Prior Authorization Approval Criteria

Effective Date: 01/01/2021

Standard Commercial
Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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

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

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

ABALOPARATIDE

Generic	Brand			
ABALOPARATIDE	TYMLOS			

GUIDELINES FOR USE

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

A. You have postmenopausal osteoporosis (weak or brittle bones after menopause)
B. You have not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo
C. You meet ONE of the following (1, 2, or 3):
   1. You have high risk for fractures defined as ONE of the following:
      i. History of osteoporotic fracture(s) (cracked bones) due to trauma (injury) or fragility (weakness)
      ii. 2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density T-score (test to determine your risk for weak bones) less than or equal to -2.5, corticosteroid use, or use of GnRH (Gonadotropin-releasing hormone) analogs such as nafarelin, etc.
      iii. No prior treatment for osteoporosis AND FRAX (Fracture Risk Assessment Tool) score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
   2. You are unable to use oral therapy due to upper gastrointestinal (stomach and intestine) problems, you cannot tolerate oral medication, you have lower gastrointestinal problems (unable to absorb oral medications), you have trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as alendronate, risedronate, ibandronate) with other oral medications in your daily routine
   3. You have had an adequate trial of, intolerance to, or a contraindication (medical reason why you cannot use) to bisphosphonates such as Fosamax, Actonel, Boniva

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Commercial Effective: 05/01/20

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ABATACEPT - SQ

Generic	Brand			
ABATACEPT - SQ	ORENCIA - SQ ORENCIA CLICKJECT - SQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABATACEPT - SQ (Orencia - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least **ONE** DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel **AND** Humira

(Initial criteria continued on next page)

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate/extended release), Otezla

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

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 04/01/20

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ABEMACICLIB

Generic	Brand			
ABEMACICLIB	VERZENIO			

GUIDELINES FOR USE

Our guideline named **ABEMACICLIB (Verzenio)** requires the following rules be met for approval:

A. You have advanced or metastatic breast cancer (cancer has spread to other parts of body) that is hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2)
B. You meet ONE of the following:
   1. **If the medication will be used in combination with fulvestrant, approval also requires:**
      i. You are a female
      ii. Your disease has gotten worse after using endocrine therapy
      iii. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)
   2. **If the medication will be used as monotherapy (used alone), approval also requires:**
      i. You are 18 years of age or older
      ii. Your disease has gotten worse after using endocrine therapy and before using chemotherapy in the metastatic setting
      iii. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)
   3. **If the medication will be used in combination with an aromatase inhibitor (e.g. Anastrozole, letrozole), approval also requires:**
      i. You are a female and postmenopausal
      ii. You have NOT received prior endocrine therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      iii. The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
      iv. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)

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ABIRATERONE

Generic	Brand			
ABIRATERONE ACETATE	ZYTIGA			
ABIRATERONE ACET, SUBMICRONIZED	YONSA			

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

GUIDELINES FOR USE

ZYTIGA

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

A. You have ONE of the following diagnoses:
   1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   2. Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)

B. The requested medication will be used in combination with prednisone

C. You meet ONE of the following:
   1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

YONSA

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

1. You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
2. The requested medication will be used in combination with methylprednisolone
3. You have previously tried or have a contraindication to (medical reason why you cannot use) Zytiga (abiraterone acetate)
4. You meet ONE of the following:
   1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

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ACALABRUTINIB

Generic	Brand			
ACALABRUTINIB	CALQUENCE			

GUIDELINES FOR USE

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:

A. You have a diagnosis of mantle cell lymphoma (MCL: a type of cancer), chronic lymphocytic leukemia (CLL: cancer of the blood and bone marrow), or small lymphocytic lymphoma (SLL: cancer of the blood and bone marrow)
B. You are 18 years of age or older
C. **If you have mantle cell lymphoma (MCL), approval also requires:**
   1. You have received at least one prior therapy for mantle cell lymphoma

Commercial Effective: 05/01/20

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ACETAMINOPHEN DAILY LIMIT OVERRIDE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **ACETAMINOPHEN DAILY LIMIT OVERRIDE** will cause a denied claim for acetaminophen when the total daily dose acetaminophen exceeds 4000mg. The claim will also deny if the requested drug is being used at the same time with other acetaminophen containing product(s) and the combination exceeds 4000mg of acetaminophen per day limit.

