumsy, but no help needed2. Can cut most foods, although clumsy and slow; some help needed1. Food must be cut by someone, but can still feed slowly0. Needs to be fed <p>5b. Cutting Food / Handling Utensils (Alt. for patients with Gastrostomy)</p> <ul style="list-style-type: none">4. Normal3. Clumsy but able to perform all manipulations independently2. Some help needed with closures and fasteners1. Provides minimal assistance to caregiver0. Unable to perform any aspect of task <p>6. Dressing and hygiene</p> <ul style="list-style-type: none">4. Normal function3. Independent and complete self-care with effort or decreased efficiency2. Intermittent assistance or substitute methods1. Needs attendant for self-care0. Total dependence	<p>7. Turning in bed</p> <ul style="list-style-type: none">4. Normal3. Somewhat slow and clumsy, but no help needed2. Can turn alone or adjust sheets, but with great difficulty1. Can initiate, but not turn or adjust sheets alone0. Helpless <p>8. Walking</p> <ul style="list-style-type: none">4. Normal3. Early ambulation difficulties2. Walks with assistance1. Non-ambulatory functional movement only0. No purposeful leg movement <p>9. Climbing stairs</p> <ul style="list-style-type: none">4. Normal3. Slow2. Mild unsteadiness or fatigue1. Needs assistance0. Cannot do	<p>10. Dyspnea</p> <ul style="list-style-type: none">4. None3. Occurs when walking2. Occurs with one or more of the following: eating, bathing, dressing (ADL)1. Occurs at rest, difficulty breathing when either sitting or lying0. Significant difficulty, considering using mechanical respiratory support <p>11. Orthopnea</p> <ul style="list-style-type: none">4. None3. Some difficulty sleeping at night due to shortness of breath. Does not routinely use more than two pillows2. Needs extra pillow in order to sleep (more than two)1. Can only sleep sitting up0. Unable to sleep <p>12. Respiratory insufficiency</p> <ul style="list-style-type: none">4. None3. Intermittent use of BiPAP2. Continuous use of BiPAP1. Continuous use of BiPAP during the night and day0. Invasive mechanical ventilation by intubation or tracheostomy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

REFERENCES

- Radicava [prescribing information]. Jersey City, NJ: MT Pharma America, Inc.; May 2017.
- Cedarbaum J, Stambler N, Malt E et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999 Oct 31;169(1-2):13-21.
- Cedarbaum J, Mitsumoto H, Pestronk A, et al. The ALSFRS @ 20: Evolution of the ALSFRS-R, history, clinimetric properties and future directions [Poster]. Available at: https://cytokinetics.com/wp-content/uploads/2015/10/2011ALS_MND_ASFRS20.pdf

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 08/17

Client Approval: 08/17

P&T Approval: 07/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ELOSULFASE ALFA	VIMIZIM	40929		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)?

If yes, **approve for lifetime by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ELOSULFASE ALFA** requires a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

RATIONALE

Promote appropriate utilization of Vimizim based on FDA approved indication.

Vimizim is the first agent approved to treat Morquio A syndrome. Prior to the approval of this medication, complications of Morquio A syndrome, such as, skeletal abnormalities, heart disease, hearing and vision loss, and breathing difficulties, are often treated medically and surgically as needed.

Morquio A syndrome, an autosomal recessive lysosomal storage disease, affects approximately 800 individuals in the United States. Morquio A syndrome is classified within a group of diseases called mucopolysaccharidoses (MPS) as MPS IV. Patients with Morquio A syndrome are deficient in the N-acetylgalactosamine-6-sulfate sulfatase (GALNS) enzyme. The first symptoms usually occur at 2-3 years of age. This enzyme deficiency causes difficulties in skeletal development and growth, and patients will typically exhibit symptoms such as abnormal bone development (including the spine), bell-shaped chest with flared ribs at bottom, coarse facial features, widely spaced teeth, hypermobile joints, knock knees, macrocephaly, and short stature. The patient with Morquio A syndrome may have physical exam abnormalities such as kyphoscoliosis, cloudy cornea, aortic regurgitation, enlarged liver, inguinal hernia, and paralysis below the neck due to underdeveloped upper vertebrae.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA

RATIONALE (CONTINUED)

The most common adverse events observed in clinical trials (occurring in 10% or greater of Vimizim patients) were nausea, vomiting, abdominal pain, chills, headache, pyrexia, and fatigue. In clinical trials 7.7% of patients had anaphylactic reactions and 18.7% had hypersensitivity reactions during or after Vimizim administration.

Vimizim contains a boxed warning regarding the risk of life-threatening anaphylactic reactions that may occur during infusion. Patients must be observed during and after Vimizim infusion by a health care provider trained to manage medical emergencies. Patients with acute febrile or respiratory conditions may be at increased risk due to potential for respiratory compromise during a hypersensitivity reaction; the healthcare provider must carefully consider the patient’s clinical condition prior to infusion and consider delaying treatment with Vimizim when appropriate.

The safety and efficacy of Vimizim have not been established in patients less than 5 years old.

DOSAGE

The recommended dose of Vimizim is 2mg per kilogram of body weight administered once weekly as an intravenous infusion. Administer Vimizim over a minimum of 3.5 to 4.5 hours (based on infusion volume). Patients should receive pretreatment with antihistamines, with or without antipyretics, 30 to 60 minutes before administration of Vimizim. If a hypersensitivity reaction occurs during the infusion, administration may be slowed, temporarily stopped or discontinued based on the severity of the reaction. Vimizim should be infused using a low-protein binding infusion set with a low-protein binding 0.2 micrometer in-line filter.

FDA APPROVED INDICATION

Vimizim is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

REFERENCES

- Vimizim [Prescribing Information]. Novato, CA: Biomarin Pharmaceutical Inc; February 2014.
- FDA Press Announcement on 2/14/14: FDA approves Vimizim to treat rare congenital disorder. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm386008.htm> Accessed February 24, 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/14

Created: 03/14

Client Approval: 05/14

P&T Approval: 05/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELOTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ELOTUZUMAB	EMPLICITI	42842		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 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. Does the patient have a diagnosis of multiple myeloma and meet **ONE** of the following criteria?

- Empliciti (elotuzumab) will be used in combination with lenalidomide and dexamethasone in patient who has received one to three prior therapies for the treatment of multiple myeloma such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation **OR**
- Empliciti (elotuzumab) will be used in combination with pomalidomide and dexamethasone in patient who has received at least two prior therapies including lenalidomide and a proteasome inhibitor

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ELOTUZUMAB (Empliciti)** requires a diagnosis of multiple myeloma in adult patients. In addition, ONE of the following must be met for approval:

- Empliciti must be used in combination with lenalidomide and dexamethasone in patients who have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation **OR**
- Empliciti must be used in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor

RATIONALE

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

REFERENCES

- Empliciti [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/19/18

Created: 12/15

Client Approval: 11/18

P&T Approval: 02/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG (NSA)

Generic	Brand	HICL	GCN	Exception/Other
EMAPALUMAB-LZSG	GAMIFANT	45503		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) and diagnosis is confirmed by **ONE** of the following criteria?
 - The patient has undergone a genetic test identifying HLH-associated gene mutation (e.g., PRF1, UNC13D)
 - The patient has at least **five** of the following eight diagnostic criteria for HLH:
 - Fever
 - Splenomegaly
 - Cytopenias (affecting ≥ 2 of 3 cell lineages)
 - Hypertriglyceridemia and/or hypofibrinogenemia
 - Hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy
 - Low or absent natural killer-cell activity
 - Ferritin level of ≥ 500 mcg/L
 - Soluble CD25 level of $\geq 2,400$ U/mL

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 refractory, recurrent, or progressive disease
 - The patient has a trial or intolerance to conventional HLH therapy (e.g., chemotherapy, steroids, immunotherapy)

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?

- The requested medication will be used concurrently with dexamethasone
- Therapy is prescribed by or in consultation with an immunologist, hematologist, or oncologist

If yes, **approve for 8 weeks by HICL.**

APPROVAL TEXT: Renewal requires that 1) patient has not received successful hematopoietic cell transplantation and 2) patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g. altered mental status), improved CBC, increased fibrinogen levels and/or reductions in D-dimer, ferritin, soluble CD25 levels.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **EMAPALUMAB-LZSG (Gamifant)** requires a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH). In addition, the following criteria must be met:

- Diagnosis is confirmed by ONE of the following:
 - The patient has undergone a genetic test identifying HLH-associated gene mutation (e.g., PRF1, UNC13D)
 - The patient has at least five of the following eight diagnostic criteria for HLH (fever, splenomegaly, cytopenias (affecting at least 2 of 3 cell lineages), hypertriglyceridemia and/or hypofibrinogenemia, hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy, low or absent natural killer-cell activity, ferritin level of at least 500 mcg/L, soluble CD25 level of at least 2,400 U/mL)
- The patient has refractory, recurrent, or progressive disease; **OR** the patient has a trial or intolerance to conventional HLH therapy (e.g., chemotherapy, steroids, immunotherapy)
- The requested medication will be used concurrently with dexamethasone
- Therapy is prescribed by or in consultation with an immunologist, hematologist, or oncologist

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

- Does the patient have a diagnosis of hemophagocytic lymphohistiocytosis (HLH) and meet **ALL** of the following criteria?
 - The patient has not received successful hematopoietic stem cell transplantation
 - The patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g., altered mental status), improved CBC, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 levels

If yes, **approve for 8 weeks by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **EMAPALUMAB-LZSG (Gamifant)** requires a diagnosis of hemophagocytic lymphohistiocytosis (HLH). In addition, the following criteria must be met:

- The patient has not received successful hematopoietic stem cell transplantation
- The patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g., altered mental status), improved CBC, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 levels

RATIONALE

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

REFERENCES

- Gamifant [Prescribing Information]. Waltham, MA: Sobi Inc.; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE

Generic	Brand	HICL	GCN	Exception/Other
IMIGLUCERASE	CEREZYME	09022		
TALIGLUCERASE ALFA	ELELYSO	38937		
VELAGLUCERASE ALFA	VPRIV	36874		

GUIDELINES FOR USE

ELELYSO

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease and meets the following criteria?

- Patient 4 years of age and above

If yes, **approve for up to 12 months.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE** requires a diagnosis of type 1 Gaucher disease. In addition, the following criteria must be met:

- Patient 4 years of age and above

VPRIV

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease and meets the following criteria?

- Patient 4 years of age and above
- Previous trial (unless contraindicated) of Elelyso

If yes, **approve for up to 12 months.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE** requires a diagnosis of type 1 Gaucher disease. In addition, the following criteria must be met:

- Patient 4 years of age and above
- Previous trial (unless contraindicated) of Elelyso

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE

GUIDELINES FOR USE (CONTINUED)

CEREZYME

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease and meets the following criteria?

- Patient 18 years of age and above
- Previous trial (unless contraindicated) of Elelyso

If yes, **approve for up to 12 months.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE** requires a diagnosis of type 1 Gaucher disease. In addition, the following criteria must be met:

- Patient 18 years of age and above
- Previous trial (unless contraindicated) of Elelyso

RATIONALE

Ensure that Cerezyme, Elelyso, and Vpriv are being used to treat patients with type 1 Gaucher disease.

FDA APPROVED INDICATIONS

CEREZYME is indicated for long term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease resulting in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly.

ELELYSO is indicated for long term enzyme replacement therapy for adult patients and pediatric patients with type 1 Gaucher disease. Dosing information is available for 4 years of age and older.

VPRIV is indicated for long term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease. Dosing information is available for 4 years of age and older.

REFERENCES

- Genzyme Corporation, Cerezyme package insert. Cambridge, MA. December 2012.
- Pfizer Labs, Elelyso package insert. New York, NY. August 2014.
- Shire Human Genetic Therapies, Inc., Vpriv package insert. Cambridge, MA. April 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/15

Created: 05/05

Client Approval: 05/15

P&T Approval: 05/15



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV

Generic	Brand	HICL	GCN	Exception/Other
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN	07323		
EPOPROSTENOL SODIUM (ARGININE)	VELETRI	37762		

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) and meets **ALL** of the following criteria?
 - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 - Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
 - The patient has NYHA/WHO Functional Class III-IV symptoms

If yes, **approve up to 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **EPOPROSTENOL (Flolan, Veletri)** requires a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). The following criteria must also be met.

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
- The patient has NYHA/WHO Functional Class III-IV symptoms

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

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 improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: The guideline for **EPOPROSTENOL (Flolan, Veletri)** renewal requires a diagnosis of pulmonary arterial hypertension (PAH). The following criteria must also be met.

- The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
- The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

RATIONALE

Ensure appropriate use of Flolan and Veletri based on FDA approved indication.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV

RATIONALE (CONTINUED)

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (e.g. diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

FDA APPROVED INDICATION

Epoprostenol is indicated for the long-term intravenous treatment of primary pulmonary hypertension and pulmonary hypertension associated with the scleroderma spectrum of disease in NYHA/WHO Class III and Class IV patients who do not respond adequately to conventional therapy.

Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

REFERENCES

- GlaxoSmithKline. Flolan package insert. Research Triangle Park, NC. April 2015.
- Actelion. Veletri package insert. South San Francisco, CA. June 2012.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 09/05

Client Approval: 09/16

P&T Approval: 08/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERIBULIN

Generic	Brand	HICL	GCN	Exception/Other
ERIBULIN MESYLATE	HALAVEN	37256		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meets the following criteria?
 - The patient has received previous treatment with **TWO** chemotherapeutic regimens for the treatment of metastatic disease which should have included at least **ONE** agent from **EACH** of the following chemotherapeutic drug classes:
 - An anthracycline [e.g., daunorubicin (Cerubidine), daunorubicin liposomal (DaunoXome), doxorubicin (Adriamycin), doxorubicin liposomal (Doxil), idarubicin (Idamycin), epirubicin (Ellence), mitoxantrone (Novantrone)]
 - A taxane [e.g., docetaxel (Taxotere), paclitaxel (Taxol or Abraxane)]

If yes, **approve for 12 months by HICL with a quantity limit of #6 vials (maximum 3 vials per dose) per 21 days.**

If no, continue to #2.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of unresectable or metastatic liposarcoma and meets the following criteria?
 - The patient has received previous treatment for liposarcoma, which included an anthracycline [e.g., daunorubicin (Cerubidine), daunorubicin liposomal (DaunoXome), doxorubicin (Adriamycin), doxorubicin liposomal (Doxil), idarubicin (Idamycin), epirubicin (Ellence), mitoxantrone (Novantrone)]?

If yes, **approve for 12 months by HICL with a quantity limit of #6 vials (maximum 3 vials per dose) per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **ERIBULIN (Halaven)** requires a diagnosis of metastatic breast cancer and previous treatment with an anthracycline and a taxane OR a diagnosis of unresectable or metastatic liposarcoma and previous treatment with an anthracycline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ERIBULIN

RATIONALE

To ensure appropriate use of Halaven based on FDA indication.

FDA APPROVED INDICATIONS

Halaven is a microtubule inhibitor indicated for the treatment of patients with:

- Metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.
- Unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

REFERENCES

- Halaven [Prescribing Information]. Eisai Inc.: Woodcliff Lake, NJ. January 2016.
- Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: <http://www.thomsonhc.com/hcs/librarian/>. [Accessed: June 28, 2011].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: NA

Commercial Effective: 05/01/16

Created: 11/10

Client Approval: 11/13

P&T Approval: 05/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ESKETAMINE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ESKETAMINE	SPRAVATO	41003		

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
- The requested medication will be used in combination with an oral antidepressant
- 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
- The patient had a trial of **TWO** oral anti-depressants from different classes for the treatment of depression (e.g., SSRIs, SNRIs, bupropion, mirtazapine, serotonin modulator, TCAs, optional MAOI) for an adequate time period defined as at least 6 weeks (unless the patient has shown little to no improvement after 4 weeks)

If yes, **approve for a total of 3 months by HICL as follows:**

- **INDUCTION DOSE:** Approve for 1 month with a quantity limit of #23 per 28 days.
- **MAINTENANCE DOSE:** Approve for 2 months with a quantity limit of #12 per 28 days (Enter a start date of 28 days from the first date of the induction dose approval).

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated clinical benefit (improvement in depression) compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ESKETAMINE (Spravato)** requires a diagnosis of treatment-resistant depression (TRD). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication will be used in combination with an oral antidepressant
- 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
- The patient had a trial of **TWO** oral anti-depressants from different classes for the treatment of depression (e.g., SSRIs, SNRIs, bupropion, mirtazapine, serotonin modulator, TCAs, optional MAOI) for an adequate time period defined as at least 6 weeks (unless the patient has shown little to no improvement after 4 weeks)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ESKETAMINE (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) **AND** meet the following criterion?

- Physician attestation that the patient has demonstrated clinical benefit (improvement in depression) compared to baseline

If yes, **approve for 12 months by HICL with a quantity limit of #12 per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ESKETAMINE (Spravato)** requires a diagnosis of treatment-resistant depression (TRD). In addition, the following criteria must be met:

- Physician attestation that the patient has demonstrated clinical benefit (improvement in depression) compared to baseline

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., March 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETELCALCETIDE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ETELCALCETIDE	PARSABIV	44093		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of secondary hyperparathyroidism (HPT) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has chronic kidney disease
- The patient is on hemodialysis
- The patient is NOT taking another calcimimetic agent (e.g., cinacalcet)

If yes, **approve for 12 months by HICL with a quantity limit of #36mL per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ETELCALCETIDE (Parsabiv)** requires a diagnosis of secondary hyperparathyroidism (HPT). The following criteria must also be met:

- The patient is 18 years of age or older
- The patient has chronic kidney disease
- The patient is on hemodialysis
- The patient is NOT taking another calcimimetic agent (e.g., cinacalcet)

RATIONALE

Promote appropriate utilization of **ETELCALCETIDE** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Parsabiv is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

DOSAGE AND ADMINISTRATION

Parasabiv is available as single-dose vials. Single-dose vials are available in 2.5 mg/0.5mL, 5 mg/1mL, and 10 mg/2 mL strengths.

The recommended starting dose of PARSABIV is 5 mg administered by intravenous (IV) bolus injection three times per week at the end of hemodialysis treatment. Administer PARSABIV only at the end of hemodialysis treatment.

The lowest maintenance dose of PARSABIV is 2.5 mg three times per week, and the highest maintenance dose of PARSABIV is 15 mg three times per week. The maintenance dose of PARSABIV is individualized and determined by titration based on parathyroid hormone (PTH) and corrected serum calcium response. The maintenance dose is the dose that maintains PTH levels within the recommended target range and corrected serum calcium within the normal range.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETELCALCETIDE (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Ensure corrected serum calcium is at or above the lower limit of normal prior to PARSABIV initiation, a PARSABIV dose increase, or re-initiation of PARSABIV therapy after a dosing interruption.

If a regularly scheduled hemodialysis treatment is missed, DO NOT administer any missed doses. Resume PARSABIV at the end of the next hemodialysis treatment at the prescribed dose. If doses of PARSABIV are missed for more than 2 weeks, re-initiate PARSABIV at the recommended starting dose of 5 mg (or 2.5 mg if that was the patient's last dose).

Monitor corrected serum calcium and PTH levels during dose initiation, dose adjustment, and dose maintenance according to the schedule in Table 1.

Table 1: Recommended Schedule for Monitoring Corrected Serum Calcium and Parathyroid Hormone Levels during PARSABIV Treatment (from *Parasabiv prescribing information*)

	Dose Initiation or Dose Adjustment	Maintenance
Corrected Serum Calcium Levels	1 week after	Every 4 weeks
Parathyroid Hormone Levels	4 weeks after	Per clinical practice

Increase the dose of PARSABIV in 2.5 mg or 5 mg increments in individuals with corrected serum calcium within the normal range and PTH levels above the recommended target range based on the patient's PTH levels no more frequently than every 4 weeks up to a maximum dose of 15 mg three times per week.

Decrease or temporarily discontinue PARSABIV dosing in individuals with PTH levels below the target range. In individuals with a corrected serum calcium below the lower limit of normal but at or above 7.5 mg/dL without symptoms of hypocalcemia, consider decreasing or temporarily discontinuing PARSABIV or use concomitant therapies to increase corrected serum calcium. If the dose is stopped, then re-initiate PARSABIV at a lower dose when the PTH is within the target range and hypocalcemia has been corrected.

Stop PARSABIV and treat hypocalcemia if the corrected serum calcium falls below 7.5 mg/dL or patients report symptoms of hypocalcemia. When the corrected serum calcium is within normal limits, symptoms of hypocalcemia have resolved, and predisposing factors for hypocalcemia have been addressed, re-initiate PARSABIV at a dose 5 mg lower than the last administered dose. If the last administered dose of PARSABIV was 2.5 mg or 5 mg, re-initiate at a dose of 2.5 mg.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EETELCALCETIDE (NSA)

REFERENCES

- Parsabiv [Prescribing Information]. Thousand Oaks, CA: Kai Pharmaceuticals; February 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 02/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN

Generic	Brand	HICL	GCN	Exception/Other
ETEPLIRSEN	EXONDYS 51	43770		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meets **ALL** of the following criteria?
 - Documented genetic testing that confirms mutation in DMD gene is amenable to exon 51 skipping
 - Prescribed by or given in consultation with a neurologist specializing in treatment of DMD at a DMD treatment center
 - Patient is ambulatory
 - Patient is currently receiving treatment with or has contraindication to corticosteroids (e.g., prednisone or prednisolone)

If yes, **approve for 24 weeks by HICL.**

APPROVAL TEXT: Renewal requires that the patient has maintained or demonstrated a less than expected decline in ambulatory function as measured by muscle function tests **OR** has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function).

If no, do not approve.

DENIAL TEXT: The guideline named **ETEPLIRSEN (Exondys 51)** requires a diagnosis of Duchenne muscular dystrophy (DMD) and that **ALL** of the following criteria are met:

- Documented genetic testing that confirms mutation in DMD gene is amenable to exon 51 skipping
- Prescribed by or given in consultation with a neurologist specializing in treatment of DMD at a DMD treatment center
- Patient is ambulatory
- Patient is currently receiving treatment with or has contraindication to corticosteroids (e.g., prednisone or prednisolone).

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

2. Over the past 24 weeks, has the patient maintained or demonstrated a less than expected decline in ambulatory ability in muscle function assessments (i.e., 6-minute walking, distance (6MWD), ascending 4 stairs, descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment (NSAA))?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Renewal requires that the patient has maintained or demonstrated a less than expected decline in ambulatory function as measured by muscle function tests **OR** has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function).

If no, continue to #2.

3. During the past 24 weeks, has the patient 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.**

APPROVAL TEXT: Renewal requires that the patient has maintained or demonstrated a less than expected decline in ambulatory function as measured by muscle function tests **OR** has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function).

If no, do not approve.

DENIAL TEXT: The guideline named **ETEPLIRSEN (Exondys 51)** renewal requires ONE of the following criteria has been met:

- Over the past 24 weeks, the patient has maintained or demonstrated a less than expected decline in ambulatory ability in muscle function assessments (i.e., 6-minute walking, distance (6MWD), ascending 4 stairs, descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment (NSAA))
- **OR** during the past 24 weeks, the patient has maintained or demonstrated a less than expected decline in other muscle function (i.e. pulmonary or cardiac function).

RATIONALE

Promote appropriate utilization of **ETEPLIRSEN** based on FDA approved indication.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

RATIONALE (CONTINUED)

Exondys 51 (eteplirsen) is a phosphorodiamidate morpholino oligomer (PMO) that selectively binds to exon 51 of the dystrophin pre-mRNA, enabling the splicing mechanisms to skip exon 51 and restore the open reading frame of the dystrophin protein, which produces a truncated but functional dystrophin protein.

Duchenne muscular dystrophy (DMD) is a rare X-linked genetic disorder that results in progressive muscle weakness, loss of independence, and early mortality. DMD affects 1 in 3,000 to 1 in 6,000 live male births. DMD occurs when there is a mutation, mainly internal deletions in the dystrophin gene that results in a near absent production of the protein dystrophin. Dystrophin contributes to functional muscle integrity by connecting muscle fibers to the surrounding extracellular matrix. Dystrophin is present in muscles at birth but repeated muscle movement leads to breakdown of the protein and production of dystrophin is needed to replenish the degraded protein. Patients with DMD are unable to produce new dystrophin and without this protein, there is progressive muscle cell degeneration and muscle fiber loss. Functional muscle units are replaced by adipose and sclerosis. Additional inflammatory and immunological processes occur in conjunction with dystrophin deficiency, contributing to muscle pathology.

DMD is present at the time of birth, but the disorder does not become apparent until around age 3 – 5 years. Children with DMD may have delayed development including starting to walk at a later age than children without DMD. Normal childhood activities such as running, jumping, and stair climbing are abnormal and done with difficulty, and patients may experience frequent falls. As the child continues to age, they experience progressive muscle weakness and dysfunction. Many patients are wheelchair bound in their early teenage years and most patients succumb to cardiac and/or respiratory failure in their 20's.

The diagnosis of DMD is definitively confirmed by genetic testing. Confirmation of DMD by genetic testing is always required even if DMD is first diagnosed by a muscle biopsy. The genetic testing will identify the types of mutations in the DMD gene, and if no deletions or duplications are detected, DNA sequencing is performed to identify point mutations (including nonsense mutations) that alter the translation of the protein. A full characterization of the mutations is necessary to determine how the genetic reading frame is affected, which is the major determinant of the phenotypic variability of DMD. Knowing which exons of the DMD gene are affected or if there is premature termination of protein production can also determine eligibility for mutation specific treatment options.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

RATIONALE (CONTINUED)

The 6-minute walking distance test (6MWD) is a validated measure of integrated function that is dependent on respiratory, cardiovascular, and nutritional status, as well as skeletal muscle function, and has been used in several studies that measure functional capabilities. Baseline 6MWD is an important predictor of subsequent ambulatory status in patients with DMD, and a baseline 6MWD of 330m or less are correlated with an increased likelihood for future loss of ambulation. Changes in values of 6MWD of 30m (or 10%) from baseline are considered clinically significant. Growing boys with DMD maintain a stable or even improving 6MWD up to about 7 years of age. After age 7, these boys experience a significant decline in walking ability compared with healthy boys of the same age. As walking ability deteriorates, the 6MWD loses value as an appropriate endpoint to measure prognosis due to its dependence on muscle tissue. As such, other endpoints are needed to determine appropriate measures of therapeutic effect in these patients. Studies of patients with DMD has resulted in the observation that the percent predicted of forced vital capacity (FVC) declines at a rate of 5% per year in DMD patients who are 5 – 24 years of age.

There is currently no cure for DMD and treatment is mainly supportive and aimed at delaying disease progression. Corticosteroids such as prednisone and prednisolone have been shown to delay muscle dysfunction and loss of ambulation by several years. Even after the loss of ambulation, treatment with corticosteroid may help preserve respiratory and cardiac function. Despite this benefit, there is no consensus on what the optimal corticosteroid regimen should be, and their long-term use is attributed to detrimental side effects.

DOSAGE

The recommended dosing regimen for eteplirsen is 30mg/kg administered once weekly as a 35 – 60 minute intravenous infusion.

FDA APPROVED INDICATION

Exondys 51 (eteplirsen) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the *DMD* gene that is amenable to exon 51 skipping.

This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51. A clinical benefit of Exondys 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

AVAILABLE STRENGTHS

100mg/2mL vials (50mg/mL)
500mg/10mL vials (50mg/mL)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN

REFERENCES

- Exondys 51 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc. September 2016.
- FDA grants accelerated approval to first drug for Duchenne muscular dystrophy [Press release]. Updated September 19, 2016. Available from: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm521263.htm>.
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- Advances in Duchenne Muscular Dystrophy Natural History and Biomarkers. Industry Therapeutic Update from BioMarin Pharmaceutical Inc. and PTC Therapeutics Inc. Presented June 22, 2015. Available from: http://files.shareholder.com/downloads/PTCT/1345262988x0x836302/7DA38D13-28CC-4C56-8905-3AB6258984F4/PTCT_BMRN_June_22_DMD_Day_FINAL_updated.pdf.
- Mendell JR, Rodino-Klapac LR, Sahenk Z, et al. Eteplirsen for the treatment of Duchenne muscular dystrophy. Ann Neurol. 2013 Nov;74(5):637-47.
- Mendell JR, Goesmans N, Lowes LP, et al. Longitudinal effect of eteplirsen vs. historical control on ambulation in DMD. Ann Neurol. 2015 Nov 17. [Epub ahead of print].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/01/16

Created: 01/16

Client Approval: 09/16

P&T Approval: 02/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FULVESTRANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
FULVESTRANT	FASLODEX	23523		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer and meet **ALL** of the following criteria?
 - The patient is female and postmenopausal
 - The patient has not previously been treated with endocrine therapy
 - The requested medication will be used as monotherapy

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, continue to #2.

2. Does the patient have a diagnosis of hormone receptor (HR)-positive advanced breast cancer and meet **ALL** of the following criteria?
 - The patient is female and postmenopausal
 - The patient has experienced disease progression following endocrine therapy
 - The requested medication will be used as monotherapy

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FULVESTRANT (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and meet **ALL** of the following criteria?

- The patient is female
- The patient has experienced disease progression following endocrine therapy
- The requested medication will be used concurrently with Ibrance (palbociclib) or Verzenio (abemaciclib)

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, continue to #4.

4. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and meet **ALL** of the following criteria?

- The patient is female and postmenopausal
- The requested medication will be used in combination with Kisqali (ribociclib)
- The patient has not received prior endocrine based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, exemestane) **OR** patient has experienced disease progression on endocrine therapy

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FULVESTRANT (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **FULVESTRANT (Faslodex)** requires a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, HR-positive advanced breast cancer or HR-positive, HER2-negative advanced or metastatic breast cancer. In addition, the following criteria must be met:

For the diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, approval requires:

- The patient is female and postmenopausal
- The patient has not previously been treated with endocrine therapy
- The requested medication will be used as monotherapy

For the diagnosis of hormone receptor (HR)-positive advanced breast cancer, approval requires:

- The patient is female and postmenopausal
- The patient has experienced disease progression following endocrine therapy
- The requested medication will be used as monotherapy

For the diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, approval requires ONE of the following:

- The requested medication will be used concurrently with Ibrance (palbociclib) or Verzenio (abemaciclib) and meet ALL of the following:
 - The patient is female
 - The patient has experienced disease progression following endocrine therapy
- The requested medication will be used in combination with Kisqali (ribociclib) and meet ALL of the following:
 - The patient is female and postmenopausal
 - The patient has not received prior endocrine based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, exemestane) **OR** patient has experienced disease progression on endocrine therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

RATIONALE

To ensure appropriate usage Faslodex (fulvestrant) based on FDA approved indications.

FDA APPROVED INDICATIONS

Faslodex is an estrogen receptor antagonist indicated for:

- Treatment of hormone receptor (HR)-positive, human epidermal growth receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
- Treatment of HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
- Treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy.
- Treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with ribociclib in postmenopausal women not previously treated with endocrine therapy or with disease progression after endocrine therapy.

DOSAGE AND ADMINISTRATION

The recommended monotherapy dose of FASLODEX and when used in combination with palbociclib, abemaciclib, or ribociclib is 500 mg to be administered intramuscularly into the buttocks (gluteal area) slowly (1 - 2 minutes per injection) as two 5 mL injections, one in each buttock, on days 1, 15, 29 and once monthly thereafter.

When Faslodex is used in combination with palbociclib, the recommended dose of palbociclib is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. Palbociclib should be taken with food. Please refer to the full prescribing information of palbociclib.

When Faslodex is used in combination with abemaciclib, the recommended dose of abemaciclib is 150 mg orally, twice daily. Abemaciclib may be taken with or without food. Please refer to the Full Prescribing Information for abemaciclib.

When Faslodex is used in combination with ribociclib, the recommended dose of ribociclib is 600mg (three 200mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days.

Pre/perimenopausal women treated with the combination Faslodex plus palbociclib or abemaciclib should be treated with luteinizing hormone-releasing hormone (LHRH) agonists according to current clinical practice standards.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

A dose of 250 mg is recommended for patients with moderate hepatic impairment (Child-Pugh class B) to be administered intramuscularly into the buttock (gluteal area) slowly (1 - 2 minutes) as one 5 mL injection on days 1, 15, 29 and once monthly thereafter.

For complete administration instructions, please see full prescribing information of Faslodex, Ibrance, Verzenio and Kisqali.

REFERENCES

- Faslodex [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/13

Client Approval: 09/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEMTUZUMAB OZOGAMICIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
GEMTUZUMAB OZOGAMICIN	MYLOTARG	21218		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed CD33-positive acute myeloid leukemia (AML) and meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory CD33-positive acute myeloid leukemia (AML) and meet the following criterion?

- The patient is 2 years of age or older

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **GEMTUZUMAB OZOGAMICIN (Mylotarg)** requires that **ONE** of the following criteria be met:

- The patient has a diagnosis of newly-diagnosed CD33-positive acute myeloid leukemia (AML) and is 18 years of age or older.
- The patient has a diagnosis of relapsed or refractory CD33-positive acute myeloid leukemia (AML) and is 2 years of age or older.

RATIONALE

Promote appropriate utilization of GEMTUZUMAB OZOGAMICIN based on FDA approved indications.

FDA APPROVED INDICATIONS

MYLOTARG is a CD33-directed antibody-drug conjugate indicated for:

- Treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults
- Treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEMTUZUMAB OZOGAMICIN (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Newly-diagnosed, de novo AML (combination regimen):

- *Induction:* 3 mg/m² (up to one 4.5 mg vial) on Days 1, 4, and 7 in combination with daunorubicin and cytarabine
 - For patients requiring a second induction cycle, do NOT administer MYLOTARG during the second induction cycle
- *Consolidation:* 3 mg/m² on Day 1 (up to one 4.5 mg vial) in combination with daunorubicin and cytarabine.

Newly-diagnosed AML (single-agent regimen):

- *Induction:* 6 mg/m² on Day 1 and 3 mg/m² on Day 8
- *Continuation:* For patients without evidence of disease progression following induction, up to 8 continuation courses of MYLOTARG 2 mg/m² on Day 1 every 4 weeks.

Relapsed or refractory AML (single-agent regimen):

- 3 mg/m² (up to one 4.5 mg vial) on Days 1, 4, and 7.

Patients should be pre-medicated with a corticosteroid, antihistamine, and acetaminophen 1 hour prior to MYLOTARG. Patients should be monitored during and for at least 1 hour after the end of the infusion.

AVAILABLE STRENGTHS

MYLOTARG (gemtuzumab ozogamicin) for injection is a white to off-white lyophilized cake or powder supplied in a carton containing one 4.5 mg single-dose vial for reconstitution and further dilution.

REFERENCES

- Mylotarg [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc. September 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 09/17

Client Approval: 12/17

P&T Approval: 10/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - IV (NSA)

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB - IV	SIMPONI ARIA - IV		34983	

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) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is concurrently using or has a contraindication to methotrexate
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel Humira, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID for Simponi Aria 50mg/4mL vials (GPID 34983).**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis (RA) requires concurrent use of methotrexate (unless contraindicated) and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID for Simponi Aria 50mg/4mL vials (GPID 34983).**

APPROVAL TEXT: Renewal for psoriatic arthritis (PsA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - IV (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID for Simponi Aria 50mg/4mL vials (GPID 34983).**

Approval Text: Renewal for ankylosing spondylitis (AS) requires that the patient has experienced or maintained an improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is concurrently using or has a contraindication to methotrexate
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz (IR/XR)

For the diagnosis of psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara

(Initial denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - IV (NSA)

INITIAL CRITERIA (CONTINUED)

For the diagnosis of ankylosing spondylitis (AS), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - The patient has experienced or maintained a 20% 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

If yes, **approve for 12 months by GPID with a duration of 2 months per fill.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID with a duration of 2 months per fill.**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
 - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months by GPID with a duration of 2 months per fill.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - IV (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient has experienced or maintained a 20% 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

For the diagnosis of psoriatic arthritis (PsA), approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis (AS), approval requires:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

RATIONALE

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

REFERENCES

- Simponi Aria [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. February 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/9

Created: 11/13

Client Approval: 03/19

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRIPTORELIN PAMOATE	TRIPTODUR, TRELSTAR		43603 15344 99764 15338 99763 28507 28506	
HISTRELIN ACETATE	SUPPRELIN LA, VANTAS		23768	
LEUPROLIDE ACETATE	LUPRON DEPOT-PED, LUPRON DEPOT, LUPANETA		84352 84350 84353 30357 30356 80254 84602 84598 84593 30083 34009 34034	
GOSERELIN ACETATE	ZOLADEX		84591 84590	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months for the requested agent and strength by GPID and override quantity limits.**

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

2. Is the request for Lupron Depot, Zoladex, Vantas, or Trelstar for a patient who has a diagnosis of advanced prostate cancer?

If yes, **approve for 12 months for the requested agent and strength with the following quantity limits:**

- Lupron Depot 7.5mg (GPID 84602): #1 syringe/kit per 28 days (every month).
- Lupron Depot 22.5mg (GPID 84593): #1 syringe/kit per 84 days (every 3 months).
- Lupron Depot 30mg (GPID 84598): #1 syringe/kit per 112 days (every 4 months).
- Lupron Depot 45mg (GPID 30083): #1 syringe/kit per 168 days (every 6 months).
- Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).
- Zoladex 10.8mg (GPID 84590): #1 implant per 84 days (every 3 months).
- Vantas 50mg (NDC 67979-0500-01): #1 kit per 12 months.
- Trelstar 3.75mg (GPID 15344; 99764): #1 Injection per 28 days (every month).
- Trelstar 11.25mg (GPID 15338; 99763): #1 Injection per 84 days (every 3 months).
- Trelstar 22.5mg (GPID 28507; 28506): #1 Injection per 168 days (every 6 months).

If no, continue to #3.

3. Is the request for Lupron Depot, Lupaneta, or Zoladex for a patient who has 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
 - The requested medication is prescribed by or in consultation with an obstetrician/gynecologist
 - The patient had a previous 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)

If yes, **approve for 6 months for the requested agent and strength with the following quantity limits:**

- Lupron Depot 3.75mg (GPID 80254): #1 syringe/kit per 28 days (every month).
- Lupron Depot 11.25mg (GPID 84350): #1 syringe/kit per 84 days (every 3 months).
- Lupaneta 3.75mg (GPID 34034): #1 syringe/kit per 28 days (every month).
- Lupaneta 11.25mg (GPID 34009): #1 syringe/kit per 84 days (every 3 months).
- Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

4. Is the request for Triptodur, Supprelin LA, or Lupron Depot-Ped for a female patient who has a diagnosis of central precocious puberty (CPP) **AND** meets **ALL** of the following criteria?
- The patient is at least 2 years of age
 - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist
 - 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/L) at diagnosis
 - Patient is younger than 8 years of age at the onset of CPP
 - Documentation of 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 for the requested agent and strength with the following quantity limits:**

- **Triptodur 22.5mg (GPID 43603): #1 vial/kit (22.5mg triptorelin pamoate) per 24 weeks.**
- **Supprelin LA 50mg (NDC 67979-0002-01): #1 implant/kit (50mg histrelin) per 52 weeks.**
- **Lupron Depot-Ped 1-months kits:**
 - **Lupron Depot-Ped 7.5mg (GPID 84352): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 11.25mg 1-month (GPID 84350): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 15mg (GPID 84353): #1 syringe/kit per 30 days.**
- **Lupron Depot-Ped 3-months kits:**
 - **Lupron Depot-Ped 11.25mg 3-month (GPID 30357): #1 syringe/kit per 90 days.**
 - **Lupron Depot-Ped 30mg (GPID 30356): #1 syringe/kit per 90 days.**

APPROVAL TEXT: Renewal requires physician attestation that Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

5. Is the request for Triptodur, Supprelin LA, or Lupron Depot-Ped for a male patient who has a diagnosis of central precocious puberty (CPP) **AND** meets **ALL** of the following criteria?

- The patient is at least 2 years of age
- The requested medication is prescribed by or given in consultation with a pediatric endocrinologist
- 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/L) at diagnosis
- Patient is younger than 9 years of age at the onset of CPP
- Documentation of 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 for the requested agent and strength with the following quantity limits:**

- **Triptodur 22.5mg (GPID 43603): #1 vial/kit (22.5mg triptorelin pamoate) per 24 weeks.**
- **Supprelin LA 50mg (NDC 67979-0002-01): #1 implant/kit (50mg histrelin) per 52 weeks.**
- **Lupron Depot-Ped 1-months kits:**
 - **Lupron Depot-Ped 7.5mg (GPID 84352): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 11.25mg 1-month (GPID 84350): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 15mg (GPID 84353): #1 syringe/kit per 30 days.**
- **Lupron Depot-Ped 3-months kits:**
 - **Lupron Depot-Ped 11.25mg 3-month (GPID 30357): #1 syringe/kit per 90 days.**
 - **Lupron Depot-Ped 30mg (GPID 30356): #1 syringe/kit per 90 days.**

APPROVAL TEXT: Renewal requires physician attestation that Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

If no, continue to #6.

6. Is the request for Zoladex to be used as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding?

If yes, **approve for 12 months with the following quantity limit:**

- **Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).**

If no, continue to #7.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

7. Is the request for Zoladex to be used in the palliative treatment of advanced breast cancer **AND** does the patient meet the following criterion?

- The patient is a premenopausal or perimenopausal female

If yes, **approve for 12 months with the following quantity limits:**

- **Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).**

If no, continue to #8.

8. Is the request for Zoladex **AND** the medication will be used in combination with flutamide for the management of locally confined carcinoma of the prostate?

If yes, **approve for 4 months for the requested agent and strength with the following quantity limits:**

- **Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).**
- **Zoladex 10.8mg (GPID 84590): #1 implant (one time fill).**

If no, continue to #9.

9. Is the request for Lupron Depot to be used concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids)?

If yes, **approve by GPID for the requested strength with the following quantity limits and approval durations:**

- **Lupron Depot 3.75mg (GPID 80254): #1 syringe/kit per 28 days (every month) for 3 months.**
- **Lupron Depot 11.25mg (GPID 84350): one fill of #1 syringe/kit.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST** requires that the patient has gender dysphoria or a diagnosis of advanced prostate cancer, moderate to severe pain associated with endometriosis, or central precocious puberty (CPP). Additionally, Zoladex may be used as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, in the palliative treatment of advanced breast cancer in pre- and perimenopausal women, or in combination with flutamide for the management of locally confined carcinoma of the prostate; Lupron Depot may be used concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids). In addition, the following criteria must also be met for the requested diagnosis:

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

Patients diagnosed with moderate to severe pain associated with endometriosis, approval requires:

- The request is for one of the following agents: Lupron Depot, Lupaneta, or Zoladex
- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an obstetrician/gynecologist
- The patient had a previous 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)

Female patients diagnosed with CPP, approval requires:

- The request is for one of the following agents: Triptodur, Supprelin LA, or Lupron Depot-Ped
- The patient is at least 2 years of age
- The requested medication is prescribed by or given in consultation with a pediatric endocrinologist
- 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/L) at diagnosis
- Patient is younger than 8 years of age at the onset of CPP
- Documentation of pubertal staging using the Tanner scale for:
 - Breast development (stage 2 or above) **AND**
 - Pubic hair growth (stage 2 or above)

Male patients diagnosed with CPP, approval requires:

- The request is for one of the following agents: Triptodur, Supprelin LA, or Lupron Depot-Ped
- The patient is at least 2 years of age
- The requested medication is prescribed by or given in consultation with a pediatric endocrinologist
- 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/L) at diagnosis
- Patient is younger than 9 years of age at the onset of CPP
- Documentation of pubertal staging using the Tanner scale for:
 - Genital development (stage 2 or above) **AND**
 - Pubic hair growth (stage 2 or above)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

Requests for Zoladex to be used in the palliative treatment of advanced breast cancer, approval requires:

- The patient is a premenopausal or perimenopausal female

Requests for Lupron Depot, Zoladex, Vantas, or Trelstar for patients with advanced prostate cancer will be approved without requiring additional criteria.

Requests for patients with gender dysphoria will be approved without requiring additional criteria.

Requests for Zoladex to be used as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding or in combination with flutamide for the management of locally confined carcinoma of the prostate will be approved without requiring additional criteria.

Requests for Lupron Depot to be used concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids) will be approved without requiring additional criteria.

RENEWAL CRITERIA

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months for the requested agent and strength by GPID.**

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Is the request for Lupron Depot, Zoladex, Vantas, or Trelstar for a patient who has a diagnosis of advanced prostate cancer?

If yes, approve for 12 months for the requested agent and strength with the following quantity limits:

- Lupron Depot 7.5mg (GPID 84602): #1 syringe/kit per 28 days (every month).
- Lupron Depot 22.5mg (GPID 84593): #1 syringe/kit per 84 days (every 3 months).
- Lupron Depot 30mg (GPID 84598): #1 syringe/kit per 112 days (every 4 months).
- Lupron Depot 45mg (GPID 30083): #1 syringe/kit per 168 days (every 6 months).
- Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).
- Zoladex 10.8mg (GPID 84590): #1 implant per 84 days (every 3 months).
- Vantas 50mg (NDC 67979-0500-01): #1 kit per 12 months.
- Trelstar 3.75mg (GPID 15344; 99764): #1 Injection per 28 days (every month).
- Trelstar 11.25mg (GPID 15338; 99763): #1 Injection per 84 days (every 3 months).
- Trelstar 22.5mg (GPID 28507; 28506): #1 Injection per 168 days (every 6 months).

If no, continue to #3.

3. Is the request for Lupron Depot, Lupaneta, or Zoladex for a patient who has a diagnosis of moderate to severe pain associated with endometriosis **AND** meet **ALL** of the following criteria?
- Physician attestation of improvement of pain related to endometriosis while on therapy
 - The patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
 - The patient has **NOT** received a total course of therapy exceeding 12 months

If yes, approve for 6 months for the requested agent and strength with the following quantity limits:

- Lupron Depot 3.75mg (GPID 80254): #1 syringe/kit per 28 days (every month).
- Lupron Depot 11.25mg (GPID 84350): #1 syringe/kit per 84 days (every 3 months).
- Lupaneta 3.75mg (GPID 34034): #1 syringe/kit per 28 days (every month).
- Lupaneta 11.25mg (GPID 34009): #1 syringe/kit per 84 days (every 3 months).
- Zoladex 3.6mg (GPID 84591): #1 implant per 28 days (every month).

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

RENEWAL CRITERIA (CONTINUED)

4. Is the request for Triptodur, Supprelin LA, or Lupron-Depot Ped for a patient who has a diagnosis of central precocious puberty (CPP) **AND** meet **ALL** of the following criteria?
- Physician attestation for **ALL** of the following:
 - Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
 - Patient has not reached actual age which corresponds to current pubertal age

If yes, approve for 12 months for the requested agent and strength with the following quantity limits:

- Triptodur 22.5mg (GPID 43603): #1 vial/kit (22.5mg triptorelin pamoate) per 24 weeks.
- Supprelin LA 50mg (NDC 67979-0002-01): #1 implant/kit (50mg histrelin) per 52 weeks.
- Lupron Depot-Ped 1-months kits:
 - Lupron Depot-Ped 7.5mg (GPID 84352): #1 syringe/kit per 30 days.
 - Lupron Depot-Ped 11.25mg 1-month (GPID 84350): #1 syringe/kit per 30 days.
 - Lupron Depot-Ped 15mg (GPID 84353): #1 syringe/kit per 30 days.
- Lupron Depot-Ped 3-months kits:
 - Lupron Depot-Ped 11.25mg 3-month (GPID 30357): #1 syringe/kit per 90 days.
 - Lupron Depot-Ped 30mg (GPID 30356): #1 syringe/kit per 90 days.

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST** requires that the patient has gender dysphoria or a diagnosis of advanced prostate cancer, moderate to severe pain associated with endometriosis, or central precocious puberty (CPP). In addition, the following criteria must also be met for the requested diagnosis:

Diagnosis of moderate to severe pain associated with endometriosis, approval requires:

- The request is for one of the following agents: Lupron Depot, Lupaneta, or Zoladex
- Physician attestation of improvement of pain related to endometriosis while on therapy
- The patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
- The patient has **NOT** received a total course of therapy exceeding 12 months
(Renewal denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

RENEWAL CRITERIA (CONTINUED)

Diagnosis of CPP, approval requires:

- The request is for one of the following agents: Triptodur, Supprelin LA, or Lupron Depot-Ped with physician attestation of all of the following:
 - Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
 - Patient has not reached actual age which corresponds to current pubertal age

Requests for Lupron Depot, Zoladex, Vantas, or Trelstar for patients with advanced prostate cancer will be approved without requiring additional criteria.

Requests for patients with gender dysphoria will be approved without requiring additional criteria.

RATIONALE

Promote appropriate utilization of **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST** (Triptodur, Trelstar, Lupaneta, Lupron Depot, Supprelin LA, Lupron Depot-Ped, Zoladex, and Vantas) based on FDA approved indications and dosing and NCCN recommendations.

NCCN guidelines recommend premenopausal patients with hormone-positive disease have ovarian ablation/suppression (with goserelin) and be treated as a postmenopausal woman.

FDA APPROVED INDICATIONS

Triptodur is a GnRH agonist indicated for the treatment of pediatric patients 2 years and older with central precocious puberty (CPP).

Trelstar is a GnRH agonist indicated for the palliative treatment of advanced prostate cancer.

Supprelin LA is a GnRH agonist indicated for the treatment of children with central precocious puberty.

Vantas is a GNRH agonist indicated for the palliative treatment of advanced prostate cancer.

Lupron Depot-Ped is a GnRH agonist indicated for the treatment of children with central precocious puberty.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Lupron Depot is a GnRH agonist indicated for:

- Palliative treatment of advanced prostatic cancer
- Management of endometriosis, including pain relief and reduction of endometriotic lesions
- Concomitant use with iron therapy for preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids)

Lupaneta is indicated in combination with norethindrone acetate for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Zoladex is a GnRH agonist indicated for:

- Use in combination with flutamide for the management of locally confined carcinoma of the prostate
- Palliative treatment of advanced carcinoma of the prostate
- The management of endometriosis
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding
- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women

DOSAGE AND ADMINISTRATION

Triptodur

Triptodur must be administered under the supervision of a physician.

The dosage of Triptodur is 22.5 mg reconstituted with accompanying diluent (Sterile Water) 2 mL, and administered as a single intramuscular injection once every 24 weeks. Triptodur treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician.

Trelstar

Trelstar must be administered under the supervision of a physician.

Trelstar is administered as a single intramuscular injection in either buttock. The recommended dose is 3.75 mg every 4 weeks, 11.25 mg every 12 weeks, and 22.5 mg every 24 weeks.

Supprelin LA

Supprelin LA must be administered under the supervision of a physician.

The recommended dose of Supprelin LA is one implant every 12 months. The implant is inserted subcutaneously in the inner aspect of the upper arm and provides continuous release of histrelin for 12 months of hormonal therapy.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

At the time an implant is removed, another implant may be inserted to continue therapy. Discontinuation of Supprelin LA should be considered at the discretion of the physician and at the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males).

Vantas

Vantas must be administered under the supervision of a physician.

The recommended dose of Vantas is one implant (50 mg) every 12 months. The implant is inserted subcutaneously in the inner aspect of the upper arm.

Lupron Depot- Ped

Lupron Depot- Ped must be administered under the supervision of a physician.

1-month administration (7.5 mg, 11.25 mg, or 15 mg)

- The starting dose 7.5 mg, 11.25 mg, or 15 mg for 1-month administration is based on the child's weight, as below:

Dosing Recommendations Based on Body Weight for Lupron Depot- Ped 1- month Formulations	
Body Weight	Recommended Dose
≤ 25 kg	7.5 mg
> 25-37.5 kg	11.25 mg
> 37.5 kg	15 mg

The dose of Lupron Depot-Ped must be individualized for each child. If adequate hormonal and clinical suppression is not achieved with the starting dose, it should be increased to the next available higher dose (e.g. 11.25 mg or 15 mg at the next monthly injection). Similarly, the dose may be adjusted with changes in body weight.

3-month administration (11.25 mg or 30 mg)

Lupron Depot- Ped 11.25 mg or 30 mg for 3-month administration should be administered once every three months (12 weeks) as a single intramuscular injection.

Each Lupron Depot- Ped 11.25 mg or 30 mg for 3-month administration strength and formulation has different release characteristics. Do not use partial syringes or a combination of syringes to achieve a particular dose. Lupron Depot- Ped 11.25 mg or 30 mg for 3-month administration treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Lupron Depot

Lupron Depot must be administered under the supervision of a physician.

Lupron Depot is administered as a single intramuscular injection in the gluteal area, anterior thigh, or deltoid. For the treatment of advanced prostate cancer, the recommended dose is 7.5 mg every 4 weeks, 22.5 mg every 12 weeks, 30 mg every 16 weeks, and 45 mg every 24 weeks. For the treatment of endometriosis, Lupron Depot 3.75 mg is administered as a single intramuscular injection every month for up to six injections (6 months of therapy) OR 11.25 mg as a single intramuscular injection every 3 months for up to two injections (6 months of therapy). For concomitant use with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids), Lupron Depot 3.75 mg is administered as a single intramuscular injection every month for up to 3 months OR 11.25 mg as a single intramuscular injection.

Lupaneta

Lupaneta Pack consists of Lupron Depot and norethindrone acetate tablets.

Lupron Depot must be administered under the supervision of a physician.

For the treatment of endometriosis, Lupron Depot 3.75 mg is administered as a single intramuscular injection every month for up to six injections (6 months of therapy) OR 11.25 mg as a single intramuscular injection every 3 months for up to two injections (6 months of therapy). Norethindrone acetate 5 mg tablets taken orally once daily for up to 6 months. Duration of initial treatment or retreatment should be limited to 6 months.

Zoladex

Zoladex must be administered under the supervision of a physician.

Zoladex 3.6mg implant is dosed every 28 days.

Zoladex 10.8mg implant should be administered subcutaneously every 12 weeks.

For patients with Stage T2b-T4 (Stage B2-C) prostatic carcinoma, treatment should be started 8 weeks prior to initiating radiotherapy and should continue during radiation therapy. A treatment regimen using Zoladex 3.6 mg depot 8 weeks before radiotherapy, followed in 28 days by Zoladex 10.8 mg depot, can be administered. Alternatively, four injections of 3.6 mg depot can be administered at 28-day intervals, two depots preceding and two during radiotherapy.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

REFERENCES

- Triptodur [Prescribing Information]. Arbor Pharmaceuticals, LLC. Atlanta, GA. June 2017.
- Supprelin LA [Prescribing Information]. Endo Pharmaceuticals. Malvern, PA. May 2017.
- Lupron Depot-Ped [Prescribing Information]. AbbVie Inc. North Chicago, IL. May 2017.
- National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer. (Version 1.2018).

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 03/18

Client Approval: 09/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYALURONATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
HYALURONATE SODIUM	EUFLEXXA, HYALGAN, GEL-ONE, GELSYN-3, ORTHOVISC, SUPARTZ FX, GENVISC 850, VISCO-3, TRIVISC		21448 32121 32122 41795	ROUTE = INTRAARTIC
HYLAN G-F 20	SYNVISC, SYNVISC-ONE	26552		
HYALURONATE SODIUM, STABILIZED	MONOVISC, DUROLANE		36397 33139	
HYALURONATE, MODIFIED, NON-CROSSLINK	HYMOVIS	42225		

GUIDELINES FOR USE

1. Has the patient received previous treatment on the same knee with Synvisc, Synvisc-One, Hyalgan, Euflexxa, Supartz FX, Gel-One, Monovisc, Orthovisc, Hymovis, Gelsyn-3, Genvisc 850, Visco-3, Trivisc, OR Durolane?

If yes, continue to #3.

If no, continue to #2.

2. Does the patient have a diagnosis of osteoarthritis of the knee and meets **ALL** of the following criteria?
 - The patient is at least 21 years of age
 - The patient has failed a minimum of a 6-week trial of non-pharmacologic therapy such as education, exercise, use of insoles or braces, weight reduction and physical therapy
 - The patient had a previous trial of intra-articular steroids

If yes, **approve for 6 months by GPID with the following quantity limits per affected knee:**

- **Euflexxa - 6mL (3 syringes)**
- **Gel-One - 3mL (1 syringe)**
- **Gelsyn-3 - 6mL (3 syringes)**
- **Hyalgan - 10mL (5 syringes/vials)**

(Approval directions continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYALURONATE (NSA)

GUIDELINES FOR USE (CONTINUED)

- Hymovis - 6mL (2 syringes)
- Monovisc - 4mL (1 syringe)
- Orthovisc - 8mL (4 syringes)
- Supartz FX - 12.5mL (5 syringes)
- Synvisc - 6mL (3 syringes)
- Synvisc-One - 6mL (one syringe)
- Genvisc 850 - 12.5mL (5 syringes)
- Visco-3 - 7.5mL (3 syringes)
- Trivisc – 7.5mL (3 syringes)
- Durolane - 3mL (one syringe)

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has it been at least 6 months since the last treatment with this agent?

If yes, approve for 6 months by GPID with the following quantity limits per affected knee:

- Euflexxa - 6mL (3 syringes)
- Gel-One - 3mL (1 syringe)
- Gelsyn-3 - 6mL (3 syringes)
- Hyalgan - 10mL (5 syringes/vials)
- Hymovis - 6mL (2 syringes)
- Monovisc - 4mL (1 syringe)
- Orthovisc - 8mL (4 syringes)
- Supartz FX - 12.5mL (5 syringes)
- Synvisc - 6mL (3 syringes)
- Synvisc-One - 6mL (one syringe)
- Genvisc 850 - 12.5mL (5 syringes)
- Visco-3 - 7.5mL (3 syringes)
- Trivisc – 7.5mL (3 syringes)
- Durolane - 3mL (one syringe)

If no, do not approve:

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYALURONATE (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **HYALURONATE** requires a diagnosis of osteoarthritis of the knee. In addition, the following criteria must also be met:

- The patient is at least 21 years of age
- The patient failed a minimum of a 6-week trial of non-pharmacologic therapy such as education, exercise, use of insoles or braces, weight reduction and physical therapy
- The patient had a previous trial of intra-articular steroids

For patients who have been previously treated on the same knee with Synvisc, Synvisc-One, Hyalgan, Euflexxa, Supartz FX, Gel-One, Monovisc, Orthovisc, Hymovis, Gelsyn-3, Genvisc 850, Visco-3, Trivisc, or Durolane, approval requires:

- At least 6 months since the last treatment has been received

RATIONALE

Ensure appropriate use of hyaluronic acids in the treatment of osteoarthritis.

FDA APPROVED INDICATIONS

Durolane, Synvisc, Synvisc-One, Hyalgan, Supartz FX, Euflexxa, Gel-One, Gelsyn-3, Orthovisc, Monovisc, Hymovis, Genvisc 850, Visco-3, and Trivisc are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen.

REFERENCES

- Genzyme Corporation. Synvisc product Information. Ridgefield, NJ, March 2010.
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- Fidia Farmaceutici. Hyalgan product Information. Padua, Italy, Jan 2009.
- Seikagaku Corporation. Supartz product Information. Tokyo, Japan. January 2007.
- Anika Therapeutics Inc. Orthovisc Product information. Woburn, MA. June 2006.
- FDA Approves Monovisc, A New Single Injection Treatment for Treatment of Pain Due to Osteoarthritis of the Knee. Accessed on 4/15/2014 at <http://www.businesswire.com/news/home/20140225007021/en/FDA-Approves-MONOVISC%C2%AE-Single-Injection-Treatment-Treatment>
- Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: <http://www.thomsonhc.com/hcs/librarian/>. [Accessed: June 22, 2010].
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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYALURONATE (NSA)

REFERENCES (CONTINUED)

- Pagnano M, Westrich G. Successful non-operative management of chronic osteoarthritis pain of the knee: safety and efficacy of retreatment with intra-articular hyaluronans. *Osteoarthritis Cartilage*. 2005; 13(9):751-61.
- Ferring Pharmaceuticals. Euflexxa product information. Parsippany, NJ. (Revision 9, no date available).
- Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee. *Arthritis and Rheumatism* 2000; 43:905-1915.
- Fidia Pharma. Hymovis product information. Parsippany, NJ. (No date available).
- Zimmer Inc. Gel-one product information. Warsaw, IN. May 20, 2011. Institut Biochimique SA (IBSA). Gelsyn-3 product information. Pambio-Noranco, Switzerland. 2016.
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- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2009. Available at: <http://www.clinicalpharmacology.com>. Accessed November 13, 2017.
- Durolane Brochure. Available at: http://durolane.com/wp-content/uploads/2016/02/DUROLANE_MDbrochure_UK.pdf. Accessed November 13, 2017.
- Durolane Patient Information. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170007C.pdf. Accessed November 13, 2017.
- Genvisc 850 Prescribing Information Information. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140005d.pdf. Accessed March 15, 2018.
- Visco-3 Prescribing Information. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf/P980044S027d.pdf. Accessed March 15, 2018
- Trivisc Prescribing Information. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160057D.pdf. Accessed October 15, 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/01/18

Created: 05/14

Client Approval: 10/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROXYPROGESTERONE CAPROATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
HYDROXYPROGESTERONE CAPROATE	MAKENA		39946 40784 44459	
HYDROXYPROGESTERONE CAPROATE	HYDROXY- PROGESTERONE CAPROATE (GENERIC FOR DELALUTIN)		11180	

GUIDELINES FOR USE

1. Is the request for Makena?

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

2. Is the request for the reduction of risk of preterm birth in women with a history of singleton spontaneous preterm birth and meets **ALL** of the following criteria?

- The patient does **NOT** have multiple gestations (twins, triplets, etc.)
- The patient has a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes
- The patient is at least 16 weeks pregnant but less than 37 weeks pregnant

If yes, **approve Makena for 6 months by GPID with a fill count of 5 and the following quantity limits:**

- **Makena 1,250mg/5mL (GPID 39946): #5mL per 28 days.**
- **Makena 250mg/mL (GPID 40784): #4mL per 28 days.**
- **Makena 275mg/1.1mL autoinjector (GPID 44459): #4.4mL per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **HYDROXYPROGESTERONE CAPROATE (Makena)** requires that the agent will be used for the reduction of risk of preterm birth in women with a history of singleton spontaneous preterm birth. The following criteria must also be met.

- The patient does **NOT** have multiple gestations (twins, triplets, etc.).
- The patient is at least 16 weeks pregnant but less than 37 weeks pregnant with a single gestation.
- The patient has a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROXYPROGESTERONE CAPROATE (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for use in a non-pregnant female who meets **ONE** of the following criteria?
- For treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV)
 - For the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer
 - As a test for endogenous estrogen production
 - For the production of secretory endometrium and desquamation

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: The guideline named **HYDROXYPROGESTERONE CAPROATE (Generic Delalutin)** requires use in non-pregnant females for **ONE** of the following:

- For treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV)
- For the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer
- As a test for endogenous estrogen production
- For the production of secretory endometrium and desquamation

RATIONALE

Ensure appropriate use of Makena consistent with its FDA approved indication. Ensure appropriate use of hydroxyprogesterone caproate with its FDA approved indication.

FDA APPROVED INDICATIONS

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy that have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

HYDROXYPROGESTERONE CAPROATE (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Hydroxyprogesterone caproate (generic for Delalutin) is indicated in non-pregnant women:

- For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV).
- In the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.
- As a test for endogenous estrogen production
- For the production of secretory endometrium and desquamation.

**DOSAGE AND ADMINISTRATION
MAKENA**

- Makena auto-injector: Administer subcutaneously using Makena auto-injector at a dose of 275 mg (1.1 mL) once weekly, in the back of either upper arm by a healthcare provider
- Makena (single- and multi-dose vials): Administer intramuscularly at a dose of 250 mg (1 mL) once weekly in the upper outer quadrant of the gluteus maximus by a healthcare provider
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation
- Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

Hydroxyprogesterone caproate (generic for Delalutin)

- Treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV)
 - Dosage: 1-7 grams IM per week until relapse occurs or after 12 weeks with no objective response
- Amenorrhea (primary or secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology
 - Dosage: 375mg IM x 1. Then begin cyclic therapy schedule after 4 days of desquamation or, if there is no bleeding, 21 days after initial injection. Discontinue after 4 cycles
- Test for endogenous estrogen production
 - Dosage: 250mg IM once and repeated once for confirmation, 4 weeks after first injection
- Production of secretory endometrium and desquamation
 - Patients not on estrogen therapy – utilize cyclic therapy schedule.
 - Patients currently on estrogen therapy
- Dosage: 375mg IM x 1. Then begin cyclic therapy schedule after 4 days of desquamation or, if there is no bleeding, 21 days after initial injection
- Cyclic therapy schedule
 - 28-day cycle; repeated every four weeks
 - Day 1 of each cycle: 20mg of estradiol valerate injection USP
 - Day 14 of each cycle: 250mg IM of hydroxyprogesterone caproate and 5mg estradiol valerate injection USP

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

HYDROXYPROGESTERONE CAPROATE (NSA)

REFERENCES

- Makena [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc. February 2018.
- Hydroxyprogesterone caproate [Prescribing Information]. Santa Ana, CA: McGuff Pharmaceuticals, Inc. August 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 05/11

Client Approval: 03/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

Generic	Brand	HICL	GCN	Exception/Other
IMMUNE GLOBULIN	BIVIGAM, CARIMUNE NF NANOFILTRE, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	04202 41798		
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED	25631		
IMMUNE GLOBULIN / MALTOSE	OCTAGAM	33220		
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA	41391		
IMMUN GLOB G(IGG)/GLY/IGA 0-50	HYQVIA IG COMPONENT	41995		
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU	41796		
IMMUN GLOB G(IGG)- IFAS/GLYCINE	PANZYGA	45354		

This drug must be reviewed by a pharmacist.