Approval requires the following rule be met:

A. You will discontinue the other acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

Commercial Effective: 05/01/20

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ACNE AGE RESTRICTION OVERRIDE

Generic	Brand				
ADAPALENE	DIFFERIN, PLIXDA				
ADAPALENE/BENZOYL PEROXIDE	EPIDUO, EPIDUO FORTE				
TRETINOIN	ATRALIN, AVITA, RETIN-A, TRETIN-X, ALTRENO				
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP				
TRIFAROTENE	AKLIEF				
TAZAROTENE	FABIOR, ARAZLO				

GUIDELINES FOR USE

Our guideline named **ACNE AGE RESTRICTION OVERRIDE** requires the following rule(s) be met for approval:

A. You are 26 years of age or older
B. The request is for a non-cosmetic (not for appearance) diagnosis.
C. Approval may also require that you have tried preferred agent(s), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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ADALIMUMAB

Generic	Brand			
ADALIMUMAB	HUMIRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints).
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. There is documentation of your most current weight

(Initial criteria continued on next page)

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% body surface area (BSA) OR psoriatic lesions (rashes) affecting the face, hands, feet, or genital area
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

G. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

I. **If you have moderate to severe hidradenitis suppurativa (HS), approval also requires:**
   1. You are 12 years of age or older
J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)
   4. If you are 2 to 17 years of age, we require documentation of your current weight

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)
B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Humira weekly dosing, we require you have tried at least a 3-month of Humira 40mg every other week
C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
D. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Renewal criteria continued on next page)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have 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

F. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have 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

G. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      i. You have development of new inflammatory chorioretinal or retinal vascular lesions (eye tumors)
      ii. A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      iii. A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

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Commercial Effective: 05/01/20

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AFATINIB

Generic	Brand			
AFATINIB DIMALEATE	GILOTRIF			

GUIDELINES FOR USE

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

A. You have metastatic squamous non-small cell lung cancer (type of cancer that has spread) or metastatic non-small cell lung cancer (a different type of lung cancer that has spread)
B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
   1. Your disease has worsened after using platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)
C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumors have non-resistant epidermal growth factor receptor (EGFR; type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test

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ALECTINIB

Generic	Brand			
ALECTINIB	ALECENSA			

GUIDELINES FOR USE

Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:

1. You have a diagnosis of metastatic non-small cell lung cancer (NSCLC; type of cancer that has spread)
2. You are positive for anaplastic lymphoma kinase (ALK; gene mutation) fusion oncogene as detected by an FDA (Food and Drug Administration) -approved test

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ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand			
HOUSE DUST MITE	ODACTRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites, with or without conjunctivitis (type of inflammation of eye and eyelid)
B. Your diagnosis is confirmed by in vitro testing (testing outside of your body in a tube) for IgE (Immunoglobulin E) antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
C. You are between 18 and 65 years old
D. The medication is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
G. You have a current claim or prescription for auto-injectable epinephrine within the past 365 days

RENEWAL CRITERIA

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

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Commercial Effective: 05/01/20

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand			
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:

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

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand			
WEED POLLEN-SHORT RAGWEED	RAGWITEK			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. Your diagnosis is confirmed by a positive skin prick test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You are 18 years of age or older
F. You have a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

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

A. You have an improvement in signs and symptoms of allergic rhinitis from baseline

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Commercial Effective: 05/01/20

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand			
GRASS POLLEN-TIMOTHY, STD	GRASTEK			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:

A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. You have a positive skin prick test and/or a positive titre (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You are at least 5 years old
F. You have a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule be met for renewal:

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

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Commercial Effective: 05/01/20

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ALPELISIB

Generic	Brand			
ALPELISIB	PIQRAY			

GUIDELINES FOR USE

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

A. You have a diagnosis of advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. Your breast cancer is hormone receptor (HR: type of gene)-positive, human epidermal growth factor receptor 2 (HER2: type of gene)-negative
C. You are a postmenopausal female or a male
D. Piqray will be used in combination with Faslodex (fulvestrant)
E. You have presence of PIK3CA (type of gene)-mutation as detected by a Food and Drug Administration approved test
F. You have experienced disease progression on or after an endocrine-based regimen (your disease has worsened after using a type of hormone therapy)

Commercial Effective: 05/01/20

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AMANTADINE EXTENDED RELEASE

Generic	Brand			
AMANTADINE EXTENDED RELEASE	GOCOVRI			
AMANTADINE HCL	OSMOLEX ER			

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

GUIDELINES FOR USE

GOCOVRI

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

A. You have dyskinesia (abnormal involuntary movements)
B. You have Parkinson's disease (nervous system disorder that affects movement)
C. You are receiving levodopa-based therapy
D. You have previously tried generic amantadine capsules, tablets or solution

OSMOLEX ER

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

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

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AMIFAMPRIDINE

Generic	Brand			
AMIFAMPRIDINE	FIRDAPSE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor) or hematologist-oncologist (blood-cancer doctor)
D. Diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing **AND** clinical triad (3 symptoms) of muscle weakness, autonomic dysfunction, and decreased tendon reflexes
E. **If you are requesting Firdapse, approval also requires:**
    1. You are 18 years of age or older
F. **If you are requesting Ruzurgi, approval also requires:**
    1. Documentation of your weight

RENEWAL CRITERIA

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

Commercial Effective: 05/01/20

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AMIKACIN LIPOSOMAL INHALATION

Generic	Brand			
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE			

GUIDELINES FOR USE

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

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:

A. You have *Mycobacterium avium complex* (MAC – group of bacteria that cause serious infections) lung disease with limited or no alternative treatment options
B. You are 18 years of age or older
C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
D. Arikayce will be used as part of a combination antibacterial drug regimen
E. Arikayce is being prescribed by or given in consultation with a pulmonologist (lung doctor) or infectious disease specialist physician

RENEWAL CRITERIA

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:

A. You have *Mycobacterium avium complex* (MAC- group of bacteria that cause serious infections) lung disease
B. You have not had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
C. You have experienced an improvement in symptoms
D. You meet ONE of the following:
    1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture (mucus test) for *Mycobacterium avium complex* by 6 months of Arikayce treatment
    2. For second or later renewal requests, approval also requires documentation of at least THREE negative sputum cultures (mucus test) for *Mycobacterium avium complex* by 12 months of Arikayce treatment

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AMLODIPINE SUSPENSION

Generic	Brand				
AMLODIPINE BENZOATE	KATERZIA				

GUIDELINES FOR USE

Our guideline named **AMLODIPINE SUSPENSION (Katerzia)** requires the following rule(s) be met for approval:

A. You are unable to swallow oral amlodipine tablets at prescribed dose

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Commercial Effective: 04/01/20

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AMLODIPINE/CELECOXIB

Generic	Brand				
AMLODIPINE BESYLATE/CELECOXIB	CONSENSI				

GUIDELINES FOR USE

Our guideline named **AMLODIPINE/CELECOXIB (Consensi)** requires the following rule(s) be met for approval:

A. You have both hypertension (abnormal high blood pressure) and osteoarthritis (a type of arthritis that occurs when tissue at the ends of your bones wears down)
B. You are 18 years of age or older
C. You have previously tried amlodipine AND celecoxib
D. You have an adherence or other challenge requiring the use of the combination product over separate agents
E. You will NOT use Consensi together with any other calcium channel blocker agents (such as diltiazem, felodipine, verapamil)

Commercial Effective: 04/01/20

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AMPHETAMINE SULFATE

Generic	Brand			
AMPHETAMINE SULFATE	EVEKEO			

GUIDELINES FOR USE

Our guideline named **AMPHETAMINE SULFATE (Evekeo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (condition where you suddenly fall asleep)
   2. Attention deficit disorder with hyperactivity (difficulty paying attention)
   3. Use for weight loss or exogenous obesity (overweight due to overeating)

B. **If you have narcolepsy, approval also requires:**
   1. You are 6 years of age or older

C. **If you have attention deficit disorder with hyperactivity, approval also requires:**
   1. You are 3 years of age or older
   2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)

D. **If the request is for weight loss or exogenous obesity, approval also requires:**
   1. You are 12 years of age or older
   2. You had a previous trial of other weight loss medications such as Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion

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

Commercial Effective: 05/01/20

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ANABOLIC STEROIDS

Generic	Brand			
OXYMETHOLONE	ANADROL-50			
OXANDROLONE	OXANDRIN			

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

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

A. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction
D. **If you have anemia, approval also requires:**
   1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's
E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in recommendation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS), or infectious disease specialist

(Initial criteria continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

4. You meet ONE of the following:
   a. You have 10% unintentional weight loss over 12 months
   b. You have 7.5% unintentional weight loss over 6 months
   c. You have 5% body cell mass (BCM) loss within 6 months
   d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
   e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
   f. You have a BMI of less than 18.5 kg per meter squared