GUIDELINES FOR USE

1. Is the request for use as a subcutaneous injection?

If yes, continue to #2.

If no, continue to #5.

2. Is the request for Hizentra and will be used for **ONE** of the following diagnoses?

- Primary immunodeficiency disease (PID)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

3. Is the request for Gammagard Liquid, Cuvitru, Gamunex-C, Gammaked, or Hyqvia (**NOTE:** Gammagard, Gamunex-C and Gammaked may be given via SC or IV route.)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a primary immunodeficiency disease (PID)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for a non-self-administered agent?

If yes, continue to #6.

If no, guideline does not apply.

6. Does the plan cover non-self-administered agents?

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 Cuvitru, Hizentra, or Hyqvia (**NOTE:** Cuvitru, Hizentra, and Hyqvia are indicated only for SC route)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #8.

8. Is the requested medication Gamastan S/D (**NOTE:** Gamastan S/D is indicated for intramuscular use only)?

If yes, continue to #9.

If no, continue to #10.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

9. Is Gamastan S/D being used for hepatitis A, measles, varicella, or rubella prophylaxis, or passive immunization?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

10. Does the patient have **ONE** of the following diagnoses?

- Primary Immunodeficiency Disease (PID)
- Idiopathic Thrombocytopenic Purpura (ITP)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Multifocal Motor Neuropathy (MMN)
- Kawasaki Syndrome
- B-cell Chronic Lymphocytic Leukemia (CLL) with Hypogammaglobulinemia, Autoimmune Hemolytic Anemia (AIHA), Immune Thrombocytopenic Purpura (ITP), or pure Red Blood Cell Aplasia (PRCA)
- Guillain-Barre Syndrome (GBS)
- Myasthenia Gravis
- Autoimmune Graves' Ophthalmopathy
- Cytomegalovirus-induced Pneumonitis 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
- Autoimmune uveitis (Birdshot retinochoroidopathy)
- Lambert-Eaton myasthenic syndrome
- IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Stiff-man syndrome
- Neonatal sepsis
- Rotaviral enterocolitis
- Toxic shock syndrome
- Enteroviral meningoencephalitis
- Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
- Autoimmune Mucocutaneous Blistering Disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **IMMUNE GLOBULIN** requires that the patient has **ONE** of the following diagnoses:

- Primary Immunodeficiency Disease (PID)
- Idiopathic Thrombocytopenic Purpura (ITP)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Multifocal Motor Neuropathy (MMN)
- Kawasaki Syndrome
- B-cell Chronic Lymphocytic Leukemia (CLL) with hypogammaglobulinemia, Autoimmune Hemolytic Anemia (AIHA), Immune Thrombocytopenic Purpura (ITP), or pure Red Cell Blood Aplasia (PRCA)
- Guillain-Barre Syndrome (GBS)
- Myasthenia Gravis
- Autoimmune Graves' Ophthalmopathy
- Cytomegalovirus-induced Pneumonitis 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
- Autoimmune uveitis (Birdshot retinochoroidopathy)
- Lambert-Eaton myasthenic syndrome
- IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Stiff-man syndrome
- Neonatal sepsis
- Rotaviral enterocolitis
- Toxic shock syndrome
- Enteroviral meningoencephalitis
- Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
- Autoimmune Mucocutaneous Blistering Disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

For prophylaxis or passive immunization of hepatitis A, measles, varicella, or rubella, only Gamastan S-D will be approved.

For requests of Hizentra, approval requires:

- Only for subcutaneous use
- Diagnosis of primary immunodeficiency disease (PID) OR chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

For requests of Cuvitru or Hyqvia, approval requires:

- Only for subcutaneous use
- Diagnosis of primary immunodeficiency disease (PID)

For requests for subcutaneous use of Gammagard, Gamunex-C, or Gammaked, approval requires:

- Diagnosis of primary immunodeficiency disease (PID)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IMMUNE GLOBULIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for the drugs listed in this guideline.

REFERENCES

- Bivigam [Prescribing Information]. Biotest Pharmaceuticals Co.: Boca Raton, FL. January 2017.
- Carimune NF [Prescribing Information]. CSL Behring LLC: Kankakee, IL. September 2013.
- Cuvitru [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. September 2016.
- Flebogamma 5% DIF [Prescribing Information]. Grifols: Barcelona, Spain. July 2017.
- Flebogamma 10% DIF [Prescribing Information]. Grifols: Barcelona, Spain. July 2017.
- Gamastan S/D [Prescribing Information]. Grifols: Research Triangle Park, NC. June 2017.
- Gammagard Liquid [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. March 2017.
- Gammagard S/D [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. March 2017.
- Gammaked [Prescribing Information]. Grifols: Research Triangle Park, NC. September 2016.
- Gammaplex 5% [Prescribing Information]. BPL Inc.: Durham, NC. December 2016.
- Gammaplex 10% [Prescribing Information]. BPL Inc.: Durham, NC. December 2016.
- Gamunex-C [Prescribing Information]. Grifols: Research Triangle Park, NC. March 2017.
- Hizentra [Prescribing Information]. CSL Behring LLC: Kankakee, IL. March 2018.
- Hyqvia [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. September 2016.
- Octagam 5% [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. April 2015.
- Octagam 10% [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. August 2015.
- Panzyga [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. August 2018.
- Privigen [Prescribing Information]. CSL Behring LLC: Kankakee, IL. September 2017.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 08/12

Client Approval: 03/19

P&T Approval: 01/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
INFLIXIMAB	REMICADE	18747		

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) 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 rheumatologist
 - The patient is currently using or has a contraindication to methotrexate
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz (IR/XR) **[NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]**

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara **[NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]**

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient is 18 years of age or older
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Cosentyx, Stelara, Otezla, Tremfya, Skyrizi [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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 patient 18 years of age or older **AND** meet the following criterion?

- The patient had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

If no, continue to #8.

8. Is the patient 6 to 17 years of age?

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **INFLIXIMAB (Remicade)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is currently using or has a contraindication to methotrexate
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz (IR/XR)

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara

For patients with ankylosing spondylitis (AS), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx

For patients with severe plaque psoriasis (PsO), approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient is 18 years of age or older
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Cosentyx, Stelara, Otezla, Tremfya, Skyrizi

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe Crohn's disease (CD), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara

For patients with moderate to severe ulcerative colitis (UC), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 to 17 years of age **OR** the patient is 18 years of age or older **AND** had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - The patient has experienced or maintained a 20% 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

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet the following criterion?
- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

If yes, **approve 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meet the following criterion?

- The patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **INFLIXIMAB (Remicade)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis, approval requires:

- The patient has experienced or maintained a 20% 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

For the diagnosis of psoriatic arthritis, approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis, approval requires:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

For the diagnosis of severe plaque psoriasis, approval requires:

- The patient has achieved or maintained clear or minimal disease **OR** that the patient has experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INFLIXIMAB (NSA)

RATIONALE

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

REFERENCES

- Remicade [Prescribing Information]. Janssen Biotech, Inc: Horsham, PA. October 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/03/19

Created: 02/03

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
INFLIXIMAB-ABDA	RENFLEXIS	44432		

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) 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 rheumatologist
 - The patient is currently using or has a contraindication to methotrexate
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz IR/XR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient is 18 years of age or older
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Cosentyx, Stelara, Otezla, Tremfya, Skyrizi [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #5.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meets **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **INFLIXIMAB-ABDA (Renflexis)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is currently using or has a contraindication to methotrexate
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz IR/XR

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara

For patients with ankylosing spondylitis (AS), approval requires all:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx

For patients with severe plaque psoriasis (PsO), approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient is 18 years of age or older
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Cosentyx, Stelara, Otezla, Tremfya, Skyrizi

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe Crohn's disease (CD), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara

For patients with moderate to severe ulcerative colitis (UC), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets **ALL** of the following criteria?
 - The patient has experienced or maintained a 20% 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

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) **AND** meet the following criterion?

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **INFLIXIMAB-ABDA (Renflexis)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis, approval requires:

- That the patient has experienced or maintained a 20% 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

For the diagnosis of psoriatic arthritis, approval requires:

- That the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis, approval requires:

- That the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

For the diagnosis of severe plaque psoriasis, approval requires:

- That the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INFLIXIMAB-ABDA (NSA)

RATIONALE

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

REFERENCES

- Renflexis [Prescribing Information]. Kenilworth, NJ: Merck & Co., Inc. April 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/03/19

Created: 07/17

Client Approval: 05/19

P&T Approval: 04/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INFLIXIMAB-DYYB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
INFLIXIMAB-DYYB	INFLECTRA	43249		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

- Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) 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 rheumatologist
 - The patient is currently using or has a contraindication to methotrexate therapy
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

- Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to at least **ONE** or more forms of systemic therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Cosentyx, Stelara, Otezla, Tremfya, Skyrizi [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal for severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to **ONE** or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to **ONE** or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **INFLIXIMAB-DYYB (Inflectra)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is currently using or has a contraindication to methotrexate therapy
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz (IR/XR)

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara

For patients with ankylosing spondylitis (AS), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx

For patients with severe plaque psoriasis (PsO), approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to at least **ONE** or more forms of systemic therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Cosentyx, Stelara, Otezla, Tremfya, Skyrizi

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe Crohn's disease (CD), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to ONE or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara

For patients with moderate to severe ulcerative colitis (UC), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to ONE or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet **ALL** of the following criteria?
 - The patient has experienced or maintained a 20% 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 therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) **AND** meet the following criterion?

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **INFLIXIMAB-DYYB (Inflectra)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis, approval requires:

- The patient has experienced or maintained a 20% 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 therapy

For the diagnosis of psoriatic arthritis, approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis, approval requires:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

For the diagnosis of severe plaque psoriasis, approval requires:

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INFLIXIMAB-DYYB (NSA)

RATIONALE

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

REFERENCES

- Inflectra [Prescribing Information]. Yeonsu-gu, Incheon, Republic of Korea: Celltrion, Inc. November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/03/19

Created: 05/16

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTUZUMAB OZOGAMICIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
INOTUZUMAB OZOGAMICIN	BESPONSA	44438		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and meet 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 received 6 cycles of Besponsa treatment previously?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 6 months by HICL.**

DENIAL TEXT: The guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following criteria be met:

- A diagnosis of relapsed or refractory B-cell pre-cursor acute lymphoblastic leukemia (ALL)
- The patient is 18 years of age or older
- The patient has **NOT** received 6 cycles of Besponsa previously

RATIONALE

Promote appropriate utilization of INOTUZUMAB OZOGAMICIN based on FDA approved indication.

FDA APPROVED INDICATION

BESPONSA is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia

DOSAGE AND ADMINISTRATION

Besponsa is infused for 1 hour at a rate of 50 mL/h at room temperature. Dosing is based on body surface area (m²) and response to preceding therapy:

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTUZUMAB OZOGAMICIN (NSA)

FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION

Dosing regimens for Cycle 1 and subsequent cycles, depending on the response to treatment:

- **For the first cycle:** the recommended total dose of Besponsa for all patients is 1.8 mg/m² per cycle, administered as 3 divided doses on Day 1 (0.8 mg/m²), Day 8 (0.5 mg/m²), and Day 15 (0.5 mg/m²). Cycle 1 is 3 weeks in duration, but may be extended to 4 weeks if the patient achieves a complete remission (CR) or complete remission with incomplete hematologic recovery (CRi), and/or to allow recovery from toxicity.
- **For subsequent cycles:** In patients who achieve a CR or CRi, the recommended total dose of Besponsa is 1.5 mg/m² per cycle, administered as 3 divided doses on Day 1 (0.5 mg/m²), Day 8 (0.5 mg/m²), and Day 15 (0.5 mg/m²). Subsequent cycles are 4 weeks in duration.
- **In patients who do not achieve a CR* or CRi**:**, the recommended total dose of Besponsa is 1.8 mg/m² per cycle given as 3 divided doses on Day 1 (0.8 mg/m²), Day 8 (0.5 mg/m²), and Day 15 (0.5 mg/m²). Subsequent cycles are 4 weeks in duration. Patients who do not achieve a CR or CRi within 3 cycles should discontinue treatment.

* **CR** is defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, full recovery of peripheral blood counts (platelets $\geq 100 \times 10^9/L$ and absolute neutrophil counts [ANC] $\geq 1 \times 10^9/L$) and resolution of any extramedullary disease.

** **CRi** is defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, incomplete recovery of peripheral blood counts (platelets $< 100 \times 10^9/L$ and/or ANC $< 1 \times 10^9/L$) and resolution of any extramedullary disease.

For patients proceeding to hematopoietic stem cell transplant (HSCT), the recommended duration of treatment with Besponsa is 2 cycles. A third cycle may be considered for those patients who do not achieve CR or CRi and minimal residual disease (MRD) negativity after 2 cycles.

For patients not proceeding to HSCT, additional cycles of treatment, up to a maximum of 6 cycles, may be administered.

Patients should be pre-medicated before each dose.

AVAILABLE STRENGTHS

Injection: supplied as a white to off-white lyophilized powder in a single-dose vial for reconstitution and further dilution. Each vial delivers 0.9 mg inotuzumab ozogamicin. Each carton contains one single-dose vial.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INOTUZUMAB OZOGAMICIN (NSA)

REFERENCES

- Besponsa [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc. August 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/17

Client Approval: 12/17

P&T Approval: 10/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IOBENGUANE IODINE 131 (NSA)

Generic	Brand	HICL	GCN	Exception/Other
IOBENGUANE I 131	AZEDRA	25483		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma and meet ALL of the following criteria?
 - The patient is 12 years of age or older
 - The patient requires systemic anticancer therapy
 - The tumors are iobenguane scan positive
 - The patient has **NOT** previously received 1 dosimetric dose and 2 therapeutic doses of Azedra

If yes, **approve by GPID for 12 months for all dosages with the following quantity limits:**

- **Azedra Dosimetric (GPID 45058): #1 vial per 12 months.**
- **Azedra Therapeutic (GPID 45059): #4 vials per 12 months.**

If no, do not approve.

DENIAL TEXT: The guideline named **IOBENGUANE IODINE 131 (Azedra)** requires a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma. In addition, the following criteria must be met:

- The patient is 12 years of age or older
- The patient requires systemic anticancer therapy
- The tumors are iobenguane scan positive
- The patient has **NOT** previously received 1 dosimetric dose and 2 therapeutic doses of Azedra

RATIONALE

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

REFERENCES

- Azedra [Prescribing Information]. New York, NY: Progenics Pharmaceuticals, Inc. Pharmaceuticals Corporation. July 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
IPILIMUMAB	YERVOY	37503		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of unresectable or metastatic melanoma **AND** meet the following criterion?

- The patient is 12 years of age or older

If yes, **approve and enter two authorizations for 4 months by GPID for 4 fills as follows:**

- **50mg/10mL (GPID 29688).**
- **200mg/40mL (GPID 29689).**

APPROVAL TEXT: Renewal criteria does not apply for this approval.

If no, continue to #2.

2. Does the patient have a diagnosis of cutaneous melanoma and meet **ALL** of the following criteria?

- The requested medication will be used for adjuvant treatment
- There is pathologic involvement of regional lymph nodes of more than 1mm
- The patient has undergone complete resection, including total lymphadenectomy

If yes, **approve and enter two authorizations (initial and maintenance dose) for 6 months for both GPIDs (GPIDs 29688, 29689) as follows:**

- **INITIAL: Approve and enter two authorizations for 4 fills in 3 months for all of the following GPIDs:**
 - **50mg/10mL (GPID 29688).**
 - **200mg/40mL (GPID 29689).**
- **MAINTENANCE (start 12 weeks after the end date of initial authorization): Approve and enter two authorizations for 1 fill in 3 months for all of the following GPIDs:**
 - **50mg/10mL (GPID 29688).**
 - **200mg/40mL (GPID 29689).**

APPROVAL TEXT: Renewal requires that the patient does not have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis) and patient has not been treated with Yervoy for more than 3 years.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB (NSA)

INITIAL CRITEIRA (CONTINUED)

3. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?

- The requested medication will be used in combination with Opdivo (nivolumab)
- The patient has intermediate or poor risk disease
- The patient has not received prior treatment for advanced renal cell carcinoma

If yes, **approve and enter two authorizations for 3 months by GPID for 4 fills as follows:**

- **50mg/10mL (GPID 29688).**
- **200mg/40mL (GPID 29689).**

APPROVAL TEXT: Renewal criteria does not apply for this approval.

If no, continue to #4.

4. Does the patient have a diagnosis of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer and meet **ALL** the following criteria?

- The patient is 12 years of age or older
- The requested medication will be used in combination with Opdivo (nivolumab)
- The patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

If yes, **approve and enter two authorizations for 3 months by GPID for 4 fills as follows:**

- **50mg/10mL (GPID 29688).**
- **200mg/40mL (GPID 29689).**

APPROVAL TEXT: Renewal criteria does not apply for this approval.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **IPILIMUMAB (Yervoy)** requires a diagnosis of unresectable or metastatic melanoma, cutaneous melanoma, advanced renal cell carcinoma, or microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer. In addition, the following criteria must be met:

For diagnosis of unresectable or metastatic melanoma, approval requires:

- The patient is 12 years of age or older

For diagnosis of cutaneous melanoma, approval requires:

- The requested medication will be used for adjuvant treatment
- There is pathologic involvement of regional lymph nodes of more than 1mm
- The patient has undergone complete resection, including total lymphadenectomy

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

For diagnosis of advanced renal cell carcinoma, approval requires:

- The requested medication will be used in combination with Opdivo (nivolumab)
- The patient has intermediate or poor risk disease
- The patient has not received prior treatment for advanced renal cell carcinoma

For diagnosis of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval requires:

- The patient is 12 years of age or older
- The requested medication will be used in combination with Opdivo (nivolumab)
- The patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

RENEWAL CRITERIA

1. Has the patient been treated with Yervoy for more than 3 years per claims history?

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 unresectable or metastatic melanoma **OR** advanced renal cell carcinoma (RCC) **OR** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #3.

3. Is the request for adjuvant treatment of cutaneous melanoma and has the following criterion been met?

- There is no evidence of disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis)

If yes, **approve and enter two authorizations for 6 months by GPID for 2 fills as follows:**

- **50mg/10mL (GPID 29688).**
- **200mg/40mL (GPID 29689).**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB (NSA)

RENEWAL CRITEIRA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **IPILIMUMAB (Yervoy)** requires that all of the following are met for renewal:

- The patient has not been treated with Yervoy for more than 3 years
- The patient does not have a diagnosis of unresectable or metastatic melanoma **OR** advanced renal cell carcinoma (RCC) **OR** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer
- The request is for adjuvant treatment of cutaneous melanoma **AND** the patient does not have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant) following treatment with Yervoy

RATIONALE

To ensure appropriate utilization of ipilimumab based on its FDA approved indications.

FDA APPROVED INDICATIONS

Ipilimumab is a human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody indicated for:

- The treatment of unresectable or metastatic melanoma in adults and pediatric patients (12 years and older).
- Adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.
- The treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with nivolumab.
- In combination with nivolumab, for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

- **Unresectable or metastatic melanoma:** 3mg/kg IV over 90 minutes every 3 weeks for a total of 4 doses. In the event of toxicity, doses may be delayed, but all treatment must be administered within 16 weeks of the first dose.
- **Adjuvant melanoma:** 10mg/kg IV over 90 minutes every 3 weeks for 4 doses, followed by 10mg/kg every 12 weeks for up to 3 years or until documented disease recurrence or unacceptable toxicity.
- **Advanced renal cell carcinoma:** Nivolumab 3 mg/kg IV over 30 minutes followed by Yervoy 1 mg/kg IV over 30 minutes on the same day, every 3 weeks for a maximum of 4 doses. After completing 4 doses of the combination, administer nivolumab intravenously over 30 minutes as a single agent until disease progression or unacceptable toxicity, either:
 - 240 mg every 2 weeks or
 - 480 mg every 4 weeks
- **Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC):** The recommended dose in combination with Yervoy (ipilimumab) is Opdivo 3 mg/kg, followed by Yervoy 1mg/kg on the same day every 3 weeks for 4 doses. After completing 4 doses of the combination, administer Opdivo 240 mg as a single agent every 2 weeks

REFERENCES

- Bristol-Myers Squibb Company. Yervoy package insert. Princeton, NJ. July 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/01/18

Created: 04/11

Client Approval: 07/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IRINOTECAN LIPOSOMAL

Generic	Brand	HICL	GCN	Exception/Other
IRINOTECAN LIPOSOMAL	ONIVYDE	42715		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic adenocarcinoma of the pancreas and have **ALL** of the following criteria been met?
 - The patient has experienced disease progression despite a trial of gemcitabine-based therapy.
 - Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin.

If yes, **approve for 12 months by HICL for 2 fills per 28 day supply.**

If no, continue to #2.

DENIAL TEXT: Our guideline for **IRINOTECAN LIPOSOMAL** requires a diagnosis of metastatic adenocarcinoma of the pancreas. In addition, the following criteria must also be met:

- The patient has experienced disease progression despite a trial of gemcitabine-based therapy.
- Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin.

RATIONALE

Promote appropriate utilization of irinotecan liposomal based on FDA approved indication and dosing.

Onivyde is a nanoliposomal encapsulated preparation of irinotecan that enables it to remain in circulation for a longer duration compared with standard irinotecan; this allows for higher drug uptake within tumor cells and conversion of irinotecan to its active form, SN38.

Pancreatic cancer can be difficult to diagnose early and treatment options are limited, especially when the disease has spread to other parts of the body and surgery to remove the tumor is not possible. The majority of these tumors (85%) are adenocarcinomas arising from the ductal epithelium. The disease is rare before the age of 45, but the incidence rises sharply thereafter. On the basis of significant improvements in clinical benefit and survival, gemcitabine was approved for first-line therapy of metastatic pancreatic cancer.

DOSAGE

The recommended dose of Onivyde is 70 mg/m² administered by intravenous infusion over 90 minutes every 2 weeks, unless the patient is known to be homozygous for the UGT1A1*28 allele, in which case, the first dose should be 50 mg/m². Onivyde requires pre-medication with a corticosteroid and an anti-emetic 30 minutes prior to the Onivyde infusion. Once the Onivyde infusion is complete, it should be followed by leucovorin 400 mg/m² intravenously over 30 minutes and then by fluorouracil 2400 mg/m² intravenously over 46 hours, every 2 weeks.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IRINOTECAN LIPOSOMAL

FDA APPROVED INDICATION

Onivyde is a topoisomerase inhibitor indicated, in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Limitation of Use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

REFERENCES

- Onivyde [Prescribing Information]. Merrimack Pharmaceuticals, Inc.: Cambridge, MA. October 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/16

Created: 11/15

Client Approval: 11/15

P&T Approval: 11/15



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXABEPILONE

Generic	Brand	HICL	GCN	Exception/Other
IXABEPILONE	IXEMPRA	35083		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced breast cancer?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic or locally advanced breast cancer and, 1) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) or, 2) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel), and being used in combination with Xeloda (capecitabine).

2. Has the patient tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

If no, continue to #3.

3. Is the requested medication being used in combination with Xeloda (capecitabine)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic or locally advanced breast cancer and, 1) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) or, 2) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel), and being used in combination with Xeloda (capecitabine).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXABEPILONE

GUIDELINES FOR USE (CONTINUED)

4. Has the patient tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic or locally advanced breast cancer and, 1) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) or, 2) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel), and being used in combination with Xeloda (capecitabine).

RATIONALE

Coverage of Ixempra (ixabepilone) is based on FDA approved indications and NCCN recommendations.

The recommended dose of Ixempra is 40 mg/m² infused intravenously over 3 hours every 3 weeks. Dose reduction is required in certain patients with elevated AST, ALT, or bilirubin.

NCCN guidelines recognize multiple chemotherapy treatment options for recurrent or metastatic breast cancer. Ixempra is considered a nonpreferred single agent therapy. NCCN no longer recognizes Ixempra with Xeloda as a valid chemotherapy regimen for the treatment of recurrent or metastatic breast cancer.

Preferred Single Agents	Other Single Agents	Combination Regimens
doxorubicin	cyclophosphamide	cyclophosphamide, doxorubicin, fluorouracil (FAC/CAF)
pegylated liposomal doxorubicin	carboplatin	fluorouracil, epirubicin, cyclophosphamide (FEC)
paclitaxel	docetaxel	doxorubicin, cyclophosphamide (AC)
Xeloda	Abraxane	epirubicin, cyclophosphamide (EC)
gemcitabine	cisplatin	cyclophosphamide, methotrexate, fluorouracil (CML)
Halaven	Ixempra	docetaxel, Xeloda
vinorelbine	epirubicin	gemcitabine, paclitaxel
		gemcitabine carboplatin
		paclitaxel, Avastin

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXABEPILONE

FDA APPROVED INDICATION

- Ixempra, a microtubule inhibitor, in combination with capecitabine is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.
- Ixempra as monotherapy is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

REFERENCES

- Bristol-Myers Squibb Company. Ixempra package insert. Princeton, NJ. October 2011.
- National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer (Version 3.2013).

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 08/13

Client Approval: 08/13

P&T Approval: 08/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LETERMOVIR IV (NSA)

Generic	Brand	HICL	GCN	Exception/Other
LETERMOVIR	PREVYMIS		44062 44063	

GUIDELINES FOR USE

1. Is the patient undergoing an allogeneic hematopoietic stem cell transplant (HSCT) and meet **ALL** of the following criteria?
- The patient is at least 18 years of age or older
 - The patient is CMV-seropositive [R+]
 - Prevmis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
 - Prevmis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
 - Patient is not receiving the medication beyond 100 days post-transplantation

If yes, **approve for 4 months by GPID for all daily dosage strengths with the following quantity limits:**

- **240mg/12mL daily dose (GPID 44062): #12mL (one single dose vial) per day.**
- **480mg/24mL (GPID 44063): #24mL (one single dose vial) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **LETERMOVIR IV (Prevmis)** requires the patient to be undergoing an allogeneic hematopoietic stem cell transplant (HSCT). In addition, the following criteria must also be met:

- The patient is at least 18 years of age or older
- The patient is CMV-seropositive [R+]
- Prevmis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
- Prevmis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
- Patient is not receiving the medication beyond 100 days post-transplantation

RATIONALE

Promote appropriate utilization of **LETERMOVIR** based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Prevmis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LETERMOVIR IV (NSA)

FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. Prevymis is recommended to be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment), and continue through Day 100 post-transplantation. Dosage of Prevymis should be decreased to 240mg once daily when co-administered with cyclosporine.

- If cyclosporine is initiated after starting Prevymis, the next dose of Prevymis should be decreased to 240mg once daily.
- If cyclosporine is discontinued after starting Prevymis, the next dose of Prevymis should be increased to 480mg once daily.
- If cyclosporine dosing is interrupted due to high cyclosporine levels, no dose adjustment of Prevymis is needed.

Prevymis injection, which contains hydroxypropyl betadex, should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis as soon as they are able to take oral medications. Prevymis tablet and injection may be used interchangeably at the discretion of the physician, and no dosage adjustment is necessary when switching formulations.

AVAILABLE STRENGTHS

Tablet: 240mg, 480mg tablets; Injection: 240mg/12 mL (20mg/mL), 480mg/24mL (20mg/mL) single dose vials

REFERENCES

- Prevymis [Prescribing Information]. Merck & Co, Inc.; Whitehouse Station, NJ. November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 03/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUTETIUM LU 177 DOTATATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
LUTETIUM LU 177 DOTATATE	LUTATHERA	44750		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient will be treated with long-acting octreotide as maintenance therapy in conjunction with the requested drug
 - The patient has been previously treated with a long acting somatostatin analog (i.e., octreotide or lanreotide) prior to the request of this medication

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 received 4 doses of Lutathera previously?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 8 months by HICL with a quantity limit of #1 vial per 56 days.**

DENIAL TEXT: The guideline named **LUTETIUM LU 177 DOTATATE (Lutathera)** requires a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient will be treated with long-acting octreotide as maintenance therapy in conjunction with the requested drug
- The patient has been previously treated with a long acting somatostatin analog (i.e., octreotide or lanreotide) prior to the request of this medication
- The patient has **NOT** previously received 4 doses of Lutathera

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LUTETIUM LU 177 DOTATATE (NSA)

RATIONALE

To promote appropriate utilization of Lutathera based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Lutathera is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

DOSAGE AND ADMINISTRATION

The recommended Lutathera dose is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. Administer pre- and concomitant medications and administer Lutathera as recommended.

Lutathera is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling Lutathera. Radiopharmaceuticals, including Lutathera, should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.

Verify pregnancy status of females of reproductive potential prior to initiating Lutathera.

REFERENCES

- Lutathera [Prescribing Information]. New York, NY: Advanced Accelerator Applications USA, Inc. February 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 05/18

Client Approval: 05/18

P&T Approval: 04/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MEPOLIZUMAB	NUCALA	42775		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome, **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #3 vials (300mg) per 28 days.**

APPROVAL TEXT: Renewal requires a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome.

If no, continue to #2.

2. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?

- The patient is 12 years of age or older
- The patient has a documented blood eosinophil level of at least 300 cells/mcL within the past 6 months
- The patient is currently adherent to a maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, a long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least 2 or more asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5 or more
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1 or more
- Nucala will be used as add-on maintenance treatment
- The patient is not concurrently treated with Xolair, Dupixent, or another anti-IL-5 asthma biologic (e.g., Cinqair, Fasentra)
- Nucala is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

If yes, **approve for 12 months by HICL with a quantity limit of #1 vial (100mg) per 28 days.**

APPROVAL TEXT: Renewal requires the patient to have experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline AND an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline. In addition, if the patient was on maintenance therapy with oral corticosteroids prior to the initiation of Nucala, then the patient must demonstrate a reduction in the total daily dose of oral corticosteroid from baseline for Nucala renewal.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **MEPOLIZUMAB (Nucala)** requires a diagnosis of severe asthma with an eosinophilic phenotype or eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome. In addition, the following criteria must also be met:

For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), approval requires:

- The patient is 18 years of age or older

For the diagnosis of severe asthma with an eosinophilic phenotype, approval requires:

- The patient is 12 years of age or older
- The patient has a documented blood eosinophil level of at least 300 cells/mcL within the past 6 months
- The patient is currently adherent to a maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, a long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least 2 or more asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5 or more
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1 or more
- Nucala will be used as add-on maintenance treatment
- The patient is not concurrently treated with Xolair, Dupixent, or another anti-IL-5 asthma biologic (e.g., Cinqair, Faserra)
- Nucala is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome?

If yes, **approve for 12 months by HICL with a quantity limit of #3 vials (300mg) per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of severe asthma **AND** meet all of the following criteria?
 - The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline
 - The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), **OR** Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline

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 the patient treated with a maintenance therapy regimen of oral corticosteroids prior to initiation of Nucala?

If yes, continue to #4.

If no, **approve for 12 months by HICL with a quantity limit of #1 vial (100mg) per 28 days.**

4. Has the patient reduced their total daily dose of oral corticosteroids from baseline?

If yes, **approve for 12 months by HICL with a quantity limit of #1 vial (100mg) 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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **MEPOLIZUMAB (Nucala)** requires a diagnosis of severe asthma or eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome for renewal. In addition, the following criteria must also be met:

For the diagnosis of severe asthma, approval requires:

- The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline
- The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
- The patient has reduced their total daily oral corticosteroid dose from baseline, if the patient was on a maintenance therapy with oral corticosteroids prior to initiation of Nucala

RATIONALE

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

REFERENCES

- Nucala [Prescribing Information]. Philadelphia, PA. GlaxoSmithKline, LLC. December 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/15

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		

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 documentation of a confirmed diagnosis of periodontitis and meets **ALL** of the following criteria?

- The requested drug 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
- No history of minocycline or tetracycline sensitivity or allergy
- No history of candidiasis or active oral candidiasis
- Not being used for acutely abscessed periodontal pocket
- Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
 - Uncontrolled diabetes mellitus
 - Chemotherapy
 - Radiation therapy
 - HIV infection
- Not being 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
- Age 18 years or older
- Prescribed and administered by an oral health care professional

If yes, **approve for 3 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

- The requested drug 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
- No history of minocycline or tetracycline sensitivity or allergy
- No history of candidiasis or active oral candidiasis
- Not being used for acutely abscessed periodontal pocket
- Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
 - Uncontrolled diabetes mellitus
 - Chemotherapy
 - Radiation therapy
 - HIV infection
- Not being 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
- Age 18 years or older
- Prescribed and administered by an oral health care professional

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

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

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MINOCYCLINE HCL MICROSPPHERES (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets the following criteria?
- The requested drug 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 for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**

If no, do not approve.

DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPPHERES (Arestin)** renewal requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

- The requested drug 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

RATIONALE

Ensure appropriate use of ARESTIN consistent with its FDA approved indication, dosing, contraindications, and precautions. In clinical trials, an average of 29.5 (5-114), 31.7 (4-137), and 31 (5-108) sites were treated at baseline in the scaling and root planning (SRP) alone, SRP + vehicle, and SRP + ARESTIN groups, respectively.

FDA APPROVED INDICATIONS

ARESTIN is indicated as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis. ARESTIN may be used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing.

DOSAGE

ARESTIN is provided as a dry powder, packaged in a unit dose cartridge with a deformable tip, which is inserted into a spring-loaded cartridge handle mechanism to administer the product.

The oral health care professional removes the disposable cartridge from its pouch and connects the cartridge to the handle mechanism. ARESTIN is a variable dose product, dependent on the size, shape, and number of pockets being treated. In US clinical trials, up to 122 unit dose cartridges were used in a single visit and up to 3 treatments, at 3-month intervals, were administered in pockets with pocket depth of 5 mm or greater.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

REFERENCES

- Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma. August 2015.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 08/01/18

Created: 08/16

Client Approval: 07/18

P&T Approval: 08/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITOXANTRONE

Generic	Brand	HICL	GCN	Exception/Other
MITOXANTRONE HCL	NOVANTRONE	03932		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the prescription written by or supervised by an oncologist?
If yes, continue to #4.
If no, continue to #2.
2. Is the patient being treated for pain related to advanced hormone refractory prostate cancer or acute nonlymphocytic leukemia?
If yes, continue to #4.
If no, continue to #3.
3. Is the patient being treated for secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis?
If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: Approval requires supervision by an oncologist or a diagnosis of pain related to advanced refractory prostate cancer or acute nonlymphocytic leukemia or secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis.
4. **Approve open ended.**
APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.
5. **Approve for 12 months. (FDA dosing regimen is 12 mg/m² IV every 3 months)**
APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MITOXANTRONE

RATIONALE

To assure safe and appropriate use of mitoxantrone.

FDA APPROVED INDICATIONS

Mitoxantrone is indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis; in combination with corticosteroids to treat pain related to advanced hormone-refractory prostate cancer; initial therapy or in combination with other approved drugs for acute nonlymphocytic leukemia in adults.

REFERENCES

- EMD Serono, Inc. Novantrone product labeling. Rockland, MA. September 2009.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 08/08

Client Approval: 08/13

P&T Approval: 08/10



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOGAMULIZUMAB-KPKC (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOGAMULIZUMAB-KPKC	POTELIGEO	45153		

GUIDELINES FOR USE

- Does the patient have a diagnosis of Mycosis Fungoides (MF) or Sézary syndrome and meet **ALL** of the following criteria?
 - The patient has relapsed or refractory disease
 - The patient has tried and failed at least one prior systemic therapy
 - The patient is 18 years or older

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires a diagnosis of Mycosis Fungoides (MF) or Sézary syndrome. In addition, the following criteria must be met:

- The patient has relapsed or refractory disease
- The patient has tried and failed at least one prior systemic therapy
- The patient is 18 years or older

RATIONALE

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

REFERENCES

- Poteligeo [Prescribing Information]. Bedminster, NJ: Kyowa Kirin; August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOMETASONE FUROATE	SINUVA		44214	

GUIDELINES FOR USE

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #2.

If no, guideline does not apply.

2. 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
 - The patient has had previous ethmoid sinus surgery (ESS)
 - The medication is prescribed by or given in consultation with an otolaryngologist
 - 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 trial of at least **TWO** intranasal corticosteroids (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

If yes, **approve #2 implants (1 per sinus) by GPID per lifetime.**

If no, do not approve.

DENIAL TEXT: The guideline named **MOMETASONE IMPLANT (Sinuva)** requires a diagnosis of nasal polyps. In addition, the following criteria must also be met:

- The patient is 18 years of age or older
- The patient has had previous ethmoid sinus surgery (ESS)
- The medication is prescribed by or given in consultation with an otolaryngologist
- 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 trial of at least **TWO** intranasal corticosteroids (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOMETASONE SINUS IMPLANT (NSA)

RATIONALE

To promote appropriate utilization of SINUVA based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Sinuva Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery

DOSAGE & ADMINISTRATION

One Sinuva Sinus Implant containing 1350 mcg of mometasone furoate. There are no studies evaluating repeat implantation of the Sinuva Sinus Implant.

The Sinuva Sinus Implant is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. The Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The Implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. Sinuva must be inserted by physicians trained in otolaryngology.

REFERENCES

- Sinuva [Prescribing Information]. Menlo Park, CA: Intersect ENT. December 2017.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 08/01/18

Created: 05/18

Client Approval: 07/18

P&T Approval: 04/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOXETUMOMAB PASUDOTOX (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOXETUMOMAB PASUDOTOX-TDFK	LUMOXITI	45363		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hairy cell leukemia (HCL) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The disease is relapsed or refractory
 - The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)

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 6 cycles of Lumoxiti?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 6 months by HICL.**

DENIAL TEXT: The guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires a diagnosis of hairy cell leukemia (HCL). In addition, the following must be met:

- The patient is 18 years of age or older
- The disease is relapsed or refractory
- The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)
- The patient has **NOT** previously received 6 cycles of Lumoxiti

RATIONALE

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

REFERENCES

- Lumoxiti [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NATALIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
NATALIZUMAB	TYSABRI	26750		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient had a previous trial of or contraindication to one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

APPROVAL TEXT: Renewal requires one of the following: 1) The patient has received at least 12 months of Tysabri therapy and has not received more than 3 months of corticosteroids for control of Crohn's disease while on Tysabri, or 2) The patient has received only 6 months of Tysabri therapy and is not currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy).

If no, continue to #2.

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient had a previous trial of **ONE** agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** other MS agents may also require prior authorization)

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **NATALIZUMAB (Tysabri)** requires a diagnosis of moderate to severe Crohn's disease or a relapsing form of multiple sclerosis (MS). In addition, the following criteria must also be met:

For the diagnosis of moderate to severe Crohn's disease, approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to ONE of the following formulary preferred immunomodulators: Humira **OR** Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

For the diagnosis of a relapsing form of multiple sclerosis (MS), approval requires:

- The patient is 18 years of age or older
- The patient had a previous trial of **ONE** agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Tecfidera)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease and meet ALL of the following criteria?

- The patient has received at least 12 months of Tysabri therapy
- The patient has **NOT** received more than 3 months of corticosteroids for control of Crohn's disease

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease and meet **ALL** of the following criteria?

- The patient has received only 6 months of Tysabri therapy
- The patient is **NOT** currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy)

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS)?

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **NATALIZUMAB (Tysabri)** requires a diagnosis of moderate to severe Crohn's disease or a relapsing form of multiple sclerosis for renewal. In addition, the following criteria must also be met:

For the diagnosis of moderate to severe Crohn's disease, approval requires one of the following:

- The patient has received at least 12 months of Tysabri therapy and has not received more than 3 months of corticosteroids for control of Crohn's disease while on Tysabri
- The patient has received only 6 months of Tysabri therapy and is not currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy)

RATIONALE

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

REFERENCES

- Tysabri [Prescribing Information]. Cambridge, MA: Biogen Inc.; April 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 08/06

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NECITUMUMAB

Generic	Brand	HICL	GCN	Exception/Other
NECITUMUMAB	PORTRAZZA	42835		

GUIDELINES FOR USE

1. Will necitumumab be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin?

If yes, **approve for 12 months by HICL with a quantity limit of #2 vials per 21 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **NECITUMUMAB (Portrazza)** requires that it be used as first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin.

RATIONALE

Promote appropriate utilization of **NECITUMUMAB** based on its FDA approved indication.

Lung cancer is the second most common cancer in the United States with about 220,000 new diagnoses each year and the leading cause of cancer-related mortality with an estimated 158,000 deaths per year. About 85% of lung cancers are classified as NSCLC, of which squamous cell carcinomas account for about 25-30%, making them the most common histological subtype after adenocarcinoma. Squamous cell carcinomas are often associated with a history of smoking and are more commonly seen in males.

Treatment selection depends upon tumor staging, histology, molecular profiling to identify driver mutations (e.g., EGFR, anaplastic lymphoma kinase [ALK]), and an evaluation of the patient's overall medical condition. Whereas patients without metastatic disease are treated with curative intent using surgery, chemotherapy, and/or radiation therapy, the primary approach for patients with metastatic disease is palliative systemic chemotherapy. The National Comprehensive Cancer Network (NCCN) Panel recommends targeted tyrosine kinase inhibitor (TKI) therapies such as EGFR inhibitors (Tarceva [erlotinib], Gilotrif [afatinib], Iressa [gefitinib]) or ALK inhibitors (Xalkori [crizotinib], Zykadia [ceritinib], Alecensa [alectinib]) as first-line for patients whose tumors contain a driver mutation; however, these mutations are typically observed with adenocarcinomas rather than with squamous cell carcinomas.

For patients whose mutation status is negative or unknown, the NCCN Panel recommends platinum-based two-drug combination regimens as first-line treatment. Platinum-based chemotherapy prolongs survival, improves symptom control, and yields superior quality of life compared to best supportive care. Based upon superior efficacy compared to cisplatin/pemetrexed, the NCCN Panel recommends cisplatin/gemcitabine as first-line therapy in patients with squamous NSCLC. Two-drug regimens are preferred; a third cytotoxic drug may increase response rate but not survival. As many of the platinum two-drug combinations yield similar objective response rates and survival and differ slightly for toxicity, convenience, and cost, clinicians can individualize therapy for their patients.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NECITUMUMAB

RATIONALE (CONTINUED)

In December 2015, NCCN updated its guideline to include cisplatin/gemcitabine/necitumumab as a first-line systemic therapy option for advanced or metastatic squamous NSCLC; however, this was designated as a category 3 recommendation, which indicates major NCCN disagreement on the appropriateness of the intervention. NCCN stated that the category 3 recommendation for this regimen is due to its toxicity, cost, and limited improvement in efficacy that is seen when necitumumab is added to cisplatin/gemcitabine. NCCN recommendations (category 1) for first-line treatment options are listed in Table 1.

Table 1. First-line systemic therapy options for advanced or metastatic squamous cell NSCLC

Carboplatin-based regimens	Cisplatin-based regimens	Non-platinum-based regimens
<ul style="list-style-type: none"> • Carboplatin/albumin-bound paclitaxel • Carboplatin/docetaxel • Carboplatin/etoposide • Carboplatin/gemcitabine • Carboplatin/paclitaxel • Carboplatin/vinorelbine 	<ul style="list-style-type: none"> • Cisplatin/docetaxel • Cisplatin/etoposide • Cisplatin/gemcitabine • Cisplatin/paclitaxel • Cisplatin/vinorelbine 	<ul style="list-style-type: none"> • Gemcitabine/docetaxel • Gemcitabine/vinorelbine

Other monoclonal antibodies have been approved for the treatment of NSCLC, but they occupy different places in therapy from Portrazza. For instance, Avastin (bevacizumab) is indicated for the first-line treatment of advanced NSCLC but only in patients with non-squamous histology. Opdivo (nivolumab) and Cyramza (ramucirumab) are indicated only as subsequent-line therapy for patients who have progressed on or after platinum-based chemotherapy. Erbitux (cetuximab) is a monoclonal antibody that also targets EGFR but is not currently indicated for the treatment of NSCLC.

The SQUIRE trial was a phase 3, multicenter, open-label, randomized trial that evaluated the efficacy of Portrazza in 1,093 patients with squamous NSCLC. Previously untreated patients with stage IV squamous NSCLC and an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 were randomized 1:1 to receive Portrazza plus gemcitabine/cisplatin or to gemcitabine/cisplatin alone. Baseline characteristics included median age of 62 years, 83% male, 84% Caucasian, 91% smokers, 91% with baseline ECOG performance status of 0-1, and 91% with metastatic disease in at least two sites (most commonly lung and lymph nodes). Gemcitabine/cisplatin was given for up to six cycles; in patients demonstrating at least stable disease (51%), Portrazza was continued alone after the completion of chemotherapy as maintenance treatment until disease progression or toxicity. Blinding was not conducted in this trial because the expected occurrence of acne-like rash would have unmasked most patients and investigators to treatment. The primary endpoint was overall survival.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NECITUMUMAB

RATIONALE (CONTINUED)

Efficacy results are shown in Table 2.

Table 2. Efficacy results of the SQUIRE trial

Outcome	Portrazza + gemcitabine/cisplatin (n = 545)	Gemcitabine/cisplatin (n = 548)	Hazard ratio (95% CI) p-value
Overall survival (OS)			
Median OS – months	11.5	9.9	0.84 (0.74, 0.96) p = 0.01
Deaths – no. (%)	418 (77)	442 (81)	--
Progression-free survival (PFS)			
Median PFS – months	5.7	5.5	0.85 (0.74, 0.98) p = 0.02
Events – no. (%)	431 (79)	417 (76)	--
Response			
Objective response rate (ORR) – no. (%)	170 (31)	158 (29)	p = 0.40

Portrazza should not be used for the treatment of non-squamous NSCLC due to a risk for increased toxicity and mortality observed in the INSPIRE trial. The INSPIRE trial was a multicenter, open-label trial that evaluated Portrazza in 633 patients with metastatic non-squamous NSCLC. Patients were randomized 1:1 to receive Portrazza plus pemetrexed/cisplatin (n = 315) or pemetrexed/cisplatin alone (n = 318). There was no significant difference in OS (HR 1.01; 95% CI 0.84, 1.21), PFS (HR 0.96; 95% CI 0.80, 1.16), or ORR (31% vs. 32%, respectively). The study was terminated early due to increased all-cause mortality and thromboembolic-related mortality in the Portrazza treatment arm.

FDA APPROVED INDICATION

Portrazza is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer.

Limitation of Use: Portrazza is not indicated for treatment of non-squamous non-small cell lung cancer.

DOSAGE

The recommended dose of Portrazza is 800 mg administered as an intravenous (IV) infusion over 60 minutes on Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion.

Gemcitabine/cisplatin chemotherapy is given for a maximum of six cycles, and Portrazza is continued thereafter as single-agent maintenance therapy until disease progression or unacceptable toxicity.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NECITUMUMAB

DOSAGE (CONTINUED)

Infusion rate should be reduced and pre-medication should be administered with all subsequent infusions for patients who have experienced a Grade 1 or 2 infusion-related reaction with previous Portrazza infusion: diphenhydramine (or equivalent) after the first occurrence; diphenhydramine (or equivalent), acetaminophen (or equivalent), and dexamethasone (or equivalent) after the second occurrence. Portrazza should be permanently discontinued for Grade 3 or 4 infusion-related reactions and certain dermatologic toxicities (e.g., rash that does not resolve, worsening or intolerable reactions at a reduced dose, Grade 3 skin induration/fibrosis, Grade 4).

REFERENCES

- FDA Press Release [Online Press Release]: FDA approves Portrazza to treat advanced squamous non-small cell lung cancer. Available at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm474131.htm>. Updated November 24, 2015.
- National Comprehensive Cancer Network. NCCN Guidelines: Non-Small Cell Lung Cancer. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Updated December 22, 2015.
- Paz-Ares K, Mezger J, Ciuleanu TE, et al. Necitumumab plus pemetrexed and cisplatin as first-line therapy in patients with stage IV non-squamous non-small-cell lung cancer (INSPIRE): an open-label, randomised, controlled phase 3 study. *Lancet Oncol.* 2015;16:328-37.
- Portrazza [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. November 2015.
- Thatcher N, Hirsch FR, Luft AV, et al. Necitumumab plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone as first-line therapy in patients with stage IV squamous non-small-cell lung cancer (SQUIRE): an open-label, randomised, controlled phase 3 trial. *Lancet Oncol.* 2015;16:763-74.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 12/15

Client Approval: 02/16

P&T Approval: 2/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
NIVOLUMAB	OPDIVO	41654		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
 - The patient will be using Opdivo as a single agent **OR** in combination with ipilimumab (Yervoy)
 - No concurrent therapy with dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), or cobimetinib (Cotellic)

If yes, **approve for 12 months by HICL.**
If no, continue to #2.

2. Does the patient have a diagnosis of melanoma with lymph node involvement or metastatic disease and meet **ALL** of the following criteria?
 - The patient has undergone complete resection
 - The requested medication will be used as an adjuvant treatment

If yes, **approve for 12 months by HICL.**
If no, continue to #3.

3. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - For patients who have an ALK mutation, there must be disease progression despite also trying an ALK-directed therapy (e.g., crizotinib, ceritinib)
 - For patients who have an EGFR mutation, there must also be disease progression despite also trying an EGFR-directed therapy (e.g., erlotinib, gefitinib, afatinib)

If yes, **approve for 12 months by HICL.**
If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic non-squamous non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
- Non-small cell lung cancer (NSCLC) tumors express PD-L1 as determined by an FDA-approved test
 - The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - For patients who have an ALK mutation, there must be disease progression despite also trying an ALK-directed therapy (e.g., crizotinib, ceritinib)
 - For patients who have an EGFR mutation, there must also be disease progression despite also trying an EGFR-directed therapy (e.g., erlotinib, gefitinib, afatinib)

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of metastatic small cell lung cancer (SCLC) and meet the following criterion?
- The patient has disease progression after platinum-based chemotherapy (e.g., cisplatin, carboplatin) and at least one other line of therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
- Opdivo will be used as a single agent and meet the following:
 - The patient has previously received **ONE** prior anti-angiogenic therapy (e.g., sunitinib (Sutent), pazopanib (Votrient), cabozantinib (Cabometyx), axitinib (Inlyta), sorafenib (Nexavar))
 - Opdivo will be used in combination with ipilimumab (Yervoy) and meet ALL of the following:
 - The patient has intermediate or poor risk disease
 - The patient has not received prior treatment for advanced renal cell carcinoma

If yes, **approve for 12 months by HICL.**

If no, continue to #7.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient's disease has relapsed or progressed after **ONE** of the following:
 - Autologous hematopoietic stem cell transplantation (HSCT) and Adcetris (brentuximab vedotin)
 - 3 or more lines of systemic therapy that includes autologous HSCT

If yes, **approve for 12 months by HICL.**

If no, continue to #8.

8. Does the patient have a diagnosis of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) **AND** meet the following criterion?

- The patient has disease progression on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by HICL.**

If no, continue to #9.

9. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma and meet at least **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.**

If no, continue to #10.

10. Does the patient have a diagnosis of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer and meet **ALL** the following criteria?

- The patient is 12 years of age or older
- The patient will be using Opdivo as a single agent OR in combination with ipilimumab (Yervoy)
- The patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

If yes, **approve for 12 months by HICL.**

If no, continue to #11.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

11. Does the patient have a diagnosis of hepatocellular carcinoma **AND** meet the following criterion?

- The patient has been previously treated with sorafenib (Nexavar)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **NIVOLUMAB (Opdivo)** requires a diagnosis of unresectable or metastatic melanoma, melanoma with lymph node involvement or metastatic disease, metastatic non-small cell lung cancer (NSCLC), metastatic small cell lung cancer (SCLC), advanced renal cell carcinoma (RCC), classical Hodgkin lymphoma (cHL), recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), locally advanced, or metastatic urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, or hepatocellular carcinoma. In addition, the following criteria must be met:

For patients with unresectable or metastatic melanoma, approval requires:

- The patient will be using Opdivo as a single agent OR in combination with ipilimumab (Yervoy)
- No concurrent therapy with dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), or cobimetinib (Cotellic)

For patients with melanoma with lymph node involvement or metastatic disease, approval requires:

- The patient has undergone complete resection
- The requested medication will be used as an adjuvant treatment

For patients with metastatic squamous non-small cell lung cancer, approval requires:

- The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- Additional requirements apply if patient has ALK or EGFR mutations. For patients who have ALK or EGFR mutations, there must be disease progression following ALK-directed therapy (e.g., crizotinib, ceritinib) or EGFR-directed therapy (e.g., erlotinib, gefitinib, afatinib)

For patients with metastatic non-squamous non-small cell lung cancer, approval requires:

- The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- Non-small cell lung cancer (NSCLC) tumors express PD-L1 as determined by an FDA-approved test
- Additional requirements apply if patient has ALK or EGFR mutations. For patients who have ALK or EGFR mutations, there must be disease progression following ALK-directed therapy (e.g., crizotinib, ceritinib) or EGFR-directed therapy (e.g., erlotinib, gefitinib, afatinib)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

For patients with metastatic small cell lung cancer (SCLC), approval requires:

- The patient has disease progression after platinum-based chemotherapy (e.g., cisplatin, carboplatin) and at least one other line of therapy

For patients with advanced renal cell carcinoma (RCC), approval requires ONE of the following:

- Opdivo will be used as a single agent and meet the following:
 - The patient has previously received one prior anti-angiogenic therapy (e.g., sunitinib (Sutent), pazopanib (Votrient), cabozantinib (Cabometyx), axitinib (Inlyta), sorafenib (Nexavar))
- Opdivo will be used in combination with ipilimumab (Yervoy) and meet all of the following:
 - The patient has intermediate or poor risk disease
 - The patient has not received prior treatment for advanced renal cell carcinoma

For patients with classical Hodgkin lymphoma (cHL), approval requires:

- The patient is 18 years of age or older
- The patient's disease has relapsed or progressed after ONE of the following:
 - Autologous hematopoietic stem cell transplantation (HSCT) and Adcetris (brentuximab vedotin)
 - 3 or more lines of systemic therapy that includes autologous HSCT

For patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), approval requires:

- The patient has disease progression on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

For patients with locally advanced or metastatic urothelial carcinoma, approval requires ONE of the following:

- 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)

For patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval requires:

- The patient is 12 years of age or older
- The patient will be using Opdivo as a single agent OR in combination with ipilimumab (Yervoy)
- The patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

For patients with hepatocellular carcinoma, approval requires:

- The patient has been previously treated with sorafenib (Nexavar)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB (NSA)

RATIONALE

Promote appropriate utilization of Opdivo based on FDA approved indications.

FDA APPROVED INDICATIONS

Opdivo is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of:

- BRAF V600 wild-type unresectable or metastatic melanoma, as a single agent.
- BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent ^a.
- Unresectable or metastatic melanoma, in combination with ipilimumab ^a.
- Melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting.
- Metastatic non-small cell lung cancer and progression on or after platinum based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.
- Metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy. ^b
- Advanced renal cell carcinoma as a single agent in patients who have received prior anti-angiogenic therapy.
- Advanced renal cell carcinoma in combination with ipilimumab in patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma (RCC).
- Adult patients with classical Hodgkin lymphoma who have relapsed or progressed after ^b
 - autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin, or
 - 3 or more lines of systemic therapy that includes autologous HSCT
- Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy
- Locally advanced or metastatic urothelial carcinoma who ^b:
 - Have disease progression during or following platinum-containing chemotherapy.
 - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer ^b
 - To be used as single agent or in combination with ipilimumab ^b, and
 - Patient has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan ^b.
- Hepatocellular carcinoma previously treated with sorafenib ^b.

^a This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

^b This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NIVOLUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Opdivo is administered as an intravenous infusion over 30 minutes until disease recurrence, progression or unacceptable toxicity.

Unresectable or metastatic melanoma:

- The recommended dose as a single agent is either 240mg every 2 weeks or 480mg every 4 weeks
- The recommended dose in combination with ipilimumab is Opdivo 1mg/kg, followed by ipilimumab 3mg/kg intravenous infusion over 90 minutes on the same day, every 3 weeks for a maximum of 4 doses or until unacceptable toxicity, whichever occurs first. After completing 4 doses of the combination, administer Opdivo as a single agent either 240mg every 2 weeks or 480mg every 4 weeks.

Adjuvant treatment of melanoma with lymph node involvement or metastatic disease:

The recommended dose is 240mg every 2 weeks or 480 mg every 4 weeks for up to 1 year.

Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC):

- The recommended dosing of Opdivo as a single agent is 240mg every 2 weeks
- The recommended dose in combination with ipilimumab is Opdivo 3 mg/kg, followed by ipilimumab 1mg/kg on the same day every 3 weeks for 4 doses. After completing 4 doses of the combination, administer Opdivo 240 mg as a single agent every 2 weeks

Metastatic NSCLC, locally advanced or metastatic urothelial carcinoma, classical Hodgkin lymphoma (cHL), squamous cell carcinoma of the head and neck (SCCHN), and hepatocellular carcinoma (HCC):

The recommended dosing of Opdivo is 240 mg every 2 weeks or 480 mg every 4 weeks.

Metastatic small cell lung cancer (SCLC):

- The recommended dose is 240 mg administered as an intravenous infusion over 30 minutes every 2 weeks until disease progression or unacceptable toxicity.

Advanced renal cell carcinoma:

- The recommended dose as a single agent is either 240mg every 2 weeks or 480mg every 4 weeks
- The recommended dose in combination with ipilimumab is Opdivo 3mg/kg, followed by ipilimumab 1mg/kg intravenous infusion over 30 minutes on the same day, every 3 weeks for 4 doses. After completing 4 doses of the combination, administer Opdivo as a single agent either 240mg every 2 weeks or 480mg every 4 weeks.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NIVOLUMAB (NSA)

REFERENCES

- Opdivo [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 09/17/18

Created: 05/15

Client Approval: 08/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NUSINERSEN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
NUSINERSEN	SPINRAZA	44016		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?
 - Diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of gene mutation analysis with bi-allelic survival motor neuron (*SMN1*) mutations (i.e., deletions and/or point mutations)
 - Therapy is prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
 - The patient has not received treatment with gene therapy (i.e., Zolgensma)

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 presymptomatic and meet **ALL** of the following criteria?
 - The patient is less than or equal to 6 weeks of age
 - There is documentation of up to three copies of survival motor neuron (*SMN2*)

If yes, **please enter TWO approvals by HICL as follows (total approval duration is 6 months):**

- **FIRST APPROVAL:** approve for 1 month for 3 fills with a quantity limit of #5mL (one 12mg/5mL vial) per each fill.
- **SECOND APPROVAL:** approve for 5 months for 2 fills, with a quantity limit of #5mL (one 12mg/5mL vial) per each fill (Please enter a start date after the end date of the first approval).

APPROVAL TEXT: Renewal requires the following: 1) patient has not received treatment with gene therapy (i.e. Zolgensma), and 2) patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NUSINERSEN (NSA)

INITIAL CRITERIA (CONTINUED)

3. Is the patient symptomatic and meet **ALL** of the following criteria?

- The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
- There is documentation of baseline motor function assessment by a neuromuscular specialist or SMA specialist

If yes, please enter **TWO** approvals by HICL as follows (total approval duration is 6 months):

- **FIRST APPROVAL:** approve for 1 month for 3 fills with a quantity limit of #5mL (one 12mg/5mL vial) per each fill.
- **SECOND APPROVAL:** approve for 5 months for 2 fills, with a quantity limit of #5mL (one 12mg/5mL vial) per each fill (Please enter a start date after the end date of the first approval).

APPROVAL TEXT: Renewal requires the following: 1) patient has not received treatment with gene therapy (i.e. Zolgensma), and 2) patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **NUSINERSEN (Spinraza)** requires a diagnosis of spinal muscular atrophy (SMA). In addition, the following criteria must be met:

- Diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of gene mutation analysis with bi-allelic survival motor neuron (*SMN1*) mutations (i.e., deletions and/or point mutations)
- Therapy is prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
- The patient has not received treatment with gene therapy (i.e., Zolgensma)
- **Requests for presymptomatic patients also requires:**
 - The patient is less than or equal to 6 weeks of age
 - There is documentation of up to three copies of survival motor neuron (*SMN2*)
- **Requests for symptomatic patients also requires:**
 - The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
 - There is documentation of baseline motor function assessment by a neuromuscular specialist or SMA specialist

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NUSINERSEN (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

- Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?
 - The patient has not received treatment with gene therapy (i.e., Zolgensma)
 - The patient meets **ONE** of the following:
 - The patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
 - The patient has improved, maintained, or demonstrated less than expected decline in other muscle function (e.g., pulmonary)

If yes, **approve for 12 months by HICL for 3 fills with a quantity limit of #5mL (one 12mg/5mL vial) per each fill.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **NUSINERSEN (Spinraza)** requires a diagnosis of spinal muscular atrophy (SMA). In addition, the following criteria must be met:

- The patient has not received treatment with gene therapy (i.e., Zolgensma)
- The patient meets **ONE** of the following:
 - The patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
 - The patient has improved, maintained, or demonstrated less than expected decline in other muscle function (e.g., pulmonary)

RATIONALE

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

REFERENCES

- Spinraza [Prescribing Information]. Cambridge, MA: Biogen, Inc. October 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Com Commercial Effective: 06/17/19

Created: 01/17

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBINUTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OBINUTUZUMAB	GAZYVA	40703		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) and meet **ALL** of the following criteria?

- The patient has not received previous treatment for chronic lymphocytic leukemia (CLL)
- The requested medication will be used in combination with chlorambucil

If yes, please enter two approvals as follows:

- **Approve for 1 month by HICL for #4 (1000mg/40mL) vials per 28 days.**
- **Approve for 5 months by HICL for #1 (1000mg/40mL) vial per 28 days with a start date one day after the end date of the first approval.**

If no, continue to #2.

2. Does the patient have a diagnosis of follicular lymphoma (FL) and meet **ALL** of the following criteria?

- The patient has relapsed after, or is refractory to, a regimen containing Rituxan (rituximab)
- The requested medication will be used in combination with bendamustine for the initial six cycles **OR** as monotherapy thereafter

If yes, please enter three approvals as follows:

- **Approve for 1 month by HICL for #3 (1000mg/40mL) vials per 28 days.**
- **Approve for 5 months by HICL for #1 (1000mg/40mL) vial per 28 days with a start date one day after the end date of the first approval.**
- **Approve for 6 months by HICL for #1 (1000mg/40mL) vial per 56 days with a start date one day after the end date of the second approval.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBINUTUZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of stage II bulky, III or IV follicular lymphoma (FL) and meet **ALL** of the following criteria?
- The patient is at least 18 years old
 - The patient has not received previous treatment for stage II bulky, III or IV follicular lymphoma
 - The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [i.e., bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] **OR** as monotherapy thereafter

If yes, please enter three approvals as follows:

- **Approve for 1 month by HICL for #3 (1000mg/40mL) vials per 28 days.**
- **Approve for 7 months by HICL for #1 (1000mg/40mL) vial per 28 days with a start date one day after the end date of the first approval.**
- **Approve for 4 months by HICL for #1 (1000mg/40mL) vial per 56 days with a start date one day after the end date of the second approval.**

If no, do not approve.