OXANDRIN

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

A. You have ONE of the following diagnoses:
   1. Weight loss
   2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
   3. Bone pain accompanying osteoporosis (weak and brittle bones)
   4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   5. Turner's Syndrome (disorder where female has one X chromosome
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction
D. **If you have weight loss, approval also requires:**
   1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
   2. Medication is being used as add-on therapy to help weight gain

(Initial criteria continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

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

RENEWAL CRITERIA

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

OXANDRIN and ANADROL-50

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

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

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ANAKINRA

Generic	Brand			
ANAKINRA	KINERET			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints) or Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

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

RENEWAL CRITERIA

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints) or Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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ANTI-OBESITY AGENTS

Generic	Brand			
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE ER			
LORCASERIN HCL	BELVIQ, BELVIQ XR			
PHENTERMINE/ TOPIRAMATE	QSYMIA			
LIRAGLUTIDE	SAXENDA			
ORLISTAT	XENICAL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANTI-OBESITY AGENTS (Contrave, Belviq, Belviq XR, Qsymia, Saxenda, Xenical)** requires the following rule(s) be met for approval:

A. The request is for weight loss OR weight loss management
B. You have evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
C. You meet ONE of the following:
    1. Body mass index (BMI) of 30 kg/m(2) or greater
    2. BMI of 27 kg/m(2) or greater **AND** at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)
D. **If you are requesting Contrave, approval also requires:**
    1. You are 18 years of age or older
E. **If you are requesting Belviq, Belviq XR, or Qsymia, approval also requires:**
    1. You are 18 years of age or older
    2. You have previously tried Contrave or Saxenda, unless there is medical reason why you cannot (contraindication)
F. **If you are requesting Saxenda, approval also requires:**
    1. You are 18 years of age or older
    2. You are **NOT** currently taking a GLP-1 receptor agonist (type of drug for type 2 diabetes such as Victoza, Byetta, Bydureon, Tanzeum)

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ANTI-OBESITY AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ANTI-OBESITY AGENTS (Contrave, Belviq, Belviq XR, Qsymia, Saxenda, Xenical)** requires the following rule(s) be met for renewal:

A. The request is for weight loss OR weight loss management
B. **If you are requesting Saxenda, approval also requires** that you have lost at least 4% of baseline body weight after 4 months of treatment
C. **If you are requesting Xenical, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment
D. **If you are requesting Belviq or Belviq XR, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment
E. **If you are requesting Contrave, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)
F. **If you are requesting Qsymia 7.5/46mg, approval also requires** that you have lost at least 3% of baseline body weight after 3 months of treatment at the requested maintenance dose. The dose should be increased or discontinued if patient has not lost at least 3% of baseline body weight after 3 months of treatment
G. **If you are requesting Qsymia 15/92mg, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment at the requested maintenance dose

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APALUTAMIDE

Generic	Brand			
APALUTAMIDE	ERLEADA			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

C. **If you have a non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] levels)

RENEWAL CRITERIA

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
   B. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

Commercial Effective: 01/01/21

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APOMORPHINE

Generic	Brand			
APOMORPHINE	APOKYN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. The requested medication is being used for acute, intermittent treatment of hypomobility (short and sudden episodes where you have decreased ability to move), OFF episodes associated with advanced Parkinson's disease
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
D. Your physician has optimized your drug therapy as evidenced by BOTH of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. You have had a trial of or contraindication to (medical reason why you cannot use) at least TWO Parkinson disease agents from two different classes: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone)

RENEWAL CRITERIA

Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You have had improvement with motor fluctuations during OFF episodes with the use of Apokyn (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

Commercial Effective: 07/01/20

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APOMORPHINE - SL

Generic	Brand				
APOMORPHINE	KYNMOBI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist
D. The physician has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to at least two Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-o-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)
E. The requested medication is being used for acute, intermittent treatment (sudden and periodic treatment) of 'OFF' episodes (when symptoms return due to your medication for Parkinson's disease wearing off)

RENEWAL CRITERIA

Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for renewal:

A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

Commercial Effective: 10/01/20

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APREMILAST

Generic	Brand			
APREMILAST	OTEZLA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Behçet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

C. If you have moderate to severe plaque psoriasis (PsO), approval also requires:
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of your body surface area (BSA) or psoriatic lesions (rashes) affecting your face, hands, feet, or genital area
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

D. If you have Behçet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (joint pain and inflammation doctor)
   3. You have previously tried ONE or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid, unless there is a medical reason why you cannot (contraindication)

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APREMILAST

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:

A. You have psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches), moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales) or Behcet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

D. **If you have Behcet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
   1. You have achieved or maintained clinical benefit compared to baseline such as an improvement in pain scores, number of ulcers, etc.