DENIAL TEXT: The guideline named **OBINUTUZUMAB (Gazyva)** requires a diagnosis of chronic lymphocytic leukemia (CLL), follicular lymphoma (FL), or stage II bulky, III or IV follicular lymphoma. In addition, the following must be met:

For the diagnosis of chronic lymphocytic leukemia (CLL), approval requires:

- The patient has not received previous treatment for chronic lymphocytic leukemia (CLL)
- The requested medication will be used in combination with chlorambucil

For the diagnosis of follicular lymphoma (FL), approval requires:

- The patient has relapsed after, or is refractory to, a regimen containing Rituxan (rituximab)
- The requested medication will be used in combination with bendamustine for the initial six cycles **OR** as monotherapy thereafter

For the diagnosis of stage II bulky, III or IV follicular lymphoma (FL), approval requires:

- The patient is at least 18 years old
- The patient has not received previous treatment for stage II bulky, III or IV follicular lymphoma
- The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [i.e., bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] **OR** as monotherapy thereafter

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBINUTUZUMAB (NSA)

RATIONALE

To promote appropriate utilization of Gazyva based on FDA approved indication.

FDA APPROVED INDICATIONS

Gazyva (obinutuzumab) is a CD20-directed cytolytic antibody and is indicated:

- In combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).
- In combination with bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen.
- In combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.

DOSAGE AND ADMINISTRATION

Each dose of Gazyva is 1000 mg, administered intravenously.

Chronic Lymphocytic Leukemia (CLL)

Recommended dose for 6 cycles (28-day cycles):

	Day of Treatment Cycle	Dose of Gazyva
Cycle 1	Day 1	100 mg
	Day 2	900 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-6	Day 1	1000 mg

The dose for chronic lymphocytic leukemia is 100 mg on day 1 and 900 mg on day 2 of Cycle 1, 1000 mg on day 8 and 15 of Cycle 1, and 1000 mg on day 1 of Cycles 2-6.

Relapsed or Refractory Follicular Lymphoma

For patients with relapsed or refractory FL, administer Gazyva in combination with bendamustine in six 28-day cycles. Patients who achieve stable disease, complete response, or partial response to the initial 6 cycles should continue on Gazyva 1000 mg as monotherapy for up to two years.

Recommended dose for 6 treatment cycles:

	Day of Treatment Cycle	Dose of Gazyva
Cycle 1	Day 1	1000 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-6	Day 1	1000 mg
Monotherapy	Every 2 months for up to 2 years	1000 mg

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBINUTUZUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Recommended dose for 6 treatment cycles:

	Day of Treatment Cycle	Dose of Gazyva
Cycle 1	Day 1	1000 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-6	Day 1	1000 mg
Monotherapy	Every 2 months for up to 2 years	1000 mg

Previously Untreated Stage II bulky, III, or IV Follicular Lymphoma

For patients with previously untreated FL, administer Gazyva with one of the following chemotherapy regimens:

- Six 28-day cycles in combination with bendamustine
- Six 21-day cycles in combination with CHOP, followed by 2 additional 21-day cycles of Gazyva alone
- Eight 21-day cycles in combination with CVP

Patients with previously untreated FL who achieve a complete response or partial response to the initial 6 or 8 cycles should continue on Gazyva 1000 mg as monotherapy for up to two years.

Recommended dose for 8 treatment cycles:

- The dose for follicular lymphoma is 1000 mg on day 1, 8, and 15 of Cycle 1, and 1000 mg on day 1 of Cycles 2-8, and then 1000 mg every 2 months for 2 years.

	Day of Treatment Cycle	Dose of Gazyva
Cycle 1	Day 1	1000 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-8	Day 1	1000 mg
Monotherapy	Every 2 months for up to 2 years	1000 mg

Patients should be premedicated with glucocorticoids, acetaminophen, and an antihistamine before infusion. Dilute and administer as intravenous infusion. Do not administer as an intravenous push or bolus. Patients with neutropenia are strongly recommended to receive antimicrobial prophylaxis throughout the treatment period. Antiviral and antifungal prophylaxis should be considered.

REFERENCES

- Genentech, Inc. Gazyva package insert. South San Francisco, CA. November 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBINUTUZUMAB (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 02/05/18

Created: 11/13
Client Approval: 01/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OCRELIZUMAB	OCREVUS	44178		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary progressive multiple sclerosis (PPMS) **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, continue to #4.

If no, continue to #2.

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) **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 had a previous trial of **ONE** agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** other MS agents may also require prior authorization)
- Physician attestation that the patient shows signs of severe disease requiring high-efficacy disease modifying therapy (DMT) (e.g., high lesion volume and/or count, walking disability, or rapid decline)

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 requesting a starting dose?

If yes, **approve for a total of 12 months by HICL with the following quantity limits:**

- **FIRST APPROVAL:** approve one fill for a quantity of #20mL (two 300mg/10mL) for 1 month. **Override quantity limits for new start dose.**
- **SECOND APPROVAL:** approve #20mL (two 300mg/10mL) every 6 months (please enter a start date of 4 months after the end date of the first approval).

If no, **approve for 12 months by HICL with a quantity limit of #20mL (two 300mg/10mL) every 6 months.**

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **OCRELIZUMAB (Ocrevus)** requires a diagnosis of primary progressive multiple sclerosis (PPMS) or a relapsing form of multiple sclerosis (MS). In addition, the following criteria must be met:

For the diagnosis of primary progressive multiple sclerosis (PPMS), approval requires:

- The patient is 18 years of age or older

For the diagnosis of a relapsing form of multiple sclerosis (MS), approval requires:

- The patient is 18 years of age or older
- The patient meets ONE of the following:
 - The patient had a previous trial of ONE agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Tecfidera)
 - Physician attestation that the patient shows signs of severe disease requiring high-efficacy disease modifying therapy (DMT) (e.g., high lesion volume and/or count, walking disability, or rapid decline)

RATIONALE

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

REFERENCE

- Ocrevus [Prescribing Information]. San Francisco, CA: Genentech, Inc.; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 01/17

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OFATUMUMAB	ARZERRA	36708		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL)?

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 previously untreated for chronic lymphocytic leukemia (CLL) and meets **ALL** of the following criteria?

- Fludara (fludarabine)-based therapy is considered inappropriate in this patient
- The requested medication will be used in combination with chlorambucil

If yes, **approve as follows by GPID and enter two prior authorizations:**

- **Approval #1: Approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials AND**
- **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
 - **Approve 12 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 28 days (total fill count of 12) OR**
 - **Approve 12 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 28 days (total fill count of 12)**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment of **relapsed** chronic lymphocytic leukemia (CLL) and does the patient meet the following criteria?

- The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

If yes, **approve as follows by GPID and enter two prior authorizations:**

- **Approval #1: approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials AND**
- **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
 - **Approve 6 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 28 days (total fill count of 6) OR**
 - **Approve 6 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 28 days (total fill count of 6)**

If no, continue to #4.

4. For extended treatment of chronic lymphocytic leukemia (CLL), does the patient meet **ALL** of the following criteria?

- The patient is in complete or partial response
- The patient has received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL)

If yes, **approve as follows by GPID and enter two prior authorizations:**

- **Approval #1: approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials AND**
- **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
 - **Approve 24 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 8 weeks (total fill count of 13) OR**
 - **Approve 24 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 8 weeks (total fill count of 13)**

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. For refractory chronic lymphocytic leukemia (CLL), does the patient meet **ALL** of the following criteria?

- The patient is refractory to Fludara (fludarabine) and Campath (alemtuzumab)

If yes, **approve as follows by GPID and enter three prior authorizations:**

- **Approval #1: approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials AND**
- **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
 - **Approve 7 weeks of Arzerra 100mg/5mL with a quantity limit of #20 vials per 7 days (total fill count of 7) OR**
 - **Approve 7 weeks of Arzerra 1,000mg/50mL with a quantity limit of #2 vials per 7 days AND**
- **Approval #3 (Please enter a start date of 4 WEEKS AFTER the end date of the second approval):**
 - **Approve 16 weeks of Arzerra 100mg/5mL with a quantity limit of #20 vials per 28 days (total fill count of 4) OR**
 - **Approve 16 weeks of Arzerra 1,000mg/50mL with a quantity limit of #2 vials per 28 days (total fill count of 4)**

If no, do not approve.

DENIAL TEXT: The guideline named **OFATUMUMAB (Arzerra)** requires a diagnosis of chronic lymphocytic leukemia (CLL). In addition, the following criteria must also be met. **For patients with previously untreated chronic lymphocytic (CLL), approval requires all of the following:**

- The patient has not received previous treatment for chronic lymphocytic (CLL)
- Fludara (fludarabine)-based therapy is considered inappropriate in this patient
- The requested medication will be used in combination with chlorambucil

For patients with relapsed chronic lymphocytic (CLL), approval requires all of the following:

- The patient has relapsed chronic lymphocytic (CLL)
- The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

(Denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

For patients requesting extended treatment of chronic lymphocytic (CLL), approval requires all of the following:

- The patient is in complete or partial response
- The patient has received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL)

For patients with refractory chronic lymphocytic (CLL), approval requires all of the following:

- The patient is refractory to Fludara (fludarabine) and Campath (alemtuzumab)

RATIONALE

Ensure appropriate utilization of Arzerra (ofatumumab) per FDA-approved indications and dosing.

FDA APPROVED INDICATION

Arzerra (ofatumumab) is a CD20-directed cytolytic monoclonal antibody indicated for the treatment of chronic lymphocytic leukemia (CLL):

- in combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate
- in combination with fludarabine and cyclophosphamide for the treatment of patients with relapse CLL
- for extended treatment of patients who are in complete or partial response
- for the treatment of patients with CLL refractory to fludarabine and alemtuzumab

FDA APPROVED DOSING

Previously untreated CLL in combination with chlorambucil recommended dosage and schedule is:

- 300 mg on Day 1, followed by 1,000 mg on Day 8 (Cycle 1)
- 1,000 mg on Day 1 of subsequent 28-day cycles for a minimum of 3 cycles until best response or a maximum of 12 cycles.

Relapsed CLL in combination with fludarabine and cyclophosphamide recommended dosage and schedule is:

- 300 mg on Day 1 followed by 1,000 mg on Day 8 (Cycle 1)
- 1,000 mg on Day 1 of subsequent 28-day cycles for a maximum of 6 cycles

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OFATUMUMAB (NSA)

FDA APPROVED INDICATION (CONTINUED)

Extended treatment in CLL recommended dosage schedule is:

- 300 mg on Day 1, followed by
- 1,000 mg 1 week later on Day 8, followed by
- 1,000 mg 7 weeks later and every 8 weeks thereafter for up to a maximum of 2 years

Refractory CLL recommended dosage and schedule is:

- 300 mg initial dose, followed 1 week later by
- 2000 mg weekly for 7 doses, followed 4 weeks later by
- 2000 mg every 4 weeks for 4 doses.

REFERENCES

- Arzerra [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/17

Created: 11/09

Client Approval: 12/16

P&T Approval: 11/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OLARATUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OLARATUMAB	LARTRUVO	43867		

GUIDELINES FOR USE

1. Is the request for continuation of Lartruvo therapy (i.e., patient is currently on Lartruvo)?

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 soft tissue sarcoma (STS) and meet **ALL** of the following criteria?

- The requested medication will be used in combination with doxorubicin for the first 8 cycles
- The histologic subtype of sarcoma (e.g., undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen
- The patient is not amenable to curative treatment with radiotherapy or surgery

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **OLARATUMAB (Lartruvo)** requires a diagnosis of soft tissue sarcoma. In addition, the following criteria must be met:

For the diagnosis of soft tissue sarcoma, approval requires:

- The request is for continuation of Lartruvo therapy (i.e., patient is currently on Lartruvo)
- The requested medication will be used in combination with doxorubicin for the first 8 cycles
- The histologic subtype of sarcoma (e.g., undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen
- The patient is not amenable to curative treatment with radiotherapy or surgery

RATIONALE

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

REFERENCES

- Lartruvo [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/11/19

Created: 11/16

Client Approval: 02/19

P&T Approval: 11/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

Generic	Brand	HICL	GCN	Exception/Other
OMADACYCLINE	NUZYRA		45478	

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 (45478) 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 (45478) 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 (45478) 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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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 (45478) 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, cephalixin, 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 (45478) 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 ABSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) 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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **OMADACYCLINE (Nuzyra)** requires a diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin or skin structure infection (ABSSSI). In addition, the following criteria must also be met:

For the diagnosis of community-acquired bacterial pneumonia (CABP), approval requires:

- 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 isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae*
- The patient meets **ONE** of the following criteria:
 - Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** 2) the culture is susceptible to Nuzyra
 - Antimicrobial susceptibility test is unavailable, and 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)

For the diagnosis of acute bacterial skin or skin structure infection (ABSSSI), approval also requires all of the following:

- The patient is 18 years of age or older
- The 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*
- The patient meets **ONE** of the following criteria:
 - Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin), **AND** 2) the culture is susceptible to Nuzyra
 - Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

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.; October 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OMALIZUMAB	XOLAIR	25399		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic idiopathic urticaria (CIU) and still experiences hives on most days of the week for at least 6 weeks **AND** meets all of the following criteria?
 - The patient is 12 years of age or older
 - The patient has tried a high dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) **AND** leukotriene antagonist for at least 2 weeks
 - Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

If yes, **approve for 24 weeks by GPID for the requested product as follows:**

- **Xolair 150mg vial (GPID 19966) with a quantity limit of #2 vials per 28 days.**
- **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #2mL per 28 days.**
- **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #2mL per 28 days.**

APPROVAL TEXT: Renewal requires a diagnosis of chronic idiopathic urticaria (CIU).

If no, continue to #2.

2. Does the patient have moderate to severe persistent asthma and meet **ALL** the following criteria?
 - The patient is 6 years of age or older
 - The patient has a positive skin prick or RAST test to a perennial aeroallergen
 - The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
 - The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
 - The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)

(Initial criteria continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

- The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
- Xolair will be used as add-on maintenance treatment
- The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
- Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

If yes, **approve for 12 months by GPID for the requested product as follows:**

- **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
- **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
- **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

APPROVAL TEXT: Renewal for the diagnosis of moderate to severe persistent asthma requires all of the following:

- The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
- The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
- The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **OMALIZUMAB (Xolair)** requires a diagnosis of chronic idiopathic urticaria or moderate to severe persistent asthma. In addition, the following criteria must also be met:

For patients with chronic idiopathic urticaria (CIU), approval requires:

- The patient is 12 years of age or older
- The patient still experiences hives on most days of the week for at least 6 weeks
- The patient has tried a high dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) **AND** leukotriene antagonist for at least 2 weeks
- Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

For patients with moderate to severe persistent asthma, approval requires:

- The patient is 6 years of age or older
- The patient has a positive skin prick or RAST test to a perennial aeroallergen
- The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
- The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
- Xolair will be used as add-on maintenance treatment
- The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
- Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic idiopathic urticaria (CIU)?

If yes, **approve for 12 months by GPID for the requested product as follows:**

- **Xolair 150mg vial (GPID 19966) with a quantity limit of #2 vials per 28 days.**
- **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #2mL per 28 days.**
- **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #2mL per 28 days.**

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?
- The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
 - The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), **OR** Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Was the patient treated with a maintenance therapy regimen of oral corticosteroids prior to initiation of Xolair?

If yes, continue to #4.

If no, **approve for 12 months by GPID for the requested product as follows:**

- **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
- **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
- **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

5. Has the patient decreased their total daily dose of oral corticosteroids from baseline?

If yes, **approve for 12 months by GPID for the requested product as follows:**

- **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
- **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
- **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL 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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **OMALIZUMAB (Xolair)** renewal requires a diagnosis of moderate to severe persistent asthma or chronic idiopathic urticaria. In addition, the following criteria must also be met:

For patients with moderate to severe persistent asthma, approval requires:

- The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
- The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
- The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

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. September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 08/03

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ONASEMNOGENE ABEPARVOVEC-XIOI	ZOLGENSMA	45760		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of the limbs, permanent ventilator dependence)?

If yes, do not approve.

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 spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?

- The patient is less than 2 years of age
- Therapy is prescribed by or in consultation with a neuromuscular specialist or SMA specialist at a SMA Specialty Center
- The patient has documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (*SMN1*) mutations (i.e., deletions and/or point mutations)
- The patient does **NOT** have anti-adenovirus-associated virus vector (anti-AAV9) antibody titers greater than 1:50 as determined by an enzyme-linked immunosorbent assay (ELISA)

If yes, **approve for one fill per lifetime.**

If no, do not approve.

DENIAL TEXT: The guideline named **ONASEMNOGENE ABEPARVOVEC-XIOI (Zolgensma)** requires a diagnosis of spinal muscular atrophy (SMA). In addition, the following criteria must be met:

- The patient is less than 2 years of age
- Therapy is prescribed by or in consultation with a neuromuscular specialist or SMA specialist at a SMA Specialty Center
- The patient has documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (*SMN1*) mutations (i.e., deletions and/or point mutations)
- The patient does **NOT** have anti-adenovirus-associated virus vector (anti-AAV9) antibody titers greater than 1:50 as determined by an enzyme-linked immunosorbent assay (ELISA)
- The patient does **NOT** have advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of the limbs, permanent ventilator dependence)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)

RATIONALE

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

REFERENCES

- Zolgensma [Prescribing Information]. Bannockburn, IL: AveXis, Inc., May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 06/17/19

Created: 06/19

Client Approval: 06/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACLITAXEL PROTEIN-BOUND

Generic	Brand	HICL	GCN	Exception/Other
PACLITAXEL PROTEIN-BOUND	ABRAXANE	26856		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer?

If yes, continue to #2.

If no, continue to #3.

2. Has the patient previously tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) or paclitaxel?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

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 locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) or Small Cell Lung Cancer (SCLC)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

If no, continue to #4.

4. Does the patient have a diagnosis of metastatic adenocarcinoma of the pancreas?

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACLITAXEL PROTEIN-BOUND

GUIDELINES FOR USE (CONTINUED)

5. Is the requested medication being used in combination with gemcitabine?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of metastatic breast cancer and trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) or paclitaxel; or a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) or Small Cell Lung Cancer (SCLC); or a diagnosis of metastatic adenocarcinoma of the pancreas and will be used in combination with gemcitabine.

RATIONALE

Based on FDA approved indications and NCCN recommendations. Abraxane is indicated for treatment of locally advanced or metastatic NSCLC as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; metastatic breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy; and metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. NCCN recommends Abraxane as a first line therapy for patients with advanced NSCLC with performance status of 0-1 and as a substitute for paclitaxel or docetaxel among patients who have experienced hypersensitivity reactions or in whom the standard premedications are contraindicated.

The recommended dose of Abraxane for metastatic breast cancer is 260 mg/m² intravenously over 30 minutes every 3 weeks. The recommended dosage for Non-Small Cell Lung Cancer is 100 mg/m² intravenously over 30 minutes on Days 1, 8, and 15 of each 21-day cycle; carboplatin AUC 6 mg•min/mL is given intravenously on Day 1 of each 21 day cycle immediately after Abraxane administration. The recommended dose for adenocarcinoma of the pancreas is 125 mg/m² intravenously over 30-40 minutes on Days 1, 8, and 15 of each 28-day cycle; administer gemcitabine on Days 1, 8, and 15 of each 28-day cycle immediately after Abraxane.

NCCN guidelines recognize multiple chemotherapy treatment options for recurrent or metastatic breast cancer. Abraxane is considered a nonpreferred single agent therapy.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACLITAXEL PROTEIN-BOUND

RATIONALE (CONTINUED)

Preferred Single Agents	Other Single Agents	Combination Regimens
doxorubicin	cyclophosphamide	cyclophosphamide, doxorubicin, fluorouracil (FAC/CAF)
pegylated liposomal doxorubicin	carboplatin	fluorouracil, epirubicin, cyclophosphamide (FEC)
paclitaxel	docetaxel	doxorubicin, cyclophosphamide (AC)
Xeloda	Abraxane	epirubicin, cyclophosphamide (EC)
gemcitabine	cisplatin	cyclophosphamide, methotrexate, fluorouracil (CML)
Halaven	Ixempra	docetaxel, Xeloda
vinorelbine	epirubicin	gemcitabine, paclitaxel
		gemcitabine carboplatin
		paclitaxel, Avastin

Abraxane versus Paclitaxel: Advanced NSCLC

A phase 3 trial compared Abraxane (100mg/m² weekly) with carboplatin to traditional solvent bound paclitaxel (200 mg/m² weekly) with carboplatin in untreated patients with stage IIIB to IV NSCLC. Abraxane demonstrated a significantly higher ORR than paclitaxel (33 versus 25 percent). There was a non-significant approximately 10 percent improvement in progression-free survival (6.3 v 5.8 months; HR, 0.902) and overall survival (12.1 v 11.2 months; HR, 0.922) in the Abraxane arm versus the paclitaxel arm, respectively.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACLITAXEL PROTEIN-BOUND

RATIONALE (CONTINUED)

**Efficacy Results from Randomized Non-Small Cell Lung Cancer Trial (Intent-to-Treat Population)
From Abraxane Prescribing Information**

	ABRAXANE (100mg/m² weekly) + carboplatin (N = 521)	Paclitaxel Injection (200mg/m² every 3 weeks) + carboplatin (N = 531)
Overall Response Rate (ORR)		
Confirmed complete or partial overall response, n (%)	107 (33%)	132 (25%)
95% CI	28.6,36.7	21.2,28.5
P-value (Chi-Square test)	0.005	
Median DoR in months (92% CI)	6.9 (5.6,8.0)	6.0 (5.6,7.1)
Overall Response Rate by Histology		
Carcinoma/Adenocarcinoma	66/254 (26%)	71/264 (27%)
Squamous Cell Carcinoma	94/229 (41%)	54/221 (24%)
Large Cell Carcinoma	3/9 (33%)	2/13 (15%)
Other	7/29 (24%)	5/33 (15%)

CI = confidence interval; DoR = Duration of response

FDA APPROVED INDICATION

Abraxane is a microtubule inhibitor indicated for the treatment of:

- Metastatic Breast Cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PACLITAXEL PROTEIN-BOUND

REFERENCES

- Celgene Corporation. Abraxane package insert. Summit, NJ. September 2013.
- National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer. (Version 3.2013).
- Celgene Corporation. Abraxane (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) Prescribing Information. Drugs at FDA. [Online] September 2013. [Cited: October 7, 2013.]
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name
- Socinski MA, Bondarenko I, Karaseva NA, et al. Weekly nab-paclitaxel in combination with carboplatin versus solvent-based paclitaxel plus carboplatin as first-line therapy in patients with advanced non-small-cell lung cancer: final results of a phase III trial. J Clin Oncol. [Online] June 10, 2012. [Cited: October 7, 2013.] <http://www.ncbi.nlm.nih.gov/pubmed/22547591>
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- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Small Cell Lung Cancer Version 2.2014. [Online] September 17, 2013. [Cited: September 25, 2013.] http://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 08/13

Client Approval: 11/13

P&T Approval: 11/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PALIVIZUMAB	SYNAGIS	18564		

This drug requires a written request for prior authorization. Please use the drug specific medication request form.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient under 12 months of age?

If yes, continue to #2.

If no, continue to #11.

2. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia (BPD) as defined below?

- Gestational age < 32 weeks and

- Patient required greater than 21% supplemental oxygen for at least the first 28 days after birth

(Note: This does not include respiratory distress in the newborn, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)

If yes, continue to #13.

If no, continue to #3.

3. Is the patient profoundly immunocompromised during the RSV season?

If yes, continue to #13.

If no, continue to #4.

4. Did the patient undergo solid-organ transplantation during the RSV season?

If yes, continue to #13.

If no, continue to #5.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have **ONE** of the following congenital heart disease conditions?
- acyanotic heart disease requiring medication to control chronic heart failure (for example, furosemide, epinephrine, dopamine, lidocaine, milrinone, atenolol, propranolol, amlodipine, clonidine) and will require cardiac surgical procedures, or
 - patient has moderate or severe pulmonary hypertension, or
 - cyanotic heart defect patient and medication made in consultation with a pediatric cardiologist (**Note:** This does not include patients with hemodynamically insignificant heart disease, infants with lesions adequately corrected by surgery, infants with mild cardiomyopathy who are not receiving medical therapy for the condition.)

If yes, continue to #13.

If no, continue to #6.

6. Was the patient born prematurely?

If yes, continue to #8.

If no, continue to #7.

7. Does the patient have congenital abnormalities of the airways (anatomic pulmonary abnormalities) or neuromuscular disease that compromises the handling of respiratory secretions?

If yes, continue to #13.

If no, continue to #8.

8. Was the patient born at less than 29 weeks gestational age?

If yes, continue to #13.

If no, continue to #9.

9. Is the patient an American Navajo or American White Mount Apache infant?

If yes, continue to #13.

If no, continue to #10.

10. Is the patient an Alaska native infant?

If yes, continue to #13.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

11. Is the patient younger than 24 months of age?

If yes, continue to #12.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

12. Does the patient meet **ONE** of the following criteria?

- profoundly immunocompromised during the RSV season
- chronic lung disease of prematurity **AND** requires medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to the start of the second RSV season
- undergo solid-organ transplantation during RSV season

If yes, continue to #13.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

13. **Approve for up to 5 months by HICL (do not enter quantity limit on number of vials) as follows: (Note: Enter the start date as requested, no earlier than October 1st of the current year. End date must be within 5 months and no later than April of the following year.)**

- **Approve with a start date of October of current year and an end date in February of the following year (10 fill counts).**
- **Approve with a start date of November of current year and an end date in March of the following year (10 fill counts).**
- **Approve with a start date of December of current year and an end date in April of the following year (10 fill counts).**
- **Approve with a start date of January of current year and an end date in April of current year (8 fill counts).**
- **Approve with a start date of February of current year and an end date in April of current year (6 fill counts).**
- **Approve with a start date of March of current year and an end date in April of current year (4 fill counts).**
- **Approve with a start date of April of current year and approved for 1 month (2 fill counts).**

Note: For requests for start date, earlier than October of current year or with an end date after April of following year, please refer to the CDC website to verify the RSV season for the specified region.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **PALIVIZUMAB (Synagis)** requires that the patient be either less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV) season. In addition, the following criteria must be met:

For patients less than 12 months old, ONE of the following criteria must be met:

- gestational age of less than 29 weeks
- chronic lung disease of prematurity, as defined as gestational age of less than 32 weeks and requiring greater than 21% supplemental oxygen for at least the first 28 days after birth
- profoundly immunocompromised during RSV season
- underwent solid-organ transplantation during RSV season
- congenital heart disease conditions such as acyanotic heart disease requiring medication to control chronic heart failure, moderate to severe pulmonary hypertension, or cyanotic heart defect and medication made in consultation with a pediatric cardiologist
- congenital abnormalities of the airways or neuromuscular disorder that compromises the handling of respiratory secretions
- American Navajo or American White Mount Apache infant, Alaska native infant born prematurely

For patients less than 24 months old, ONE of the following criteria must be met:

- chronic lung disease of prematurity and require medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to start of the second RSV season
- underwent Solid-organ transplantation during RSV season
- profoundly immunocompromised during RSV season

RENEWAL CRITERIA

1. Is the patient younger than 24 months of age?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Did the patient undergo cardiopulmonary bypass surgery during their RSV prophylaxis season?

If yes, **approve for 1 month by HICL with a fill count of 2 (do not enter quantity limit on number of vials).**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Is this a request for a second year of coverage (e.g., a previous approval in the previous RSV season)?

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 have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia (BPD) and requires medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to start of the second RSV season; (**Note:** This does not include respiratory distress in the newborn period, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)?)

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

5. Approve for up to 5 months by HICL (do not enter a quantity limit on the number of vials) as follows: (Note: Enter the start date as requested, no earlier than October 1st of the current year. End date must be within 5 months and no later than April of the following year.)
- Approve with a start date of October of current year and an end date in February of the following year (10 fill counts).
 - Approve with a start date of November of current year and an end date in March of the following year (10 fill counts).
 - Approve with a start date of December of current year and an end date in April of the following year (10 fill counts).
 - Approve with a start date of January of current year and an end date in April of current year (8 fill counts).
 - Approve with a start date of February of current year and an end date in April of current year (6 fill counts).
 - Approve with a start date of March of current year and an end date in April of current year (4 fill counts).
 - Approve with a start date of April of current year and approved for 1 month (2 fill counts).

Note: For requests for start date earlier than October of current year or with an end date after April of following year, please refer to the CDC website to verify the RSV season for the specified region.

RENEWAL DENIAL TEXT: Renewal of **PALIVIZUMAB (Synagis)** requires that the patient is under 24 months of age and meets **ONE** of the following criteria:

- Patient underwent cardiopulmonary bypass surgery during RSV prophylaxis season, or
- Patient has chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 month period before the start of the second RSV season

RATIONALE

To ensure the optimal use of palivizumab in high-risk patients for the prophylaxis of RSV by following the most recent American Academy of Pediatrics guidelines for the use of palivizumab for the prevention of serious RSV infections. Variations in the onset and offset of the RSV season in different regions may affect the timing of palivizumab administration. A maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons. RSV seasons within the continental United States may start in October/November and end in March/April.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

FDA APPROVED INDICATIONS

For the prevention of serious, lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

REFERENCES

- MedImmune, Inc. Synagis package insert. Gaithersburg, MD. March 2009.
- American Academy of Pediatrics, Committee on Infectious Diseases and Committee on Fetus and Newborn. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics 2003; 112(6):1442-1446.
- American Academy of Pediatrics. Policy statement – modified recommendations for use of palivizumab for prevention of respiratory syncytial virus infections. Pediatrics 2009;124:1694-1701.
- American Academy of Pediatrics, Subcommittee on Diagnosis and Management of Bronchiolitis. Pediatrics 2006; 118; 1774-1798.
- American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infections. Pediatrics 2014;134:415-420
- Reducing RSV hospitalizations. AAP modifies recommendations for use of palivizumab in high-risk infants, young children. AAP News 2009; 30:1.
- Thomas Healthcare. Palivizumab. DRUGDEX® System [database online]. Greenwood Village, CO. [Accessed: August 7 2009].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/01/18

Created: 08/09

Client Approval: 01/18

P&T Approval: 11/15



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PANITUMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PANITUMUMAB	VECTIBIX	34054		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) and meet **ONE** of the following criteria?
 - Vectibix will be used as monotherapy **AND** the patient has been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy
 - Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **PANITUMUMAB (Vectibix)** requires a diagnosis of metastatic colorectal cancer (mCRC) with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use). In addition, **ONE** of the following criteria must be met:

- Vectibix will be used as monotherapy **AND** the patient has been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy
- Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

RATIONALE

To ensure appropriate use of Vectibix consistent with FDA approved indication.

The FOLFOX regimen includes leucovorin calcium (folinic acid), fluorouracil, oxaliplatin.

FDA APPROVED INDICATIONS

Vectibix is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) metastatic colorectal carcinoma (mCRC):

- In combination with FOLFOX for first-line treatment. **OR**
- As monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.

Limitation of Use: Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC or for whom RAS mutation status is unknown.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PANITUMUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

The recommended dose of Vectibix is 6 mg/kg every 14 days administered as an intravenous infusion over 60 minutes (\leq 1000 mg) or 90 minutes ($>$ 1000 mg). Reduce infusion rate by 50% for mild reactions.

REFERENCES

- Vectibix [Prescribing Information]. Thousand Oaks, CA: Amgen Inc., June 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/01/18

Created: 02/13

Client Approval: 02/18

P&T Approval: 10/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PATISIRAN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PATISIRAN	ONPATTRO	45155		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
 - Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm the presence of TTR protein
 - DNA genetic sequencing to confirm hATTR
 - The requested medication is being prescribed by or given in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
 - Physician attestation that the patient has Stage 1 or 2 polyneuropathy

If yes, **approve for 6 months by HICL with a quantity limit of 15mL (30mg) per 21 days.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PATISIRAN (Onpattro)** requires a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient has a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
 - Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm the presence of TTR protein
 - DNA genetic sequencing to confirm hATTR
- The requested medication is being prescribed by or given in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
- Physician attestation that the patient has Stage 1 or 2 polyneuropathy

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PATISIRAN (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary TTR amyloidosis (hATTR) with polyneuropathy **AND** meet the following criterion?

- Physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (30mg) per 21 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PATISIRAN (Onpattro)** requires a diagnosis of hereditary TTR amyloidosis (hATTR) with polyneuropathy and physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

RATIONALE

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

REFERENCES

- Onpattro [Prescribing Information]. Cambridge, MA: Alnylam; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 08/18

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGAPTANIB

Generic	Brand	HICL	GCN	Exception/Other
PEGAPTANIB SODIUM	MACUGEN	26805		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is this medication being prescribed by an ophthalmologist and/or retina specialist?

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 neovascular (wet) age-related macular degeneration (AMD)?

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 receiving treatment in both eyes at this time?