Commercial Effective: 04/01/20

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ARIPIPRAZOLE SENSOR TABS

Generic	Brand			
ARIPIPRAZOLE TABLETS WITH SENSOR	ABILIFY MYCITE			

GUIDELINES FOR USE

Our guideline named **ARIPIPRAZOLE SENSOR TABS (Abilify MyCite)** requires the following rule(s) be met for approval:

A. You have a diagnosis of schizophrenia, bipolar I disorder, or major depressive disorder
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a psychiatrist
D. You have a medical necessity for medication ingestion tracking
E. **If you have major depressive disorder (MDD),** approval also requires:
   a. The medication will be used as an adjunctive (add-on) treatment
F. **If you have bipolar I disorder,** approval also requires **ONE** of the following**:**
   1. The request is for acute (short-term) treatment of manic and mixed episodes as monotherapy, OR as an adjunct (add-on) to lithium or valproate
   2. The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

Commercial Effective: 07/01/20

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ASFOTASE ALFA

Generic	Brand			
ASFOTASE ALFA	STRENSIQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP; genetic disorder causing abnormal development of bones and teeth) or juvenile-onset hypophosphatasia (HPP).

B. **If you have perinatal/infantile-onset hypophosphatasia (HPP), all of the following criteria must be met:**
   1. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You were 6 months of age or younger at hypophosphatasia onset
   3. You are not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
   4. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing **OR** you meet at least **TWO** of the following criteria:

   a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
   b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
   c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
   d. Radiographic evidence of hypophosphatasia [e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
   e. Presence of **two or more** of the following:
      i. Rachitic chest deformity (chest bones are not normal)
      ii. Craniosynostosis (premature closure of skull bones)
      iii. Delay in skeletal growth resulting in delay of motor development
      iv. History of vitamin B6 dependent seizures
      v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
      vi. History or presence of fracture after birth not due to injury or delayed fracture healing

(Initial criteria continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

C. **If you have juvenile-onset hypophosphatasia (HPP), approval also requires:**
   1. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You were 18 years of age or younger at hypophosphatasia onset
   3. You are not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
   4. You are positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meet at least **TWO** of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia (e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)
      e. Presence of **two or more** of the following:
         i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
         ii. Premature loss of primary teeth prior to 5 years of age
         iii. Delay in skeletal growth leading to motor development delay
         iv. History or presence of fracture after birth not due to injury or delayed fracture healing

Strensiq will not be approved for the following patients:
1. Patients with serum calcium or phosphate levels below the normal range
2. Patients with a treatable form of rickets (A softening and weakening of bones in children, usually due to low Vitamin D)

RENEWAL CRITERIA

Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule is met for renewal:

A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.

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ASPIRIN ER

Generic	Brand			
ASPIRIN ER	DURLAZA			

GUIDELINES FOR USE

Our guideline named **ASPIRIN ER (Durlaza)** requires the following rules be met for approval:

1. You have ONE of the following:
   a. Diagnosis of chronic coronary artery disease [damage or disease in the heart's major blood vessels; may include a history of myocardial infarction (heart attack) or unstable angina (chest pain when your heart doesn't get enough oxygen)] OR
   b. History of an ischemic stroke or transient ischemic attack (arteries to your brain become narrowed or blocked, causing blood flow loss).
2. You have previously tried aspirin over-the-counter (OTC)
3. Durlaza is NOT being used for acute treatment (short term treatment) of myocardial infarction (heart attack) or before percutaneous coronary intervention (non-surgical procedure used to treat narrowing of the coronary arteries of the heart)

Commercial Effective: 07/01/20

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ASPIRIN-OMEPRAZOLE

Generic	Brand			
ASPIRIN-OMEPRAZOLE	YOSPRALA, ASPIRIN-OMEPRAZOLE			

GUIDELINES FOR USE

Our guideline named **ASPIRIN-OMEPRAZOLE (Yosprala)** requires the following rule(s) be met for approval:

A. The request is for secondary prevention of cardiovascular (related to heart and blood vessels) or cerebrovascular (related brain and blood vessels) events
B. You have ONE of the following:
   1. Ischemic stroke (arteries to your brain become narrowed or blocked, causing less blood flow)
   2. Transient ischemia of the brain due to fibrin platelet emboli (blood flow to your brain gets cut off for a short time due to temporary blockage)
   3. Previous myocardial infarction (heart attack)
   4. Unstable angina pectoris (chest pain when your heart doesn't get enough oxygen)
   5. Chronic stable angina pectoris (chest pain when your heart doesn't get enough oxygen)
   6. History of undergoing revascularization procedures (procedures that restore blood flow to heart such as coronary artery bypass graft, percutaneous transluminal coronary angioplasty)
C. You have a risk of developing aspirin associated gastrointestinal (GI) ulcers due to age (55 years or older) **AND** have a documented history of gastrointestinal (GI) ulcers
D. You have tried both aspirin over-the-counter (OTC) **AND** generic proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole, rabeprazole)

Commercial Effective: 07/01/20

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AVAPRITINIB

Generic	Brand				
AVAPRITINIB	AYVAKIT				

GUIDELINES FOR USE

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

A. You have unresectable (cannot be removed completely through surgery) or metastatic (cancer that has spread to other parts of the body) gastrointestinal stromal tumor (GIST: type of growth in the digestive system tract, most commonly in the stomach or small intestine)
B. You are 18 years of age or older
C. You have a platelet-derived growth factor receptor alpha (PDGFRA: a type of gene/protein) exon 18 mutation, including PDGFRA D842V mutations (a change in your DNA that make up your gene)

Commercial Effective: 07/01/20

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AVATROMBOPAG

Generic	Brand			
AVATROMBOPAG	DOPTELET			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   a. Thrombocytopenia (low amount of a type of blood cell that prevents bleeding)
   b. Chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)

B. **If you have thrombocytopenia, approval also requires:**
   1. You are 18 years of age or older
   2. You have chronic liver disease
   3. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   4. You have a platelet (type of blood cell that prevents bleeding) count of less than 50 x 10(9)/L measured within the last 30 days
   5. Therapy is prescribed by or given in consultation with a hematologist (blood specialist), gastroenterologist (digestive system doctor), hepatologist (liver specialist), immunologist (allergy/immune system specialist), or endocrinologist (hormone doctor)
   6. You are not receiving other thrombopoietin receptor agonist therapy such as Promacta

C. **If you have chronic immune thrombocytopenia (cITP), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried corticosteroids or immunoglobulins, unless there is a medical reason why you cannot (contraindication) **OR** you had an insufficient response to splenectomy (surgical removal of spleen)
   3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system specialist)

RENEWAL CRITERIA

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of thrombocytopenia (low amount of a type of blood cell that prevents bleeding) or chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)
B. You had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10(9)/L (at least 50,000 per microliter), compared to baseline.

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AXITINIB

Generic	Brand			
AXITINIB	INLYTA			

GUIDELINES FOR USE

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

A. You have advanced renal cell carcinoma (RCC; type of kidney cancer)
B. You also meet ONE of the following:
   1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
   2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
   3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

Commercial Effective: 07/01/20

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AZACITIDINE

Generic	Brand				
AZACITIDINE	ONUREG				

GUIDELINES FOR USE

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

A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
B. You are 18 years of age or older
C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
D. You are not able to complete intensive curative therapy (treatment to cure the disease)

Commercial Effective: 01/01/21

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AZTREONAM INHALED

Generic	Brand			
AZTREONAM LYSINE	CAYSTON			

GUIDELINES FOR USE

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

A. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 7 years of age or older
C. You have a lung infection with a Gram negative species such as *Pseudomonas aeruginosa*

Commercial Effective: 07/01/20

BACLOFEN ORAL SOLUTION

Generic	Brand			
BACLOFEN	OZOBAX			

GUIDELINES FOR USE

Our guideline named **BACLOFEN ORAL SOLUTION (Ozobax)** requires the following rule be met for approval:

A. You are unable to swallow oral baclofen tablets at the prescribed dosing.

Commercial Effective: 07/01/20

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BARICITINIB

Generic	Brand			
BARICITINIB	OLUMIANT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
E. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

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

RENEWAL CRITERIA

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in the joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Commercial Effective: 04/01/20