If yes, **approve for duration of 12 months by HICL for up to 18 syringes (2 syringes per 6 weeks).**

If no, and a single eye is being treated, **approve for duration of 12 months by HICL for up to 9 syringes (1 syringe per 6 weeks).**

DENIAL TEXT: Our guideline for **PEGAPTANIB** requires a diagnosis of neovascular (wet) age-related macular degeneration (AMD) and that the medication is being prescribed by an ophthalmologist and/or retina specialist.

RATIONALE

To ensure appropriate use of MACUGEN consistent with FDA approved indication.

FDA-APPROVED INDICATIONS

Macugen is indicated for the treatment of neovascular (wet) age-related macular degeneration.

REFERENCES

- Macugen [Prescribing Information]. San Dimas, CA: Eyetech Inc.; October 2011.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGAPTANIB

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/14

Created: 05/14

Client Approval: 05/14

P&T Approval: 05/14



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGLOTICASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PEGLOTICASE	KRYSTEXXA	37154		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic gout that is refractory to conventional therapy and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - There is physician attestation of symptomatic gout as evidenced by **ONE** of the following:
 - At least 3 or more gout flares in the previous 18 months
 - History of at least 1 gout tophus
 - Gouty arthritis
 - The patient has a baseline serum uric acid levels ≥ 8 mg/dL while on conventional gout medications (e.g., allopurinol, lesinurad)
 - The patient does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency
 - The patient will not be on concurrent urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) while using pegloticase
 - The patient has experienced failure, contraindication, intolerance or inadequate response to previous therapy with a maximum tolerated dose for **TWO** conventional gout medications for at least 3 months (e.g., allopurinol, probenecid, lesinurad)

If yes, **approve for 6 months by HICL for #2mL per 28 days.**

APPROVAL TEXT: Renewal requires sustained serum uric acid levels below 6 mg/dL.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PEGLOTICASE (Krystexxa)** requires a diagnosis of chronic gout that is refractory to conventional therapy. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is physician attestation of symptomatic gout as evidenced by **ONE** of the following:
 - At least 3 or more gout flares in the previous 18 months
 - History of at least 1 gout tophus
 - Gouty arthritis

(Initial denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGLOTICASE (NSA)

INITIAL CRITERIA (CONTINUED)

- The patient has a baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications (e.g., allopurinol, lesinurad)
- The patient does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency
- The patient will not be on concurrent urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) while using pegloticase
- The patient has experienced failure, contraindication, intolerance or inadequate response to previous therapy with a maximum tolerated dose for **TWO** conventional gout medications for at least 3 months (e.g., allopurinol, probenecid, lesinurad)

RENEWAL CRITERIA

1. Does the patient have sustained serum uric acid levels below 6 mg/dL?

If yes, **approve for 12 months by HICL for #2mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level below 6 mg/dL for renewal.

RATIONALE

To ensure appropriate utilization of Krystexxa based on the FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Krystexxa is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Important Limitations of Use:

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

DOSAGE AND ADMINISTRATION

The recommended dose and regimen of Krystexxa for adult patients is 8 mg (uricase protein) given as an intravenous infusion every two weeks. Do not administer as an intravenous push or bolus. The pegloticase admixture should only be administered by intravenous infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump.

It is recommended that before starting Krystexxa patients discontinue oral urate-lowering medications and not institute therapy with oral urate-lowering agents while patients are on Krystexxa therapy. Monitor serum uric acid levels before each infusion. Patients should be pre-medicated with antihistamines and corticosteroids.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGLOTICASE (NSA)

REFERENCES

- Krystexxa [Prescribing Information]. Horizon Pharma Rheumatology LLC. Lake Forest, IL. Jul 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PEMBROLIZUMAB	KEYTRUDA	41369		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma?

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of melanoma with involvement of lymph node(s) following complete resection and meet the following criterion?

- The requested medication will be used as an adjuvant treatment

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

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 not received prior systemic chemotherapy treatment for metastatic NSCLC
- The tumor is classified as nonsquamous (e.g., adenocarcinoma, large cell carcinoma)
- The medication is used in combination with pemetrexed and platinum chemotherapy
- The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #4.

4. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?

- The patient has not received prior systemic chemotherapy treatment for metastatic NSCLC
- The tumor is classified as metastatic squamous
- The medication is used in combination with carboplatin and either paclitaxel or nab-paclitaxel

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #5.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of stage III non-small cell lung cancer (NSCLC) AND meet ALL of the following criteria?

- The patient is not a candidate for surgical resection or definitive chemoradiation
- The patient has not received prior systemic chemotherapy treatment for stage III NSCLC
- The medication will be given as a single agent (i.e., not in combination with chemotherapy)
- NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an FDA-approved test
- The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #6.

6. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?

- The patient has not received prior systemic chemotherapy treatment for metastatic NSCLC
- The medication will be given as a single agent (i.e., not in combination with chemotherapy)
- NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an FDA-approved test
- The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #7.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?

- The medication will be given as a single agent (i.e., not in combination with chemotherapy)
- NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an FDA-approved test
- The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
- Disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #8.

8. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?

- The medication will be given as a single agent (i.e., not in combination with chemotherapy)
- NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an FDA-approved test
- The patient has an anaplastic lymphoma kinase (ALK) genomic tumor aberration
- Disease progression on or after treatment with **ALL** of the following:
 - Platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - ALK-directed therapy [e.g., Xalkori (crizotinib), Zykadia (ceritinib)]

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #9.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?

- The medication will be given as a single agent (i.e., not in combination with chemotherapy)
- NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an FDA-approved test
- The patient has an epidermal growth factor receptor (EGFR) genomic tumor aberration
- Disease progression on or after treatment with **ALL** of the following:
 - Platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - EGFR-directed therapy [e.g., Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #10.

10. Does the patient have a diagnosis of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) **AND** meets the following criterion?

- Disease progression on or after treatment a with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #11.

11. Does the patient have a diagnosis of classical Hodgkin Lymphoma (cHL) **AND** meet **ONE** of the following criteria?

- The patient has refractory classical Hodgkin Lymphoma (cHL)
- The patient has relapsed after 3 or more prior lines of therapy

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #12.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

12. Does the patient have a diagnosis of primary mediastinal large B-cell lymphoma (PMBCL) **AND** meet **ONE** of the following criteria?

- The patient has refractory PMBCL
- The patient has relapsed after 2 or more prior lines of therapy

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #13.

13. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma **AND** meet **ONE** of the following criteria?

- Disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- The patient is not eligible to receive cisplatin-containing chemotherapy and patient's tumors express PD-L1 [Combined Positive Score (CPS) \geq 10] as determined by an FDA approved test
- The patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #14.

14. Does the patient have a diagnosis of an unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient **AND** meet **ONE** of the following criteria?

- The patient has a solid tumor that has progressed following prior treatment and has no satisfactory alternative treatment options
- The patient has colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #15.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

15. Does the patient have a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma **AND** meet **ALL** of the following criteria?

- The patient has tumors that express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test
- Disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #16.

16. Does the patient have a diagnosis of recurrent or metastatic cervical cancer **AND** meet **ALL** of the following criteria?

- The patient has disease progression on or after chemotherapy
- The patient has tumors that express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #17.

17. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?

- The patient has previously been treated with sorafenib

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #18.

18. Does the patient have a diagnosis of recurrent locally advanced or metastatic Merkel cell carcinoma?

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, continue to #19

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

19. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet ALL of the following criteria?

- The patient has not received prior systemic chemotherapy treatment for renal cell carcinoma (RCC)
- The medication is used in combination with axitinib

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- **50mg powder (GPID 37028): 4 vials per 21 days.**
- **100mg/4mL (GPID 37754): 8mL per 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **PEMBROLIZUMAB (Keytruda)** requires a diagnosis of unresectable or metastatic melanoma, melanoma with involvement of lymph node(s) following complete resection, stage III or metastatic non-small cell lung cancer (NSCLC), recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), classical Hodgkin Lymphoma (cHL), locally advanced or metastatic urothelial carcinoma, unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient, recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, recurrent or metastatic cervical cancer, primary mediastinal large B-cell lymphoma (PMBCL), hepatocellular carcinoma (HCC), recurrent locally advanced or metastatic Merkel cell carcinoma, or advanced renal cell carcinoma (RCC). The following criteria must also be met:

For patients with a diagnosis of melanoma with involvement of lymph node(s) following complete resection, approval requires:

- The requested medication will be used as adjuvant treatment

For patients with non-small cell lung cancer (NSCLC), approval requires:

- *For patients who have not received prior systemic chemotherapy treatment for metastatic NSCLC:*
 - *For patients receiving pembrolizumab in combination with pemetrexed and platinum chemotherapy, approval also requires:*
 - The tumor is classified as nonsquamous (e.g., adenocarcinoma, large cell carcinoma)
 - The patient does not have anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations
 - *For patients receiving pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel, approval also requires:*
 - The tumor is classified as metastatic squamous

(Denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- *For patients receiving pembrolizumab as a single agent (i.e., not in combination with chemotherapy), approval also requires:*
 - NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) greater than or equal to 1%] as determined by an FDA-approved test
 - The patient does not have anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations
- *For patients who have not received prior systemic chemotherapy treatment for stage III NSCLC, and are receiving pembrolizumab as a single agent (i.e., not in combination with chemotherapy), approval also requires:*
 - NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) greater than or equal to 1%] as determined by an FDA-approved test
 - The patient does not have ALK or EGFR genomic tumor aberrations
 - The patient is not a candidate for surgical resection or definitive chemoradiation
- *For patients who have received prior systemic chemotherapy treatment for metastatic NSCLC and are receiving pembrolizumab as a single agent (i.e., not in combination with chemotherapy), approval also requires:*
 - NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) greater than or equal to 1%] as determined by an FDA-approved test
 - *For patients who do not have anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations, approval also requires:*
 - Disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - *For patients who have anaplastic lymphoma kinase (ALK) genomic tumor aberrations, approval also requires:*
 - Disease progression on or after treatment with ALK-directed therapy [e.g., Xalkori (crizotinib), Zykadia (ceritinib)] and with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - *For patients who have epidermal growth factor receptor (EGFR) genomic tumor aberrations, approval also requires:*
 - Disease progression on or after treatment with EGFR-directed therapy [e.g., Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)] and with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

For patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), approval requires:

- Disease progression on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

For patients with classical Hodgkin Lymphoma (cHL), approval requires ONE of the following:

- The patient has refractory classical Hodgkin Lymphoma (cHL)
- The patient has relapsed after 3 or more prior lines of therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

For patients with primary mediastinal large B-cell lymphoma (PMBCL), approval requires ONE of the following:

- The patient has refractory PMBCL
- The patient has relapsed after 2 or more prior lines of therapy

For patients with locally advanced or metastatic urothelial carcinoma, approval requires ONE of the following:

- Disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g. cisplatin, carboplatin, oxaliplatin)
- The patient is not eligible to receive cisplatin-containing chemotherapy and patient's tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test
- The patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status

For patients with unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient, approval requires one of the following:

- The patient has a solid tumor that has progressed following prior treatment and has no satisfactory alternative treatment options
- The patient has colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

For patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires ALL of the following:

- The patient has tumors that express PD-L1 [Combined Positive Score (CPS) greater than or equal to 1] as determined by an FDA-approved test
- Disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy

For patients with recurrent or metastatic cervical cancer, approval requires:

- The patient has disease progression on or after chemotherapy
- The patient has tumors that express PD-L1 [Combined Positive Score (CPS) greater than or equal to 1] as determined by an FDA-approved test

For patients with hepatocellular carcinoma, approval requires:

- The patient has previously been treated with sorafenib

For patients with advanced renal cell carcinoma (RCC), approval requires:

- The patient has not received prior systemic chemotherapy treatment for renal cell carcinoma (RCC)
- The medication is used in combination with axitinib

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

RATIONALE

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

REFERENCES

- Keytruda [Prescribing Information]. Whitehouse Station, NJ: Merck & Co, Inc.; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/06/19

Created: 09/14

Client Approval: 04/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMETREXED (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PEMETREXED DISODIUM	ALIMTA	25905		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ONE** of the following criteria?
 - The requested medication is being used in combination with cisplatin for initial treatment
 - The requested medication is being used as a single agent, maintenance therapy and meet the following:
 - The patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The requested medication is being used for initial treatment
 - The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
 - The patient does not have EGFR or ALK genomic tumor aberrations

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The requested medication is being used as a single agent
 - The patient has received prior chemotherapy

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMETREXED (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of malignant pleural mesothelioma and meet **ALL** of the following criteria?
- The requested medication is being used in combination with cisplatin for initial treatment
 - The patient's disease is unresectable **OR** the patient is not a candidate for curative surgery

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **PEMETREXED (Alimta)** requires ONE of the following diagnoses and related criteria to be met:

For diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) approval requires ONE of the following:

- The requested medication is being used in combination with cisplatin for initial treatment
- The requested medication is being used as a single agent, maintenance therapy and meet the following:
 - The patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy

For diagnosis of metastatic, non-squamous, non-small cell lung cancer (NSCLC) approval requires:

- The requested medication is being used for initial treatment
- The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
- The patient does not have EGFR or ALK genomic tumor aberrations

For diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC), approval requires:

- The requested medication is being used as a single agent
- The patient has received prior chemotherapy

For diagnosis of malignant pleural mesothelioma, approval requires:

- The requested medication is being used in combination with cisplatin for initial treatment
- The patient's disease is unresectable **OR** the patient is not a candidate for curative surgery

RATIONALE

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

REFERENCES

- Alimta [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/25/19

Created: 11/13

Client Approval: 02/19

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PERTUZUMAB	PERJETA	39102		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 - The patient's breast cancer is HER2- positive
 - The patient has not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease
 - The requested medication will be used in combination with trastuzumab and docetaxel; (**PAC NOTE:** The patient must have an active prior authorization for trastuzumab [Herceptin] before proceeding)

If yes, please enter two approvals as follows:

- Approve for 1 month by HICL for #28mL (two 420mg/14mL) vials per 21 days.
- Approve for 11 months by HICL for #14mL (one 420mg/14mL) vial per 21 days with a start date of 22 days post the first approval start date.

If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) and meet ALL of the following criteria?
 - The patient's breast cancer is HER2- positive
 - The requested medication will be used in the neoadjuvant setting
 - The requested medication will be used in combination with trastuzumab and chemotherapy as part of a complete treatment regimen for early breast cancer; (**PAC NOTE:** The patient must have an active prior authorization for trastuzumab [Herceptin] before proceeding)

If yes, please enter two approvals as follows:

- Approve for 1 month by HICL for #28mL (two 420mg/14mL) vials per 21 days.
- Approve for 5 months by HICL for #14mL (one 420mg/14mL) vial per 21 days with a start date of 22 days post the first approval start date.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of early breast cancer and meet **ALL** of the following criteria?
- The patient's breast cancer is HER2- positive
 - The patient is at a high risk of recurrence
 - The requested medication will be used in the adjuvant setting
 - The requested medication will be used in combination with trastuzumab and chemotherapy;
(PAC NOTE: The patient must have an active prior authorization for trastuzumab [Herceptin] before proceeding)

If yes, please enter two approvals as follows:

- Approve for 1 month by HICL for #28mL (two 420mg/14mL) vials per 21 days.
- Approve for 11 months by HICL for #14mL (one 420mg/14mL) vial per 21 days with a start date of 22 days post the first approval start date.

If no, do not approve.

DENIAL TEXT: The guideline named **PERTUZUMAB (Perjeta)** requires a diagnosis of HER2- positive metastatic breast cancer, OR HER2- positive locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), OR HER2- positive early breast cancer. In addition, the following criteria must be met:

For the diagnosis of metastatic breast cancer, approval requires:

- The patient has not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease
- The requested medication will be used in combination with trastuzumab and docetaxel

For the diagnosis of locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), approval requires:

- The requested medication will be used in the neoadjuvant setting
- The requested medication will be used in combination with trastuzumab and chemotherapy as part of a complete treatment regimen for early breast cancer

For the diagnosis of early breast cancer, approval requires:

- The patient is at a high risk of recurrence
- The requested medication will be used in the adjuvant setting
- The requested medication will be used in combination with trastuzumab and chemotherapy

RATIONALE

To promote appropriate utilization of Perjeta based on FDA approved indication.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PERTUZUMAB (NSA)

FDA APPROVED INDICATIONS

Perjeta is a HER2/neu receptor antagonist indicated for:

- Use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
- Use in combination with trastuzumab and chemotherapy as:
 - Neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.
 - Adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

DOSAGE AND ADMINISTRATION

The initial dose of Perjeta is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks by a dose of 420 mg administered as an intravenous infusion over 30 to 60 minutes.

Metastitic Breast Cancer

When administered with Perjeta, the recommended initial dose of docetaxel is 75 mg/m² administered as an intravenous infusion. The dose may be escalated to 100 mg/m² administered every 3 weeks if the initial dose is well tolerated.

Neoadjuvant Treatment of Breast Cancer

Perjeta should be administered every 3 weeks for 3 to 6 cycles as part of one of the following treatment regimens for early breast cancer.

- Four preoperative cycles of Perjeta in combination with trastuzumab and docetaxel followed by 3 postoperative cycles of fluorouracil, epirubicin, and cyclophosphamide (FEC) as given in NeoSphere.
- Three or four preoperative cycles of FEC alone followed by 3 or 4 preoperative cycles of Perjeta in combination with docetaxel and trastuzumab as given in TRYPHAENA and BERENICE, respectively.
- Six preoperative cycles of Perjeta in combination with docetaxel, carboplatin, and trastuzumab (TCH) (escalation of docetaxel above 75 mg/m² is not recommended) as given in TRYPHAENA.
- Four preoperative cycles of dose-dense doxorubicin and cyclophosphamide (ddAC) alone followed by 4 preoperative cycles of Perjeta in combination with paclitaxel and trastuzumab as given in BERENICE Following surgery, patients should continue to receive Perjeta and trastuzumab to complete 1 year of treatment (up to 18 cycles).

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Adjuvant Treatment of Breast Cancer

Perjeta should be administered in combination with trastuzumab every 3 weeks for a total of 1 year (up to 18 cycles) or until disease recurrence or unmanageable toxicity, whichever occurs first, as part of a complete regimen for early breast cancer, including standard anthracycline and/or taxane-based chemotherapy as given in APHINITY. Perjeta and trastuzumab should start on Day 1 of the first taxane-containing cycle.

Patients should be selected based on HER2 protein overexpression or HER2 gene amplification in tumor specimens. Assessment of HER2 protein overexpression and HER2 gene amplification should be performed using FDA-approved tests specific for breast cancer by laboratories with demonstrated proficiency.

For delayed or missed doses, if the time between two sequential infusions is less than 6 weeks, the 420 mg dose of Perjeta should be administered. Do not wait until the next planned dose. If the time between two sequential infusions is 6 weeks or more, the initial dose of 840 mg Perjeta should be re-administered as a 60-minute intravenous infusion followed every 3 weeks thereafter by a dose of 420 mg administered as an intravenous infusion over 30 to 60 minutes. Perjeta should be discontinued if trastuzumab treatment is discontinued. Dose reductions are not recommended for Perjeta.

REFERENCES

- Genentech, Inc. Perjeta package insert. South San Francisco, CA. December 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/15/18

Created: 08/12

Client Approval: 12/17

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLERIXAFOR

Generic	Brand	HICL	GCN	Exception/Other
PLERIXAFOR	MOZOBIL	36021		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the prescription written or currently being supervised by a hematologist or an oncologist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Approval requires initiation or supervision by a hematologist or an oncologist and a diagnosis of non-Hodgkin's lymphoma or multiple myeloma.

2. Is the patient diagnosed with non-Hodgkin's lymphoma or multiple myeloma?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: Approval requires initiation or supervision by a hematologist or an oncologist and a diagnosis of non-Hodgkin's lymphoma or multiple myeloma.

3. Is the request for more than 4 vials?

If yes, obtain patient's weight in kg and **approve for one fill with the following quantity limits:**

- **IF GREATER THAN 100kg: up to #8 vials (24mg/1.2mL) for 1 day supply.**
 - **IF LESS THAN OR EQUAL TO 100kg: up to #4 vials (24mg/1.2mL) for 1 day supply.**
- If no, **approve for one fill up to #4 vials (24mg/1.2mL) for 1 day supply.**

RATIONALE

Ensure appropriate utilization based on FDA approved indication.

FDA APPROVED INDICATIONS

Plerixafor is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PLERIXAFOR

REFERENCES

- Genzyme Corporation. Mozobil package insert, Cambridge, Massachusetts, April 2010.
- Stewart DA, Smith C, et al. Pharmacokinetics and pharmacodynamics of plerixafor in patients with non-Hodgkin lymphoma and multiple myeloma. Biol Blood Marrow Transplant. 2009 Jan; 15(1):39-46.
- Stiff P, Micallef I, et al. Treatment with plerixafor in non-Hodgkin's lymphoma and multiple myeloma patients to increase the number of peripheral blood stem cells when given a mobilizing regimen of G-CSF: implications for the heavily pretreated patient. Biol Blood Marrow Transplant. 2009 Feb; 15(2):249-56.
- Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: June 27, 2011].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/09

Client Approval: 11/13

P&T Approval: 11/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PORFIMER

Generic	Brand	HICL	GCN	Exception/Other
PORFIMER SODIUM	PHOTOFRIN	11790		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication being used for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC)?

If yes, **approve once by HICL.**

If no, continue to #2.

2. Is the requested medication being used for the treatment of microinvasive endobronchial non-small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated?

If yes, **approve once by HICL.**

If no, continue to #3.

3. Is the requested medication being used for the palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy?

If yes, **approve once by HICL.**

If no, continue to #4.

4. Is the requested medication being used for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy?

If yes, **approve once by HICL.**

If no, do not approve.

DENIAL TEXT: Approval requires that requested medication is being used for, 1) the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or, 2) treatment of microinvasive endobronchial non small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated or, 3) the palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy or, 4) the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PORFIMER

RATIONALE

Based on FDA approved indications. Photofrin is indicated for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC; treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated; palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy; and ablation of high-grade dysplasia in Barrett’s esophagus patients who do not undergo esophagectomy.

Photofrin versus Nd: YAG Laser Therapy: Endobronchial NSCLC

Two randomized studies were conducted to compare Photofrin versus Nd:YAG laser therapy for reduction of obstruction and palliation of symptomatic patients with partially or completely obstructing endobronchial NSCLC. A course of therapy consisted of one injection of Photofrin (2 mg/kg administered as a slow intravenous injection over 3–5 minutes) followed by up to two nonthermal applications of 630 nm laser light. Assessments were made at one week and at monthly intervals after treatment. Objective tumor response rates (CR + PR), which demonstrate reduction of obstruction, were 59 percent for PDT and 58 percent for Nd:YAG at Week 1. The response rate at 1 month or later was 60 percent for PDT and 41 percent for Nd:YAG.

From Photofrin Prescribing Information

TABLE 11. Efficacy Results from Studies in Late-stage Obstructing Endobronchial Cancer – All Randomized Patients^a

EFFICACY PARAMETER	PDT	Nd:YAG
	N=102 % Patients	N=109 % Patients
OBJECTIVE TUMOR RESPONSE^b		
Week 1	59%	58%
Month 1 or later	60%	41% ^a
ATELECTASIS IMPROVEMENT^c	n=60	N=71
Week 1	35%	18%
Month 1 or later	35%	20%

^a Statistical comparisons were precluded by the amount of missing data at Month 1 or later (e.g., for tumor response, PDT 28% missing, Nd:YAG 38%).

^b CR+PR where CR = complete response (absence of bronchoscopically visible tumor) and PR = partial response (increase of ≥50% in the smallest luminal diameter; or any appearance of a lumen for completely obstructing tumors).

^c In patients with atelectasis at baseline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PORFIMER

FDA APPROVED INDICATIONS

Photofrin is a photodynamic therapy drug indicated for:

Esophageal Cancer

- Palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy

Endobronchial Cancer

- Treatment of microinvasive endobronchial non-small-cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated
- Reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC

High-Grade Dysplasia in Barrett's Esophagus

- Ablation of high-grade dysplasia (HGD) in Barrett's esophagus (BE) patients who do not undergo esophagectomy

REFERENCES

- Axcan Scandipharm Inc. Photofrin (porfimer sodium) for Injection Prescribing Information. Drugs at FDA. [Online] June 2011. [Cited: October 14, 2013.]
[HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRUGSATFDA/](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 11/13

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PRALATREXATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PRALATREXATE	FOLOTYN	36644		

GUIDELINES FOR USE

1. Will the requested medication be used for the treatment of a patient with relapsed or refractory peripheral T-cell lymphoma (PTCL)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **PRALATREXATE (Folotyn)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL).

RATIONALE

Promote appropriate utilization of **PRALATREXATE** based on FDA approved indication.

DOSAGE

The recommended dose of Folotyn is 30 mg/m² administered as an intravenous push over 3-5 minutes via the side port of a free-flowing 0.9% Sodium Chloride Injection, intravenous line once weekly for 6 weeks in 7-week cycles until progressive disease or unacceptable toxicity. The calculated dose of Folotyn should be aseptically withdrawn into a syringe for immediate use. Do not dilute Folotyn.

For patients with severe renal impairment (eGFR 15 to < 30 mL/min/1.73 m²), the recommended dose of Folotyn is 15 mg/m².

FDA APPROVED INDICATION

Folotyn is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.

REFERENCES

- Folotyn [Prescribing Information]. Westminster, CO: Spectrum Pharmaceuticals. May 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 08/16

Client Approval: 08/16

P&T Approval: 08/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAMUCIRUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RAMUCIRUMAB	CYRAMZA	41109		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma and meet the following criteria?
 - The requested medication will be used as a single agent or in combination with paclitaxel
 - The patient has experienced disease progression on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) **OR** platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis metastatic non-small cell lung cancer and meet the following criteria?
 - The requested medication will be used in combination with docetaxel
 - The patient has experienced disease progression on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin) **OR** if the patient has an EGFR or ALK genomic tumor aberration, there is disease progression on an FDA-approved therapy for these aberrations (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of metastatic colorectal cancer and meet the following criteria?
 - The requested medication will be used in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil)
 - The patient has experienced disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of hepatocellular carcinoma and meet the following criteria?
 - The requested medication will be used as a single agent
 - Patient has an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
 - Patient has been treated with sorafenib (Nexavar)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAMUCIRUMAB (NSA)

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **RAMUCIRUMAB (Cyramza)** requires a diagnosis of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, metastatic non-small cell lung cancer, metastatic colorectal cancer, or hepatocellular carcinoma. In addition, the following criteria must be met:

For the diagnosis of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval requires:

- The requested medication will be used as a single agent or in combination with paclitaxel
- The patient has experienced disease progression on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) **OR** platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

For the diagnosis of metastatic non-small cell lung cancer, approval requires:

- The requested medication will be used in combination with docetaxel
- The patient has experienced disease progression on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin) **OR** if the patient has an epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberration, there is disease progression on an FDA-approved therapy for these aberrations (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza

For the diagnosis of metastatic colorectal cancer, approval requires:

- The requested medication will be used in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil)
- The patient has experienced disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)

For the diagnosis of hepatocellular carcinoma, approval requires:

- The requested medication will be used as a single agent
- Patient has an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
- Patient has been treated with sorafenib (Nexavar)

RATIONALE

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

REFERENCES

- Cyramza [Prescribing Information]. Eli Lilly and Company: Indianapolis, IN. May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 04/14

Client Approval: 05/19

P&T Approval: 07/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RANIBIZUMAB	LUCENTIS	33861		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is this medication being prescribed by an ophthalmologist or retina specialist?

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 one of the following diagnoses?

- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

If yes, continue to #5.

If no, continue to #3.

3. Does the patient have one of the following diagnoses?

- Neovascular (wet) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)

If yes, continue to #6.

If no, continue to #4.

4. Does the patient have a diagnosis of myopic choroidal neovascularization (mCNV)?

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 12 months by GPID with the following quantity limits:**

- **0.3mg/0.05mL prefilled syringe (GPID 44547): #0.1mL (two 0.3mg prefilled syringes) per 4 weeks.**
- **0.3mg/0.05mL vial (GPID 32959): #0.1mL (two 0.3mg vials) per 4 weeks.**

If no, and a single eye is being treated, **approve for 12 months by GPID with the following quantity limits:**

- **0.3mg/0.05mL prefilled syringe (GPID 44547): #0.05mL (one 0.3mg prefilled syringes) per 4 weeks.**
- **0.3mg/0.05mL (GPID 32959): #0.05mL (one 0.3mg vial) per 4 weeks.**

6. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 12 months by GPID (27289 or 37135) with a quantity limit of #0.1mL (two 0.5mg vials or prefilled syringes) per 4 weeks.**

If no, and a single eye is being treated, **approve for 12 months by GPID (27289 or 37135) with a quantity limit of #0.05mL (one 0.5mg vial or prefilled syringe) per 4 weeks.**

7. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 3 months by GPID (27289 or 37135) with a quantity limit of #0.1mL (two 0.5mg vials or prefilled syringes) per 4 weeks.**

If no, and a single eye is being treated, **approve for 3 months by GPID (27289 or 37135) with a quantity limit of #0.05mL (one 0.5mg vial or prefilled syringe) per 4 weeks.**

DENIAL TEXT: The guideline named **RANIBIZUMAB (Lucentis)** requires a diagnosis of neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), macular edema following retinal vein occlusion (RVO), or myopic choroidal neovascularization (mCNV), and that the medication is prescribed by an ophthalmologist or retina specialist.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB (NSA)

RATIONALE

To ensure appropriate use of Lucentis consistent with its FDA approved indications and dosing.

FDA APPROVED INDICATIONS

Lucentis, a vascular endothelial growth factor VEGF inhibitor, is indicated for the treatment of patients with:

- Neovascular (Wet) Age-related macular degeneration (AMD)
- Macular Edema following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy
- Myopic Choroidal Neovascularization (mCNV)

DOSAGE AND ADMINISTRATION

- Neovascular (Wet) Age-Related Macular Degeneration (AMD): Lucentis 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days).
- Macular Edema following Retinal Vein Occlusion (RVO): Lucentis 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days).
- Diabetic Macular Edema (DME) and Diabetic Retinopathy: Lucentis 0.3 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days).
- Myopic Choroidal Neovascularization (mCNV): Lucentis 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.

AVAILABLE STRENGTHS

- Single-use vials
 - 10mg/mL solution (Lucentis 0.5 mg)
 - 6mg/mL solution (Lucentis 0.3 mg)
- Single-use prefilled syringe
 - 10mg/mL solution (Lucentis 0.5 mg)
 - 6mg/mL solution (Lucentis 0.3 mg)

REFERENCES

- Lucentis [Prescribing Information]. South San Francisco, CA: Genentech; March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/16/18

Created: 05/14

Client Approval: 04/16

P&T Approval: 07/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAVULIZUMAB-CWVZ (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RAVULIZUMAB-CWVZ	ULTOMIRIS	45548		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication is prescribed by or in consultation with a hematologist
 - The patient has confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
 - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
 - PNH granulocyte clone size of 10% or greater
 - Documentation of the patient's current weight

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 transitioning from an alternative complement inhibitor therapy (e.g., Soliris)
 - Documentation of evidence of intravascular hemolysis (e.g., lactate dehydrogenase [LDH] level $\geq 1.5 \times$ ULN, hemoglobinuria) **OR** history of major adverse vascular event from thromboembolism

If yes, **approve for 6 months by HICL as follows:**

Patient's weighing 40kg to less than 60kg

Enter both of the following approvals:

- **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of 540mL per 28 days for 1 fill.**
- **Maintenance dose: Approve for 5 months with a quantity limit of 300mL per 8 weeks for 2 fills (Please enter a start date of 5 weeks from the end date of the first approval).**

Patient's weighing 60kg to less than 100kg

Enter both of the following approvals:

- **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of 600mL per 28 days for 1 fill.**
- **Maintenance dose: Approve for 5 months with a quantity limit of 330mL per 8 weeks for 2 fills (Please enter a start date of 5 weeks from the end date of the first approval).**

(Approval directions continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAVULIZUMAB-CWVZ (NSA)

INITIAL CRITERIA (CONTINUED)

Patient's weighing greater than or equal to 100kg

Enter both of the following approvals:

- **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of 660mL per 28 days for 1 fill.**
- **Maintenance dose: Approve for 5 months with a quantity limit of 360mL per 8 weeks for 2 fills (Please enter a start date of 5 weeks from the end date of the first approval).**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a hematologist
- The patient has confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
 - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
 - PNH granulocyte clone size of 10% or greater
- Documentation of the patient's current weight
- The patient meets **ONE** of the following:
 - Transitioning from alternative complement inhibitor therapy (e.g., Soliris)
 - Documentation of evidence of intravascular hemolysis (e.g. lactate dehydrogenase [LDH] level at least 1.5 X ULN, hemoglobinuria) **OR** history of major adverse vascular event from thromboembolism

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAVULIZUMAB-CWVZ (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND** meet the following criterion?

- Physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

If yes, approve for 12 months by HICL as follows:

- **Weight of 40kg to less than 60kg:** Approve with a quantity limit of 300mL per 8 weeks.
- **Weight of 60kg to less than 100kg:** Approve with a quantity limit of 330mL per 8 weeks.
- **Weight greater than or equal to 100kg:** Approve with a quantity limit of 360mL per 8 weeks.

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH). In addition, the following criterion must be met:

- Physician attestation of clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels) compared to baseline

RATIONALE

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

REFERENCES

- Ultomiris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RESLIZUMAB	CINQAIR	43211		

This drug requires a written request for prior authorization.

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 and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has a documented blood eosinophil level of at least 300 cells/mcL within the past 6 months
 - The patient is currently adherent to a maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, a long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
 - The patient has experienced at least 2 or more asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
 - The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5 or more
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1 or more
 - Cinqair will be used as add-on maintenance treatment
 - The patient is not being concurrently treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (e.g. Nucala, Fasentra)
 - Cinqair is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Renewal requires the patient to have experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline AND an improvement in Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline. In addition, if the patient was on maintenance therapy with oral corticosteroids prior to the initiation of Cinqair, then the patient must demonstrate a reduction in the total daily dose of oral corticosteroids for Cinqair renewal.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **RESLIZUMAB (Cinqair)** requires a diagnosis of severe asthma with an eosinophilic phenotype. In addition, the following criteria must also be met:

- The patient is 18 years of age or older
- The patient has a documented blood eosinophil level of at least 300 cells/mcL within the past 6 months
- The patient is currently adherent to a maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, a long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least 2 or more asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- The patient has **ONE** of the following:
 - Asthma Control Test (ACT) score of less than 20
 - Asthma Control Questionnaire (ACQ) score of at least 1.5 or more
 - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1 or more
- Cinqair will be used as add-on maintenance treatment
- The patient is not being concurrently treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (e.g. Nucala, Fasenra)
- Cinqair is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma **AND** meet all of the following criteria?
 - The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline
 - The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), **OR** Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Was the patient treated with a maintenance therapy regimen of oral corticosteroids prior to initiation of Cinqair?

If yes, continue to #3.

If no, **approve for 12 months by HICL.**

3. Has the patient decreased their total daily dose of oral corticosteroids from baseline?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **RESLIZUMAB (Cinqair)** requires a diagnosis of severe asthma. In addition, the following must be met:

- The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline
- The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
- The patient has decreased their total daily oral corticosteroid dose from baseline, if the patient was on maintenance therapy with oral corticosteroids prior to initiation of Cinqair

RATIONALE

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

REFERENCES

- Cinqair [Prescribing Information]. Frazer, PA. Teva Pharmaceutical Industries Ltd.; March 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 04/17

Client Approval: 11/18

P&T Approval: 10/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RITUXIMAB	RITUXAN	16848		

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) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient is 18 years of age or older
 - The patient is currently using or has a contraindication to methotrexate
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz IR/XR [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL for #2 fills.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of Non Hodgkin's Lymphoma (NHL) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with an oncologist
 - The patient is 18 years of age or older

If yes, **approve for 6 months by HICL for up to #8 fills.**

If no, continue to #3.

3. Does the patient have a diagnosis of Chronic Lymphocytic Leukemia (CLL) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with an oncologist
 - The patient is on concurrent chemotherapy
 - The patient is 18 years of age or older

If yes, **approve for 6 months by HICL for up to #6 fills.**

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA) and meet **ALL** of the following criteria?
- The patient is on concurrent glucocorticoids (such as methylprednisolone or prednisone)
 - The patient is 18 years of age or older

If yes, **approve for 1 month by HICL for #4 fills.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Pemphigus Vulgaris (PV) and meet the following criteria?
- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL for #3 fills.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **RITUXIMAB (Rituxan)** requires a diagnosis of moderate to severe rheumatoid arthritis, Non Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Wegener's Granulomatosis (WG), Microscopic Polyangiitis (MPA), or moderate to severe Pemphigus Vulgaris. The following criteria must also be met.

For patients with moderate to severe rheumatoid arthritis (RA), all of the following criteria are required for approval:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient is currently using or has a contraindication to methotrexate
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Xeljanz IR/XR

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.

For patients with Non Hodgkin's Lymphoma (NHL), all of the following criteria are required for approval:

- Therapy is prescribed by or given in consultation with an oncologist
- The patient is 18 years of age or older

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with Chronic Lymphocytic Leukemia (CLL), all of the following criteria are required for approval:

- Therapy is prescribed by or given in consultation with an oncologist
- The patient is on concurrent chemotherapy
- The patient is 18 years of age or older

For patients with Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), all of the following criteria are required for approval:

- The patient is on concurrent glucocorticoids (such as methylprednisolone or prednisone)
- The patient is 18 years of age or older

For patients with moderate to severe Pemphigus Vulgaris, approval requires:

- The patient is 18 years of age or older

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and has the patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

If yes, **approve for 12 months by HICL for #3 fills.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **RITUXIMAB (Rituxan)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA) and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy for renewal.

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.; June 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 01/09

Client Approval: 03/19

P&T Approval: 07/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RITUXIMAB/ HYALURONIDASE, HUMAN - SQ	RITUXAN HYCELA	44378		

GUIDELINES FOR USE

1. Is the patient 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 received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of the requested medication?

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 Follicular Lymphoma (FL) and meet **ONE** of the following criteria?

- The medication will be used as a single agent for a patient with relapsed or refractory FL
- The medication will be used in combination with first line chemotherapy for a patient with previously untreated FL
- The medication will be used as a single-agent for maintenance therapy for a patient who has achieved a complete or partial response to rituximab in combination with chemotherapy
- The medication will be used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy in a patient with non-progressing (including stable disease) FL

If yes, **approve for 12 months by GPID (36469).**

If no, continue to #4.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of Diffuse Large B-cell Lymphoma (DLBCL) and meet the following criterion?

- The medication will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or other anthracycline-based chemotherapy regimens for previously untreated Diffuse Large B-cell Lymphoma (DLBCL)

If yes, **approve for 12 months by GPID (36469).**

If no, continue to #5.

5. Does the patient have a diagnosis of Chronic Lymphocytic Leukemia (CLL) and meet the following criterion?

- The medication will be used in combination with fludarabine and cyclophosphamide (FC)

If yes, **approve for 12 months by GPID (43561).**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires a diagnosis of Follicular Lymphoma (FL), Diffuse Large B-cell Lymphoma (DLBCL), or Chronic Lymphocytic Leukemia (CLL) in adult patients who have received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of the requested medication. In addition, the following criteria must be met:

For patients with Follicular Lymphoma (FL), one of the following criteria must be met:

- The medication will be used as a single agent for a patient with relapsed or refractory FL
- The medication will be used in combination with first line chemotherapy for a patient with previously untreated FL
- The medication will be used as a single-agent for maintenance therapy for a patient who has achieved a complete or partial response to rituximab in combination with chemotherapy
- The medication will be used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy in a patient with non-progressing (including stable disease) FL

For patients with Diffuse Large B-cell Lymphoma (DLBCL):

- The medication will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or other anthracycline-based chemotherapy regimens for previously untreated Diffuse Large B-cell Lymphoma (DLBCL)

For patients with Chronic Lymphocytic Leukemia (CLL):

- The medication will be used in combination with fludarabine and cyclophosphamide (FC)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

RATIONALE

Ensure appropriate utilization of Rituxan Hycela consistent with FDA approved indication.

Rituxan Hycela is for subcutaneous use only and should only be administered by a healthcare professional with appropriate be fatal if they occur.

All patients must first receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions before starting treatment with Rituxan Hycela. If patients are not able to receive one full dose by intravenous infusion, they should continue subsequent cycles with a rituximab product by intravenous infusion and not switch to Rituxan Hycela until a full intravenous dose is successfully administered.

FDA APPROVED INDICATIONS

Indicated for the treatment of adult patients with:

Follicular Lymphoma (FL)

- Relapsed or refractory, follicular lymphoma as a single agent
- Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

Diffuse Large B-cell Lymphoma (DLBCL)

- Previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens

Chronic Lymphocytic Leukemia (CLL)

- Previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC)

Limitations of Use:

- Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.
- Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

REFERENCES

- Rituxan Hycela [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 08/17

Client Approval: 08/17

P&T Approval: 07/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIDEPSIN

Generic	Brand	HICL	GCN	Exception/Other
ROMIDEPSIN	ISTODAX	36898		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (also known as Mycosis Fungoides/Sezary Syndrome) **AND** meet ONE of the following criteria?
 - The patient has a trial of or contraindication to Zolinza (vorinostat) **AND** is not able to tolerate oral medications
 - The patient has tried at least one form of systemic therapy (e.g., retinoids, interferons, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) **AND** is able to tolerate oral medications.

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Is the requested medication being used for the treatment of peripheral T-cell lymphoma in a patient who has received at least one prior therapy?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ROMIDEPSIN (Istodax)** requires a diagnosis of cutaneous T-cell lymphoma or peripheral T-cell lymphoma. The following criteria must also be met.

For patients with cutaneous T-cell lymphoma, approval requires the following criteria:

- The patient has a trial of or contraindication to Zolinza (vorinostat) **AND** is not able to tolerate oral medications.
- The patient has tried at least one form of systemic therapy (e.g., retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) **AND** is able to tolerate oral medications.

For patients with peripheral T-cell lymphoma, approval requires that the patient has received at least one prior treatment.

RATIONALE

Promote appropriate utilization of **ROMIDEPSIN** based on FDA approved indications.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ROMIDEPSIN

FDA APPROVED INDICATIONS

Isotodax is indicated for:

- Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy
- Treatment of peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy

These indications are based on response rate. Clinical benefit such as improvement in overall survival has not been demonstrated.

SYSTEMIC TREATMENT OPTIONS	
Retinoids (bexarotene, retinoic acid, isotretinoin, acitretin)	Chlorambucil (Leukeran)
Interferons (Intron A)	Pentostatin
Extracorporeal photopheresis	Etoposide (VePesid)
Denileukin diftitox (Ontak)	Cyclophosphamide (Cytoxan)
Methotrexate	Temozolomide (Temodar)
Liposomal doxorubicin (Doxil)	Bortezomib (Velcade)
Gemcitabine (Gemzar)	

REFERENCES

- Istodax [Prescribing Information]. Celgene Corporation: Summit, NJ. October 2014.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 3.2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 02/10

Client Approval: 09/16

P&T Approval: 08/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ROMIPLOSTIM	NPLATE	35798		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (ITP) **AND** meet the following criterion?
 - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy

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 age 1 and 17 years old **AND** meet the following criterion?
 - The patient has had ITP for at least 6 months

If yes, **approve for 2 months by HICL with a quantity limit of #8 vials per 28 days.**

APPROVAL TEXT: Renewal requires the patient to have a clinical response, as defined by an increase in platelet count to at least 50 X 10⁹/L **OR** received the maximum dose of 10mcg/kg for 4 consecutive weeks with a clinical response as defined by an increase in platelet count to at least 50 X 10⁹/L.

If no continue to #3.

3. Is the patient 18 years of age or older?

If yes, **approve for 2 months by HICL with a quantity limit of #8 vials per 28 days.**

APPROVAL TEXT: Renewal requires the patient to have a clinical response, as defined by an increase in platelet count to at least 50 X 10⁹/L **OR** received the maximum dose of 10mcg/kg for 4 consecutive weeks with a clinical response as defined by an increase in platelet count to at least 50 X 10⁹/L.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ROMIPLOSTIM (Nplate)** requires a diagnosis of chronic immune thrombocytopenia (ITP) and the patient is 1 year of age or older. In addition, the following criteria must be met:

- The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy

For patients between 1 and 17 years old, approval requires:

- The patient has had ITP for at least 6 months

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (ITP) **AND** meet the following criterion?

- The patient had a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$

If yes, **approve for 12 months by HICL with a quantity limit of #8 vials per 28 days.**

If no, continue to #2.

2. Did the patient receive the maximum dose of 10mcg/kg for 4 consecutive weeks?

If yes, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ROMIPLOSTIM (Nplate)** requires a diagnosis of chronic immune thrombocytopenia (ITP) and **ONE** of the following criteria must be met:

- The patient had a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$
- The patient received the maximum dose of 10mcg/kg for 4 consecutive weeks with a clinical response

If no, **approve for 1 month by HICL with a quantity limit of #8 vials per 28 days.**

RENEWAL APPROVAL TEXT: Approval for a longer duration than 1 month requires that the patient had a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ROMIPLOSTIM (NSA)

RATIONALE

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

REFERENCES

- Nplate [Prescribing Information] Thousand Oaks, CA: Amgen Inc.; December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/19

Created: 10/08

Client Approval: 04/19

P&T Approval: 01/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ROMOSOZUMAB-AQQG	EVENITY	45681		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and 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, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score greater than or equal to 20% for any major fracture **OR** greater than or equal to 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 has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

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 received a total of 12 months of Evenity therapy?

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 with a quantity limit of #2.34mL per month.**

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **ROMOSOZUMAB (Evenity)** requires a diagnosis of postmenopausal osteoporosis and the patient has not received a total of 12 months or more of Evenity therapy. In addition, one of the following criteria must be met:

- 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, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score greater than or equal to 20% for any major fracture **OR** greater than or equal to 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 has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

RATIONALE

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

REFERENCES

- Evenity [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/19

Created: 04/19

Client Approval: 04/19

P&T Approval: 02/17



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
SEBELIPASE ALFA	KANUMA	42747		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Was the medication prescribed by or in consultation with an endocrinologist, hepatologist, gastroenterologist, medical geneticist, or lipidologist?

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 rapidly progressive lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life (also known as Wolman Disease), as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) plus **ANY** of the following?

- A blood test indicating low or absent levels of LAL enzyme activity
- A dried blood spot test indicating low or absent LAL enzyme activity
- A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive (also known as cholesteryl ester storage disease (CESD)), as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) plus **ANY** of the following?
- A blood test indicating low or absent levels of LAL enzyme activity
 - A dried blood spot test indicating low or absent LAL enzyme activity
 - A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires that the patient has a documented improvement in any one of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency while on therapy with Kanuma:

- A relative reduction from baseline in any one of the following lipid levels (LDL-c, non-HDL-c, or triglycerides).
- Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges.
- A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI).

Any one of the following baseline measurements will be required to assess renewal criteria: lipids (LDL-c, Non-HDL-c, or triglycerides), aspartate aminotransferase (AST), or MEGE MRI.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **SEBELIPASE ALFA (Kanuma)** requires that the medication be prescribed by or in consultation with an endocrinologist, hepatologist, gastroenterologist, medical geneticist, or lipidologist, **AND** a diagnosis of lysosomal acid lipase (LAL) deficiency, as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) plus **ANY** of the following:

- A blood test indicating low or absent levels of LAL enzyme activity
- A dried blood spot test indicating low or absent LAL enzyme activity
- A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive?

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 documented improvement in any one of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
 - A relative reduction from baseline in any one of the following lipid levels (LDL-c, Non-HDL-c, or triglycerides)
 - Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges
 - A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **SEBELIPASE ALFA (Kanuma)** renewal requires a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive, and that the patient have documented improvement in any one of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:

- A relative reduction from baseline in any one of the following lipid levels (LDL-c, Non-HDL-c, or triglycerides)
- Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges
- A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SEBELIPASE ALFA

RATIONALE

To ensure appropriate use of Kanuma (sebelipase alfa) consistent with FDA approved indication.

Kanuma is a human therapeutic biologic and the first FDA-approved treatment for lysosomal acid lipase (LAL) deficiency. Kanuma was granted orphan drug designation, breakthrough therapy designation, FDA priority review, and the manufacturer of Kanuma was granted a rare pediatric disease voucher. Kanuma is a recombinant form of the human LAL enzyme which serves as a replacement for the lacking enzyme in patients with deficiency. Kanuma is to be administered as an intravenous infusion by a healthcare professional.

LAL deficiency is a rare, autosomal recessive, inherited genetic disorder in which patients have little or no LAL enzyme activity due to mutations in the Lipase A, Lysosomal Acid, Cholesterol Esterase (LIPA) gene which encodes the LAL enzyme. LAL deficiency can be divided into two major phenotypes which differ by rate of progression and severity. When LAL deficiency is diagnosed in infancy, it is referred to as Wolman disease and represents the more rapidly progressing phenotype of the disease. These patients historically have a life expectancy of 3-6 months with a disease course characterized by liver failure, malabsorption, and growth failure.

LAL deficiency presenting post-infancy is generally referred to as cholesteryl ester storage disease (CESD) and causes hepatic steatosis, hepatic fibrosis, and cirrhosis. These patients are also at increased risk for accelerated atherosclerosis and cardiovascular disease. It is estimated that Wolman disease affects 1-2 infants per million births and CESD affects 25 individuals per million births.

Diagnostic criteria for LAL includes the presence of clinical features, blood tests and dried blood spot test for LAL enzyme activity, and genetic testing. Testing for LAL without clinical features is not indicated and may result in false positives, whereas genetic testing shows that both alleles are affected by mutations.

The efficacy of Kanuma in pediatric and adult patients with LAL was assessed in the clinical trial, LAL-CL02. The primary endpoint was normalization of the alanine aminotransferase level (ALT) and secondary endpoints included LDL-c relative reduction, non-HDL-C relative reduction, normalization of aspartate aminotransferase (AST), and triglyceride (TG) relative reduction. Results are provided in Table 1 below. Baseline assessments conducted in participants revealed substantially elevated aminotransferase levels and high LDL-c levels (≥ 190 mg/dL) in 38 of 66 patients (58%). As the most frequently reported complications of LAL deficiency are hepatic manifestations, the trial addressed common markers of liver injury. Patients treated with Kanuma had a significant reduction in hepatic fat content as assessed by MRI (mean reduction: -32% in the Kanuma group vs. -4.2% in the placebo group). The significance of reductions in ALT values and liver fat content to disease progression has not been established.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA

RATIONALE (CONTINUED)

Table 1. Pediatric and Adult Patients with LAL Deficiency, Trial Results [NEJM. Burton et al 2015]

Endpoint	Population	Sebelipase Alfa (n = 36)	Placebo (n = 30)	Treatment Difference (p-value)
PRIMARY ENDPOINT:				
Normalization of ALT, % (n/N)	All, N = 66	31% (11/36)	7% (2/30)	24% (0.0271)
SECONDARY ENDPOINTS:				
Relative reduction in LDL-c, Mean (SD)	All, N = 66	-28% (22.3)	-6% (13.0)	-22% (<0.0001)
Relative reduction in triglyceride, Mean (SD)	All, N = 66	-25% (29.4)	-11% (28.8)	-14% (0.0375)
Relative increase in HDL-c, Mean (SD)	All, N = 66	20% (16.8)	-0.3% (12.3)	20% (<0.0001)

The efficacy of Kanuma in patients with rapidly progressive LAL deficiency presenting within the first 6 months of life was assessed in the clinical trial, LAL-CL03, a multinational, single-arm, open label, Phase II/III study of nine infants (aged 1 – 6 months at trial entry). Efficacy was assessed by comparing the survival of Kanuma-treated patients at 12 months of age with a historical cohort of 21 untreated patients with similar clinical characteristics and age at onset. In LAL-CL03, improvement in survival was accompanied by substantial and rapid improvements in markers of hepatic injury (i.e., AST/ALT), growth, and hematological abnormalities.

FDA APPROVED INDICATION

Kanuma (sebelipase) is indicated for the treatment of patients with a diagnosis of lysosomal acid lipase (LAL) deficiency.

DOSAGE

Patients with rapidly progressive LAL deficiency presenting within the first 6 months of life:

The recommended starting dosage is 1mg/kg as an intravenous infusion once weekly. For patients who do not achieve an optimal clinical response, increase to 3mg/kg once weekly.

Pediatric and adult patients with LAL deficiency:

The recommended dosage is 1mg/kg as an intravenous infusion once every other week.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBELIPASE ALFA

AVAILABLE STRENGTH:

- 20mg/10ml solution in a single-use vial

REFERENCES

- Kanuma [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc. December 2015.
- Kanuma [AMCP Dossier]. Cheshire, CT: Alexion Pharmaceuticals, Inc. December 2015.
- Burton, B.K., Balwani, M., Feillet, I., et.al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. *The New England Journal of Medicine*. Abstract (2015) 373:1010-20.
- Jones, S.A., Rojas-Caro, S., Quinn, A.G., et.al. Impact of sebelipase alfa on survival and liver function in infants with rapidly progressive lysosomal acid lipase deficiency. *Journal of Inherited Metabolic Disease*. (2015) 38 (Suppl 1):S35–S378.
- Lysosomal acid lipase deficiency testing. LabCorp. 2013.
<http://m3.wyanokecdn.com/8bf88c2ed28280df9ef39e5614da71177.pdf>

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 12/15

Client Approval: 02/16

P&T Approval: 02/16



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILTUXIMAB

Generic	Brand	HICL	GCN	Exception/Other
SILTUXIMAB	SYLVANT	41101		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multi-centric Castleman's disease (MCD)?

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 positive for either human immunodeficiency virus (HIV) or human herpesvirus-8 (HHV-8)?

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.**

DENIAL TEXT: Our guideline for **SILTUXIMAB** requires a diagnosis of multi-centric Castleman's disease (MCD) and that the patient is negative for both human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).

RATIONALE

Promote appropriate utilization of Sylvant based on FDA approved indication.

Castleman's disease (CD), also known as angiofollicular lymph node hyperplasia, is comprised of two distinct diseases: unicentric and multicentric. Unicentric CD usually affects a single group of lymph nodes and removal of the mass cures 90-95% of cases. Multicentric CD (MCD) involves more than a single group of lymph nodes and can affect other organs containing lymphoid tissue. Patients with MCD often have serious infections, severe fatigue, night sweats, recurrent fever, and weight loss. Patients may also experience peripheral edema, anemia, hypoalbuminemia, peripheral neuropathy and hepatosplenomegaly. CD is not officially a cancer, but the multicentric disease form is more aggressive than unicentric CD and roughly 20% of patients with MCD develop lymphoma.

Because MCD is a rare disease and most cases are seen in patients who are HIV/HHV-8 positive, the utilization of Sylvant is expected to be relatively minimal given its specific FDA indication for HIV/HHV-8 negative MCD patients.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SILTUXIMAB

RATIONALE (CONTINUED)

DOSAGE

Sylvant 11 mg/kg is given over 1 hour as an intravenous infusion administered every 3 weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression or deterioration in performance status) or unacceptable toxicity.

FDA APPROVED INDICATION

Sylvant is indicated for the treatment of patients with Multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitation of Use: Sylvant was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

REFERENCES

- Sylvant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; May 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/14

Created: 6/14

Client Approval: 08/14

P&T Approval: 08/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SUFENTANIL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
SUFENTANIL CITRATE	DSUVIA		45928	

GUIDELINES FOR USE

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

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

2. Does the patient have a diagnosis of acute pain and meet **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 for which alternative treatments are inadequate (e.g., non-opioid analgesic products or opioid combination products)
- The patient's treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

If yes, **approve for 3 days by GPID (45928) for one fill with a quantity limit of #12 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **SUFENTANIL (Dsuvia)** requires a diagnosis of acute pain. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient's pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate (e.g., non-opioid analgesic products or opioid combination products)
- The patient's treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

RATIONALE

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

REFERENCES

- Dsuvia [Prescribing Information]. Redwood City, CA: AcclRx Pharmaceutical, Inc. November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAGRAXOFUSP-ERZS (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TAGRAXOFUSP-ERZS	ELZONRIS	45555		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) **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 #1 fill per 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN). In addition, the following criteria must be met:

- The patient is 2 years of age or older

RATIONALE

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

REFERENCES

Elzonris [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc., December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALIMOGENE LAHERPAREPVEC

Generic	Brand	HICL	GCN	Exception/Other
TALIMOGENE LAHERPAREPVEC	IMLYGIC	42741		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable melanoma and have all of the following criteria been met?
 - Patient has a recurrence of melanoma lesions after initial surgery.
 - Patient does not have a history of primary or acquired immunodeficient states, leukemia, lymphoma, or AIDS.
 - Patient is not currently receiving immunosuppressive therapy.
 - The patient is not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy.

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Imlygic be injected into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance?

If yes, **approve for a total of 12 months and enter three prior authorizations (initial, second, and maintenance doses) by GPID as follows:**

- **First authorization: approve for 1 fill of Imlygic 10⁶ (1 million) PFU/mL vial (GPID= 39983): 4mL (#4 vials)**
- **Second authorization (starting 3 weeks after initial authorization): approve for 1 fill of Imlygic 10⁸ (100 million) PFU/mL vial (GPID= 39984): 4mL (#4 vials)**
- **Third authorization (starting 5 weeks after initial authorization): approve for 11 months for Imlygic 10⁸ (100 million) PFU/mL vial (GPID= 39984): 8mL (#8 vials) every 28 days**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TALIMOGENE LAHERPAREPVEC

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline for **TALIMOGENE LAHERPAREPVEC** requires a diagnosis of unresectable melanoma. Additional guideline requirements apply.

- Patient has a recurrence of melanoma lesions after initial surgery.
- Patient does not have a history of primary or acquired immunodeficient states, leukemia, lymphoma, or AIDS.
- Patient is not currently receiving immunosuppressive therapy.
- The patient is not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy.
- The request must be for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance.

RATIONALE

Promote appropriate utilization of Imlygic (talimogene laherparepvec) based on FDA-approved indications.

Imlygic is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. Imlygic is a live, attenuated herpes simplex virus and may cause life-threatening disseminated herpetic infection in patients who are immunocompromised. Imlygic should not be administered to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy. Imlygic should be discontinued if there are no injectable lesions to treat or if other treatment is required for melanoma. Other melanoma treatments include pembrolizumab, nivolumab, ipilimumab, dabrafenib, trametinib, vemurafenib, dabrafenib, interleukin-2, interferon, dacarbazine, temozolomide, paclitaxel, carboplatin, imatinib, melphalan, imiquimod, or radiation therapy.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALIMOGENE LAHERPAREPVEC

DOSAGE

Imlygic is administered by injection into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance.

The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment. Previously injected and/or uninjected lesion(s) may be injected at subsequent treatment visits. The initial recommended dose is up to 4 mL of Imlygic at a concentration of 10^6 (1 million) PFU per mL. The recommended dose for subsequent administrations is up to 4 mL of IMLYGIC at a concentration of 10^8 (100 million) PFU per mL. The recommended dosing schedule for Imlygic is shown in Table 1.

Table 1. Recommended Dose and Schedule for IMLYGIC

Treatment	Treatment Interval	Maximum Injection Volume per Treatment Visit (all lesions combined)	Dose Strength	Prioritization of Lesions to be Injected
Initial	–	4 mL	10^6 (1 million) PFU per mL	<ul style="list-style-type: none">Inject largest lesion(s) first.Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.
Second	3 weeks after initial treatment	4 mL	10^8 (100 million) PFU per mL	<ul style="list-style-type: none">Inject any new lesion(s) (lesions that have developed since initial treatment) first.Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.
All subsequent treatments (including reinitiation)	2 weeks after previous treatment	4 mL	10^8 (100 million) PFU per mL	<ul style="list-style-type: none">Inject any new lesion(s) (lesions that have developed since previous treatment) first.Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TALIMOGENE LAHERPAREPVEC

FDA APPROVED INDICATION

Imlygic (talimogene laherparepvec) is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

AVAILABLE STRENGTHS:

- 10⁶ (1 million) PFU/mL 1ml vial
- 10⁸ (100 million) PFU/mL 1ml vial

REFERENCES

- Imlygic [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc. October 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/09/15

Created: 11/15

Client Approval: 11/15

P&T Approval: 11/15



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE - IV

Generic	Brand	HICL	GCN	Exception/Other
TEMOZOLOMIDE - IV	TEMODAR - IV		17724	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have one of the following diagnoses: metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC)?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC).

RATIONALE

Based on FDA approved indications and NCCN recommendations. Temodar is approved for the treatment of newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment; and refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine. NCCN recommends Temodar for SCLC patients with relapse <2-3 months, performance status 0-2 or relapse >2-3 up to 6 months (most useful if brain metastases are present); and for the treatment of metastatic melanoma. NCCN considers temozolomide to be a systemic therapy option for advanced or metastatic melanoma. No quantity limit is included within this guideline since there are multiple dosing regimens available, all of which are based on body surface area.

FDA APPROVED INDICATIONS

Temodar is an alkylating drug indicated for the treatment of adult patients with:

- Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment.
- Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE - IV

REFERENCES

- National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology Melanoma. (Version 3.2012).
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Small Cell Lung Cancer Version 2.2014. [Online] September 17, 2013. [Cited: September 25, 2013.] http://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf
- Schering Corporation, a subsidiary of Merck & Co., Inc. Temodar package insert. Whitehouse Station, NJ. February 2011.
- Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: January 24, 2012].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/12

Client Approval: 11/13

P&T Approval: 11/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMSIROLIMUS

Generic	Brand	HICL	GCN	Exception/Other
TEMSIROLIMUS	TORISEL	34870		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

If yes, **approve for 12 months with a quantity limit of #4 kits (vials) per month.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of advanced renal cell carcinoma (RCC).

RATIONALE

Ensure appropriate utilization of temsirolimus based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATION

Temsirolimus is indicated for the treatment of advanced renal cell carcinoma.

REFERENCES

- Wyeth Pharmaceuticals Inc. Torisel package insert. Philadelphia, PA. September 2010.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. (Version 2.2011).

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 05/11

Client Approval: 08/13

P&T Approval: 05/11



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

THYROTROPIN ALFA FOR INJECTION

Generic	Brand	HICL	GCN	Exception/Other
THYROTROPIN ALFA FOR INJECTION	THYROGEN	18855		

GUIDELINES FOR USE

1. Is the requested product being used as diagnostic tool for serum thyroglobulin (Tg) testing?

If yes, do not approve.

DENIAL TEXT: The requested product is not covered for diagnostic purposes under the pharmacy benefit. This product may be covered under the medical benefit.

If no, continue to #2.

2. Is the requested product being used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease?

If yes, **approve one fill of #2 vials.**

If no, do not approve.

DENIAL TEXT: Approval requires that the requested product being used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease.

RATIONALE

To ensure appropriate use of Thyrogen based on FDA approved indication and dosage. Limit diagnostic use to the medical benefit.

Two-injection regimen of Thyrogen 0.9 mg IM, followed by a second 0.9 mg IM injection 24 hours later.

FDA APPROVED INDICATION

Thyrogen (thyrotropin alfa for injection) is indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Thyrogen (thyrotropin alfa for injection) is indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

REFERENCES

- Thyrogen (thyrotropin alfa for injection) [Prescribing Information]. Cambridge, MA: Genzyme Corporation.; July 2012.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

THYROTROPIN ALFA FOR INJECTION

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 08/13

Client Approval: 08/13

P&T Approval: 08/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TILDRAKIZUMAB-ASMN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		

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) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a dermatologist
 - The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
 - The patient had a previous trial of or contraindication to at least **ONE** or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Stelara, Otezla, Tremfya, Skyrizi [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, approve for 6 months by entering **TWO** approvals by HICL as follows:

- **FIRST APPROVAL:** approve for 1 month with a quantity limit of #2mL (#2 100mg/mL syringes) per 28 days.
- **SECOND APPROVAL:** approve for 5 months with a quantity limit of #1mL (#1 100mg/mL syringe) per 84 days (Please enter a start date of 1 WEEK AFTER the END date of the first approval).

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TILDRAKIZUMAB-ASMN (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least **ONE** or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Stelara, Otezla, Tremfya, Skyrizi

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
 - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL with a quantity limit of #1mL (#1 100mg/mL syringe) per 84 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) for renewal. The following criterion must also be met:

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TILDRAKIZUMAB-ASMN (NSA)

RATIONALE

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

REFERENCES

- Ilumya [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/03/19

Created: 08/18

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISAGENLECLEUCEL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TISAGENLECLEUCEL	KYMRIAH	44483		

*******Customer Service/PAC Alert*****
(For Internal Use Only)**

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

- Does the patient meet **ALL** of the following criteria?
 - Treatment is prescribed by a Kymriah-certified hematologist or oncologist
 - Kymriah will be administered at a treatment center that is certified to administer Kymriah
 - The patient has not received a previous trial of Kymriah

If yes, continue to #2.
If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Is the patient 25 years of age or younger **AND** have a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL)?

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

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISAGENLECLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the physician attest that the patient meets **ONE** of the following criteria?

- The patient is in second or greater bone marrow relapse
- The patient is currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT)
- The patient has not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (i.e., primary refractory disease)
- The patient has not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
- The patient has Philadelphia chromosome positive (Ph+) ALL and meets at least **ONE** of the following:
 - The patient has had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
 - The patient is unable to tolerate TKI therapy
 - The patient has a contraindication to TKI therapy
- The patient is not eligible for allogeneic stem cell transplantation (SCT)

If yes, **approve GPID 43799 for 1 fill.**

APPROVAL TEXT: Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, the Risk Evaluation and Mitigation Strategy (REMS) program requires that certified healthcare facilities must have on-site, immediate access to tocilizumab (Actemra). The patient must also meet all criteria in the Actemra guideline to be approvable for both agents.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient 18 years of age or older **AND** have **ONE** of the following diagnoses?

- relapsed or refractory Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
- High grade B-cell lymphoma
- DLBCL arising from follicular lymphoma (FL) [i.e. transformed follicular lymphoma (TFL)]

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISAGENLECLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the physician attest that the patient meets **ALL** of the following criteria?

- The patient is refractory or has had disease progression (relapsed) after two or more lines of systemic therapy including rituximab and an anthracycline **AND**
- The patient has had disease progression or relapsed after autologous hematopoietic stem cell transplantation (ASCT) **OR** the patient is not eligible for ASCT

If yes, **approve GPID 44689 for 1 fill.**

APPROVAL TEXT: Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, the Risk Evaluation and Mitigation Strategy (REMS) program requires that certified healthcare facilities must have on-site, immediate access to tocilizumab (Actemra). The patient must also meet all criteria in the Actemra guideline to be approvable for both agents

If no, do not approve.

DENIAL TEXT: The guideline named **TISAGENLECLEUCEL (Kymriah)** requires a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) OR relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma (FL) [i.e. transformed follicular lymphoma (TFL)]. In addition, the following criteria must be met:

- Treatment is prescribed by a Kymriah-certified hematologist or oncologist
- Kymriah will be administered at a treatment center that is certified to administer Kymriah
- The patient has not had a previous trial of Kymriah

For diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

- The patient is 25 years of age or younger
- Physician attestation of **ONE** of the following criteria:
 - The patient is in second or greater bone marrow relapse
 - The patient is currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT)
 - The patient has not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (i.e., primary refractory disease)
 - The patient has not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
 - The patient has Philadelphia chromosome positive (Ph+) ALL and meets at least **ONE** of the following:
 - The patient has had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
 - The patient is unable to tolerate TKI therapy
 - The patient has a contraindication to TKI therapy
 - The patient is not eligible for allogeneic stem cell transplantation (SCT)

(Denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISAGENLECLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

For diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma (FL) [i.e. transformed follicular lymphoma (TFL)], approval requires:

- The patient is 18 years of age or older
- Physician attestation of **ALL** of the following criteria:
 - The patient is refractory or has had disease progression (relapsed) after two or more lines of systemic therapy including rituximab and an anthracycline **AND**
 - The patient has had disease progression or relapsed after autologous hematopoietic stem cell transplantation (ASCT) **OR** the patient is not eligible for ASCT

RATIONALE

Promote appropriate utilization of **KYMRIAH** based on FDA approved indication, dosing, and clinical trial design.

NOTE: Kymriah is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological events. The FDA is requiring that hospitals and their associated clinics that dispense Kymriah be specially certified. As part of that certification, staff involved in the prescribing, dispensing, or administering of Kymriah are required to be trained to recognize and manage CRS and neurological events. Additionally, the certified health care settings are required to have protocols in place to ensure that Kymriah is only given to patients after verifying that tocilizumab is available for immediate administration.

BACKGROUND

Kymriah is the first gene therapy to be approved by the FDA and was granted Priority Review and Breakthrough Therapy designations. Kymriah is an engineered chimeric antigen receptor (CAR) product that targets CD19, a protein expressed on the surface of B cell leukemia and lymphoma cells. The CAR product is utilized in the process of autologous cell therapy in which a patient's own white blood cells are collected, T cells are isolated, the CAR gene is inserted into the T cells, the T cell colony is expanded, and then the engineered T cells are infused back into the patient. This process results in an expanded number of tumor-specific T cells that circulate throughout the body to target and kill cancer cells.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISAGENLECLEUCEL (NSA)

FDA APPROVED INDICATIONS

Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Limitation of Use: KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma (PCNSL).

DOSAGE AND ADMINISTRATION

- Kymriah is supplied as a frozen suspension of genetically modified autologous T cells in one infusion bag labeled for the specific recipient. Kymriah is shipped directly to the cell lab associated with the infusion center. Kymriah is given as a one-time treatment.
- Kymriah is for autologous use and is administered by intravenous infusion only.
- Prior to infusion:
 - Verify the patient's identity
 - Pre-medicate with acetaminophen and an H1-antihistamine
 - Confirm availability of tocilizumab
- Kymriah dosing is based on the number of chimeric antigen receptor (CAR) positive viable T cells.
- **Pediatric and Young Adult Relapsed or Refractory B-Cell ALL (up to 25 years of age):**
 - For patients 50 kg or less, administer 0.2 to 5.0×10^6 CAR-positive viable T cells per kg body weight intravenously.
 - For patients above 50 kg, administer 0.1 to 2.5×10^8 CAR-positive viable T cells (non-weight based) intravenously.
- **Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma:**
 - Administer 0.6 to 6.0×10^8 CAR-positive viable T cells intravenously.

AVAILABLE STRENGTHS

- **Pediatric and Young Adult B-Cell ALL (up to 25 years of age):**
 - A single-dose unit of Kymriah contains 0.2 to 5.0×10^6 CAR-positive viable T cells per kg of body weight for patients 50 kg or less, or 0.1 to 2.5×10^8 CAR-positive viable T cells for patients more than 50 kg, suspended in a patient-specific infusion bag.
- **Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma:**
 - A single-dose unit of Kymriah contains 0.6 to 6.0×10^8 CAR-positive viable T cells suspended in one or more patient-specific infusion bag.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISAGENLECLEUCEL (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

AVAILABLE STRENGTHS

The actual number of CAR-positive T cells in the product is reported on the Certificate of Analysis that is shipped with Kymriah. The volume in the infusion bag ranges from 10 mL to 50 mL.

REFERENCES

- Kymriah [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. May 2018.
- FDA approval brings first gene therapy to the United States. [Press release]. August 30, 2017. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm>. Accessed August 31, 2017.
- ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT 02435849. Determine Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-cell ALL (ELIANA). Available at: <https://clinicaltrials.gov/ct2/show/NCT02435849?term=eliana&draw=1&rank=1>. Accessed October 18, 2017.
- ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT 02445248. Study of Efficacy and Safety of CTL019 in Adult DLBCL Patients. Available at: <https://clinicaltrials.gov/ct2/show/NCT02445248?term=02445248&rank=1>. Accessed May 17, 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 10/17

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TOCILIZUMAB – IV (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TOCILIZUMAB - IV	ACTEMRA - IV		27366 27367 27368	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

- Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older

If yes, **approve for 6 months by GPID for a maximum quantity limit of 40mL per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

- Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 2 years of age or older
 - The patient had a previous trial of or contraindication to the following formulary preferred immunomodulator: Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID.**

APPROVAL TEXT: Renewal for polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 2 years of age or older

If yes, **approve for 6 months by GPID.**

APPROVAL TEXT: Renewal for systemic juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
- Request is for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
 - The patient is 2 years of age or older

If yes, **approve for 1 fill by GPID 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: The guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA), systemic juvenile idiopathic arthritis (SJIA), or chimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (CRS). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with polyarticular juvenile idiopathic arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 2 years of age or older
- The patient had a previous trial of or contraindication to the following formulary preferred immunomodulator: Humira

For patients with systemic juvenile idiopathic arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 2 years of age or older

For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), approval requires all:

- The patient is 2 years of age or older

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID for a maximum quantity limit of 40mL per 28 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) **OR** systemic juvenile idiopathic arthritis (SJIA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy for renewal.

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. December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 02/10

Client Approval: 03/19

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRABECTEDIN

Generic	Brand	HICL	GCN	Exception/Other
TRABECTEDIN	YONDELIS	35367		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma and meets the following criterion?

- The patient has received prior therapy with an anthracycline-containing regimen such as doxorubicin

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **TRABECTEDIN (Yondelis)** requires a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma. Additional guideline requirements apply.

- The patient must have received prior therapy with an anthracycline-containing regimen such as doxorubicin.

RATIONALE

Promote appropriate utilization of Yondelis based on FDA-approved indications.

DOSAGE

Administer at 1.5 mg/m² body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line.

Yondelis requires premedication with dexamethasone 20 mg IV, 30 minutes before each infusion.

FDA APPROVED INDICATION

Yondelis is an alkylating drug indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.

AVAILABLE STRENGTHS

- 1 mg vial

REFERENCES

- Yondelis [Package Insert]. Janssen Products. Horsham, PA. November 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/16

Created: 11/15

Client Approval: 03/16

P&T Approval: 11/15



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB	HERCEPTIN	18801		
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA	45653		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

If yes, continue to #3.

If no, continue to #2.

2. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
 - The request is for adjuvant therapy
 - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, continue to #3.

If no, continue to #4.

3. Is the patient 18 years of age or older?

If yes, **approve for 12 months by HICL for all of the following:**

- **Herceptin (HICL 18801): no quantity limit.**
- **Herceptin Hylecta (HICL 45653): #5mL per 21 days.**

If no, **approve Herceptin for 12 months by HICL (18801) with no quantity limit.**

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
- The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
 - Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 - The patient has not received prior treatment for metastatic disease

If yes, **approve Herceptin for 12 months by HICL (18801) with no quantity limit.**

If no, do not approve.

DENIAL TEXT: The guideline named **TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta)** requires the following:

Requests for Herceptin (Trastuzumab) require ONE of the following diagnoses and associated criteria:

- **For the diagnosis of metastatic breast cancer, approval requires:**
 - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease
- **For the diagnosis of breast cancer, approval requires:**
 - The request is for adjuvant therapy
 - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

GUIDELINES FOR USE (CONTINUED)

- **For the diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:**
 - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
 - Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 - The patient has not received prior treatment for metastatic disease

Requests for Herceptin Hylecta (Trastuzumab-Hyaluronidase) require ONE of the following diagnoses and associated criteria:

- **For the diagnosis of metastatic breast cancer, approval requires:**
 - The patient is 18 years of age or older
 - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease
- **For the diagnosis of breast cancer, approval requires:**
 - The patient is 18 years of age or older
 - The request is for adjuvant therapy
 - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

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., November 2018.
- Herceptin Hylecta [Prescribing Information]. San Francisco, CA: Genentech, Inc., February 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 08/12

Client Approval: 05/19

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB	STELARA	36187		

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) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a dermatologist
 - The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
 - The patient had a previous trial of or contraindication to at least one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 - The patient is 12 years of age or older
 - Documentation of the patient's current weight

If yes, **approve for a total of 6 months by GPID as follows:**

Patients weighing 100kg (220 lbs) or less:

Enter both of the following approvals:

- **Loading dose: Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.**
- **Maintenance dose: Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.**

Patients weighing over 100kg (220 lbs):

Enter both of the following approvals:

- **Loading dose: Approve for 1 month with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 28 days for 1 fill.**
- **Maintenance dose: Approve for 5 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days for 2 fills with a start date after the end date of the previous fill.**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis **OR** moderate to severe PsO with co-existent psoriatic arthritis requires that the patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more **AND** documentation of the patient's current weight.

If no, continue to #2.

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older

If yes, **approve for a total of 6 months by GPID as follows:**

- **Loading dose: Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.**
- **Maintenance dose: Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient had a previous trial of or contraindication to at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - Documentation of the patient's current weight

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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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #5.

If no, **approve maintenance dose for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

APPROVAL TEXT: Stelara subcutaneous has been approved for 6 months for maintenance treatment. Stelara intravenous loading dose is excluded from your pharmacy benefit coverage.

5. Has the patient **already received** the intravenous loading dose of Stelara for the treatment of moderate to severe Crohn's disease (CD)?

If yes, **approve for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

If no, **enter two approvals for a total of 6 months by GPID as follows:**

First approval - Please enter one of the following loading doses based on the patient's weight (NOTE: Do not enter a loading dose if the member does not have coverage for non-self-administered drug benefit. Please deny for benefit exclusion.):

Patients weighing 55kg (121 lbs.) or less:

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 52mL (two 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 55kg up to 85kg (122 lbs. up to 187 lbs.):

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 78mL (three 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 85kg (187 lbs.):

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 104mL (four 130mg/26mL vials) per 56 days for 1 fill.**

Second approval:

- **Maintenance dose: Approve for 4 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 2 fills with a start date after the end date of the previous fill.**

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of moderate to severe plaque psoriasis, moderate to severe plaque psoriasis with co-existent psoriatic arthritis, psoriatic arthritis without co-existent plaque psoriasis, or moderate to severe Crohn's disease. In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 12 years of age or older
- Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with moderate to severe Crohn's disease (CD), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- Documentation of the patient's current weight

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

If yes, **approve for 12 months by GPID with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) 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% or more
- Documentation of the patient's current weight

If yes, **approve for 12 months by GPID as follows:**

Patients weighing 100kg (220 lbs.) or less:

- **Approve for 12 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

Patients weighing over 100kg (220 lbs.):

- **Approve for 12 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

If yes, **approve for 12 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of psoriatic arthritis without co-existent plaque psoriasis, moderate to severe plaque psoriasis **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, or moderate to severe Crohn's disease. The following criteria must also be met:

For the diagnosis of psoriatic arthritis without co-existent plaque psoriasis, approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

For the diagnosis of moderate to severe plaque psoriasis or moderate to severe plaque psoriasis with co-existent psoriatic arthritis, approval requires:

- The patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
- Documentation of the patient's current weight.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

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. February 2018.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 10/09

Client Approval: 03/19

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
VEDOLIZUMAB	ENTYVIO	41146		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's (CD) disease and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months as follows:**

Please enter two authorizations by HICL as follows:

- **FIRST APPROVAL:** Approve for 1 month (total fill count of 1) with a quantity limit of **#600mg (#2 vials)** for the first 4 weeks, then
- **SECOND APPROVAL:** Approve for 5 months (total fill count of 3) with a quantity limit of **#300mg (#1 vial)** per 56 days (Please enter a start date of **ONE** week after the last date of the first approval).

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to **TWO** of the following formulary preferred immunomodulators: Humira **AND** Simponi or Xeljanz IR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months as follows:**

Please enter two authorizations by HICL as follows:

- **FIRST APPROVAL:** Approve for 1 month (total fill count of 1) with a quantity limit of #600mg (#2 vials) for the first 4 weeks, then
- **SECOND APPROVAL:** Approve for 5 months (total fill count of 3) with a quantity limit of #300mg (#1 vial) per 56 days (Please enter a start date of **ONE** week after the last date of the first approval).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe Crohn's disease, approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe ulcerative colitis, approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to TWO of the following formulary preferred immunomodulators: Humira AND Simponi or Xeljanz IR

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL with a quantity limit of #1 vial (300mg) per 8 weeks (total 6 fills in 12 months).**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis for renewal.

RATIONALE

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

REFERENCES

- Entyvio [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 05/14

Client Approval: 03/19

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VESTRONIDASE ALFA-VJBK (NSA)

Generic	Brand	HICL	GCN	Exception/Other
VESTRONIDASE ALFA-VJBK	MEPSEVII	44653		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) and meet **ALL** of the following criteria?
 - The patient is 5 years of age or older
 - The patient has a documented urinary GAG (glycosaminoglycan) level of greater than three times the upper level of normal based on the laboratory assay
 - MPS VII diagnosis confirmed by documentation of beta-glucuronidase enzyme activity deficiency or genetic testing
 - The patient has at least one of the following clinical signs of MPS VII: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary dysfunction
 - The patient has NOT undergone successful bone marrow or stem cell treatment for MPS VII
 - The patient has limitation in mobility, but remains sufficiently ambulatory for the six-minute walk test (6MWT) to be measured and evaluated
 - The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires the patient has improved, maintained, or demonstrated less than expected decline in ambulatory ability based on 6MWT compared to baseline.

If no, do not approve.

DENIAL TEXT: The guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome). In addition, the following criteria must be met:

- The patient is 5 years of age or older
- The patient has a documented urinary GAG (glycosaminoglycan) level of greater than three times the upper level of normal based on the laboratory assay
- MPS VII diagnosis confirmed by documentation of beta-glucuronidase enzyme activity deficiency or genetic testing
- The patient has at least one of the following clinical signs of MPS VII: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary dysfunction
- The patient has not undergone successful bone marrow or stem cell treatment for MPS VII
- The patient has limitation in mobility, but remains retains ambulatory capacity for the six-minute walk test (6MWT) to be measured and evaluated
- The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VESTRONIDASE ALFA-VJBK (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) **AND** meet the following criterion?

- Patient has improved, maintained, or demonstrated less than expected decline in ambulatory ability based on 6MWT compared to baseline

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) for renewal. The following criteria must also be met:

- Patient has improved, maintained, or demonstrated less than expected decline in ambulatory ability based on 6MWT compared to baseline

RATIONALE

Promote appropriate utilization of **VESTRONIDASE ALFA-VJBK** based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Mepsevii is a recombinant human lysosomal beta glucuronidase indicated in pediatric and adult patients for the treatment of Mucopolysaccharidosis VII (MPS VII, Sly syndrome).

Limitations of Use: The effect of Mepsevii on the central nervous system manifestations of MPS VII has not been determined.

DOSAGE AND ADMINISTRATION

The recommended dosage of Mepsevii is 4 mg/kg administered every two weeks as an intravenous infusion under the supervision of a healthcare professional. Premedication with a non-sedating antihistamine with or without an anti-pyretic is recommended 30 to 60 minutes prior to the start of the infusion. Administer the infusion over approximately 4 hours. In the first hour of infusion, infuse 2.5% of the total volume. After the first hour, the rate can be increased to infuse the remainder of the volume over 3 hours as tolerated.

AVAILABLE STRENGTHS

Injection: Mepsevii 10 mg/5 mL (2 mg/mL) solution, single-dose vial

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VESTRONIDASE ALFA-VJBK (NSA)

REFERENCES

- Mepsevii [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc. November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 03/18

Client Approval: 03/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VINCRIStINE LIPOSOMAL

Generic	Brand	HICL	GCN	Exception/Other
VINCRIStINE SULFATE LIPOSOMAL	MARQIBO	39542		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) and meets **ALL** of the following criteria?
 - The patient has experienced a Ph- ALL relapse two or more times
 - The patient has tried at least two anti-leukemia therapies (refer to Table 1)

If yes, **approve for 12 months by HICL with a quantity limit of #4 kits per 28 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **VINCRIStINE LIPOSOMAL (Marqibo)** requires a diagnosis of Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL); patient has experienced a Ph- ALL relapse two or more times; and the patient has tried at least two anti-leukemia therapies.

RATIONALE

To promote appropriate utilization of Marqibo based on FDA approved indication and NCCN guidelines.

In the US, approximately 6,000 patients are diagnosed with ALL on an annual basis of which approximately 1,600 patients can be categorized as Ph- ALL in second or greater relapse. The median age of diagnosis for ALL is 14 years. ALL represents 75 to 80 percent of childhood acute leukemias. Vincristine is indicated for the treatment of a number of malignancies including ALL, Hodgkin's disease, malignant glioma, neuroblastoma, non-Hodgkin's lymphoma, rhabdomyosarcoma, and Wilms' tumor. It is also used off-label for head and neck cancer, idiopathic thrombocytopenic purpura, Kaposi's sarcoma, multiple myeloma, small cell lung cancer, thymoma, and trophoblastic disease. The National Comprehensive Cancer Network (NCCN) guidelines recommend vincristine, corticosteroids, and anthracyclines as the basis of an induction regimen for Ph- ALL.

Marqibo can be accessed through Spectrum Therapy Access Resources (STAR) which is a reimbursement support, co-pay assistance, and patient assistance program designed to help patients and healthcare professionals gain appropriate access to drugs.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VINCRIStINE LIPOSOMAL

RATIONALE (CONTINUED)

Table 1: Examples of Anti-Leukemia Therapies

CALGB 8811 Larson regimen: daunorubicin, vincristine, prednisone, Oncaspar (pegaspargase), and cyclophosphamide
Linker 4-drug regimen: daunorubicin, vincristine, prednisone, and Oncaspar
Hyper-CVAD +/- Rituxan (rituximab): hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine; with or without rituximab for CD20-positive disease
MRC UKALLXII/ECOG2993 regimen: daunorubicin, vincristine, prednisone, and Oncaspar (induction phase I); and cyclophosphamide, cytarabine, and 6-mercaptopurine (induction phase II)
GRAALL-2003 regimen: daunorubicin, vincristine, prednisone, Oncaspar, and cyclophosphamide (patients aged <60 years)
COG AALL-0434 regimen with nelarabine (for T-ALL): daunorubicin, vincristine, prednisone, and Oncaspar; Arranon (nelarabine) added to consolidation regimen
CCG-1961 regimen: daunorubicin, vincristine, prednisone, Oncaspar (patients age ≤21 years)
PETHEMA ALL-96 regimen: daunorubicin, vincristine, prednisone, Oncaspar, and cyclophosphamide (patients aged <30 years)
CALGB 10403 regimen: daunorubicin, vincristine, prednisone, and Oncaspar (patients aged <40 years)
DFCI ALL regimen based on DFCI Protocol 00-01: doxorubicin, vincristine, prednisone, high-dose methotrexate, and Oncaspar (patients ages <50 years)
Clolar (clofarabine)-containing regimens
cytarabine-containing regimens
alkylator combination regimens
Arranon (for T cell based-ALL)
augmented hyper-CVAD (hyper-fractionated cyclophosphamide, intensified vincristine, doxorubicin, intensified dexamethasone, and Oncaspar; alternating with high-dose methotrexate and cytarabine)

Induction Regimens for Ph- ALL (Adult patients aged ≥40 years)

- CALGB 8811 Larson regimen: daunorubicin, vincristine, prednisone, Oncaspar (pegaspargase), and cyclophosphamide
- Linker 4-drug regimen: daunorubicin, vincristine, prednisone, and Oncaspar
- Hyper-CVAD +/- Rituxan (rituximab): hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine; with or without rituximab for CD20-positive disease
- MRC UKALLXII/ECOG2993 regimen: daunorubicin, vincristine, prednisone, and Oncaspar (induction phase I); and cyclophosphamide, cytarabine, and 6-mercaptopurine (induction phase II)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VINCRIPTINE LIPOSOMAL

RATIONALE (CONTINUED)

Induction Regimens for patients aged 15-39 years

- GRAALL-2003 regimen: daunorubicin, vincristine, prednisone, Oncaspar, and cyclophosphamide (patients aged <60 years)
- COG AALL-0434 regimen with nelarabine (for T-ALL): daunorubicin, vincristine, prednisone, and Oncaspar; Arranon (nelarabine) added to consolidation regimen
- CCG-1961 regimen: daunorubicin, vincristine, prednisone, Oncaspar (patients age ≤ 21 years)
- PETHEMA ALL-96 regimen: daunorubicin, vincristine, prednisone, Oncaspar, and cyclophosphamide (patients aged <30 years)
- CALGB 10403 regimen: daunorubicin, vincristine, prednisone, and Oncaspar (patients aged <40 years)
- DFCI ALL regimen based on DFCI Protocol 00-01: doxorubicin, vincristine, prednisone, high-dose methotrexate, and Oncaspar (patients ages <50 years)

NCCN recommends monthly vincristine prednisone pulses for 2 to 3 years with weekly methotrexate and daily 6-mercaptopurine as tolerated for the maintenance treatment of Ph- ALL.

Recommended salvage regimens for relapsed or refractory ALL include:

- Clolar (clofarabine)-containing regimens
- cytarabine-containing regimens
- alkylator combination regimens
- Arranon (for T cell based-ALL)
- augmented hyper-CVAD (hyper-fractionated cyclophosphamide, intensified vincristine, doxorubicin, intensified dexamethasone, and Oncaspar; alternating with high-dose methotrexate and cytarabine)
- Marqibo

FDA APPROVED INDICATIONS

Marqibo is a vinca alkaloid indicated for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. This indication is based on overall response rate. Clinical benefit such as improvement in overall survival has not been verified.

DOSAGE

Administer Marqibo at a dose of 2.25 mg/m^2 intravenously over 1 hour once every 7 days. Each single-dose vial of Marqibo contains 5 mg/31 mL (0.16 mg/mL) vincristine sulfate.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VINCRIStINE LIPOSOMAL

REFERENCES

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Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/16

Created: 10/13

Client Approval: 03/16

P&T Approval: 11/13



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORETIGENE NEPARVOVEC-RZYL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
VORETIGENE NEPARVOVEC- RZYL	LUXTURNA	44720		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient have a diagnosis of biallelic RPE65 mutation-associated retinal dystrophy and meet **ALL** of the following criteria?
 - Biallelic RPE65 mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
 - The patient is 3 years of age or older
 - The requested medication is prescribed by or in consultation with an ophthalmologist or retinal specialist
 - The patient has a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
 - The treating physician attests that the patient has sufficient retinal cells as demonstrated by sufficient retinal thickness
 - The patient does NOT have pre-existing eye conditions that may lead to blindness independently of RPE65-mutation associated retinal dystrophy (e.g., leukemia with CNS/optic nerve involvement, macular edema or CMV retinitis)
 - Patient has NOT previously received gene therapy (including Luxturna) for the treatment of vision loss
 - The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

If yes, **approve for 1 fill per lifetime by HICL with a quantity limit of 0.5mL (one single dose vial) per affected eye.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORETIGENE NEPARVOVEC-RZYL (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **VORETIGENE NEPARVOVEC-RZYL (Luxturna)** requires that the patient has a diagnosis of confirmed biallelic RPE65 mutation-associated retinal dystrophy. In addition, the following criteria must be met:

- Biallelic RPE65 mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
- The patient is 3 years of age or older
- The requested medication is prescribed by or in consultation with an ophthalmologist or retinal specialist
- The patient has a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
- The treating physician attests that the patient has sufficient retinal cells as demonstrated by sufficient retinal thickness
- The patient does NOT have pre-existing eye conditions that may lead to blindness independently of RPE65-mutation associated retinal dystrophy (e.g., leukemia with CNS/optic nerve involvement, macular edema or CMV retinitis)
- Patient has NOT previously received gene therapy (including Luxturna) for the treatment of vision loss
- The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

RATIONALE

Promote appropriate utilization of **LUXTURNA** based on FDA approved indication.

FDA APPROVED INDICATIONS

Luxturna is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

DOSAGE AND ADMINISTRATION

- The recommended dose of Luxturna for each eye is 1.5×10^{11} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL.
- Luxturna is administered by a surgeon via subretinal injection.
 - Perform subretinal administration of Luxturna to each eye on separate days within a close interval, but no fewer than 6 days apart.
 - Recommend systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum of 40 mg/day) for a total of 7 days (starting 3 days before administration of Luxturna to each eye), and followed by a tapering dose during the next 10 days.

CONTINUED ON NEXT PAGE



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VORETIGENE NEPARVOVEC-RZYL (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

AVAILABLE STRENGTH(S)

Luxturna is a suspension for subretinal injection, supplied in a 0.5 mL extractable volume in a single-dose 2 mL vial for a single administration in one eye. The supplied concentration (5×10^{12} vg/mL) requires a 1:10 dilution prior to administration.

REFERENCES

- Luxturna [Prescribing Information]. Spark Therapeutics, Inc: Philadelphia, PA. December 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 03/18

Client Approval: 03/18

P&T Approval: 01/18



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIV-AFLIBERCEPT

Generic	Brand	HICL	GCN	Exception/Other
ZIV-AFLIBERCEPT	ZALTRAP		32988 32989	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC)?

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 an oxaliplatin-containing regimen (such as FOLFOX)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is Zaltrap being used in combination with FOLFIRI or irinotecan?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of metastatic colorectal cancer, a trial of an oxaliplatin-containing regimen (such as FOLFOX), and concurrent use with FOLFIRI or irinotecan.

RATIONALE

To ensure appropriate use of Zaltrap consistent with FDA approved indication and National Comprehensive Cancer Network (NCCN) recommendations.

CONTINUED ON NEXT PAGE



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ZIV-AFLIBERCEPT

RATIONALE (CONTINUED)

Zaltrap is a fully humanized recombinant fusion protein that inhibits angiogenesis by binding to the vascular endothelial growth factor (VEGF)-A receptor. In addition to blocking all human VEGF-A isoforms, Zaltrap also inhibits VEGF-B, and placental growth factor (PIGF) with a higher affinity than native receptors. Zaltrap is given as a 4mgg intravenous infusion over 1 hour every 2 weeks. It should not be given as an intravenous push or bolus. It is given in combination with the FOLFIRI chemotherapy regimen. Zaltrap therapy must be suspended for both 4 weeks prior to and 4 weeks following major surgery. Aflibercept, marketed as Eylea, is approved for the treatment of macular degeneration.

NCCN Guidelines Version 2.2013: Colon Cancer / NCCN Guidelines Version 3.2013 Rectal Cancer

Surgical removal is the preferred treatment for early stage disease. Surgery is accompanied by adjuvant chemotherapy for patients with high-risk features or more extensive cancer involvement.

Primary treatment options for resectable synchronous metastases are:

- Chemotherapy (FOLFIRI, FOLFOX, or CapeOX) with or without Avastin Chemotherapy (FOLFIRI or FOLFOX) with or without Vectibix (*KRAS* wild-type patients only)
- Chemotherapy (FOLFIRI) with or without Erbitux (*KRAS* wild-type patients only)
- Staged resection
- Infusional IV 5-FU with radiation

Primary treatment options for unresectable metachronous metastases previously treated with adjuvant FOLFOX are:

- FOLFIRI with or without Avastin
- FOLFIRI with or without Zaltrap
- Irinotecan with or without Avastin
- Irinotecan with or without Zaltrap
- FOLFIRI or irinotecan with Erbitux or Vectibix (*KRAS* wild-type patients only)

Initial therapy options for treatment of mCRC in patients appropriate for intensive therapy are:

- FOLFOX, with or without Avastin
- FOLFOX, with or without Vectibix (*KRAS* wild-type patients only)
- CapeOX with or without Avastin
- FOLFIRI with or without Avastin
- FOLFIRI with our without Erbitux or Vectibix (*KRAS* wild-type patients only)
- 5-FU/leucovorin or Xeloda with or without Avastin
- FOLFOXIRI

CONTINUED ON NEXT PAGE



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIV-AFLIBERCEPT

RATIONALE (CONTINUED)

Initial therapy options for treatment of mCRC in patients not appropriate for intensive therapy are:

- Infusional 5-FU with leucovorin or Xeloda with or without Avastin
- Erbitux (KRAS wild-type patients only)
- Vectibix (KRAS wild-type patients only)

Zaltrap in combination with FOLFIRI is a recommended therapeutic regimen following progression of mCRC after an oxaliplatin containing chemotherapy regimen. Stivarga is considered a treatment option in therapy after first, second, or third progression, depending on previous lines of therapy.

Other treatment options after first or second progression include:

- Erbitux or Vectibix with irinotecan (KRAS wild-type patients only)
- FOLFOX, FOLFIRI, CapeOX, or irinotecan with or without Avastin
- Irinotecan and oxaliplatin with or without Avastin

FDA APPROVED INDICATIONS

Zaltrap, in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI), is indicated for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

REFERENCES

- Zaltrap [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.
- National Comprehensive Cancer Network. Colon Cancer Guideline Version 2.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/colon.pdf [Accessed January 16, 2013].
- National Comprehensive Cancer Network. Rectal Cancer Guideline Version 3.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf [Accessed January 16, 2013].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/13

Client Approval: 11/13

P&T Approval: 11/13



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