BEDAQUILINE FUMARATE

Generic	Brand			
BEDAQUILINE FUMARATE	SIRTURO			

GUIDELINES FOR USE

Our guideline named **BEDAQUILINE FUMARATE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
   2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. **If you have pulmonary multi-drug resistant tuberculosis (MDR-TB), approval also requires ONE of the following:**
   1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
   2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
   3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. **If you have pulmonary extensively drug resistant tuberculosis (XDR-TB), approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Sirturo in combination with pretomanid and linezolid

Commercial Effective: 08/01/20

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BELIMUMAB - SQ

Generic	Brand			
BELIMUMAB	BENLYSTA			

GUIDELINES FOR USE

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

Our guideline named **BELIMUMAB (Benlysta SQ)** requires the following rule(s) be met for approval:

A. You have autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

RENEWAL CRITERIA

Our guideline named **BELIMUMAB (Benlysta SQ)** requires the following rule(s) be met for renewal:

A. You have autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
B. You had clinical improvement while on Benlysta

Commercial Effective: 01/01/21

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BENRALIZUMAB

Generic	Brand			
BENRALIZUMAB	FASENRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
B. You are 12 years of age or older
C. Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
D. Fasenra will be used as add-on maintenance treatment
E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
F. You had a prior therapy with medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid **AND** at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as tiotropium), leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
G. You have experienced at least ONE 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)
H. You are NOT receiving concurrent treatment with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Cinqair)

RENEWAL CRITERIA

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:

1. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
2. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
3. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

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BEROTRALSTAT

Generic	Brand				
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Orladeyo together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

RENEWAL CRITERIA

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

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Commercial Effective: 01/01/21

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BEXAROTENE

Generic	Brand				
BEXAROTENE SOFTGEL	TARGRETIN				
BEXAROTENE 1% TOPICAL GEL	TARGRETIN				

GUIDELINES FOR USE

Our guideline named **BEXAROTENE (Targretin)** requires the following rule to be met for approval:

A. You have cutaneous T-cell lymphoma (CTCL: a type of cancer that starts in white blood cells and attacks the skin)
B. **If the request is for bexarotene capsules, approval also requires:**
   1. Your condition is refractory (resistant) to previous systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or Velcade
C. **If the request is for topical bexarotene treatment, approval also requires:**
   1. You have cutaneous T-cell lymphoma (CTCL) Stage IA or IB
   2. You meet ONE of the following:
      a. Your condition is refractory or persistent after previous therapy
      b. You have not tolerated previous therapy

Commercial Effective: 07/01/20

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BINIMETINIB

Generic	Brand			
BINIMETINIB	MEKTOVI			

GUIDELINES FOR USE

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

A. You have a diagnosis of unresectable (cannot completely remove by surgery) or metastatic (disease that has spread) melanoma (skin cancer)
B. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration-approved test
C. The medication will be used in combination with Braftovi (encorafenib)

Commercial Effective: 07/01/20

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BOSUTINIB

Generic	Brand			
BOSUTINIB	BOSULIF			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+; small abnormal chromosome found in leukemia) chronic myelogenous leukemia (CML; blood-cell cancer that begins in the bone marrow)
   2. Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML; blood-cell cancer that begins in the bone marrow)

B. You are 18 years of age or older

C. **If you have chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+; small abnormal chromosome found in leukemia) chronic myeloid leukemia (CML; blood-cell cancer that begins in the bone marrow), approval also requires:**
   1. You have previously tried or have a contraindication to (a medical reason why you cannot use) other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)
   2. You do NOT have the T315I, V299L, G250E, or F317L mutations as shown by Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (type of lab test)

Commercial Effective: 07/01/20

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BREMELANOTIDE

Generic	Brand			
BREMELANOTIDE	VYLEESI			

GUIDELINES FOR USE

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

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

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You had a previous trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are **NOT** currently using Addyi (flibanserin)

RENEWAL CRITERIA

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

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder [FSIAD] where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are **NOT** currently using Addyi (flibanserin)
D. You have experienced continued improvement in symptoms of HSDD/FSIAD such as increased sexual desire, lessened distress)

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BRIGATINIB

Generic	Brand			
BRIGATINIB	ALUNBRIG			

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA) as detected by a Food and Drug Administration (FDA)-approved test

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Commercial Effective: 07/01/20

BRODALUMAB

Generic	Brand			
BRODALUMAB	SILIQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have moderate to severe plaque psoriasis (PsO; scaly, itchy dry skin patches)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You had a previous trial of at least ONE or more forms of conventional therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
F. You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
G. You have previously tried any **TWO** of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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

RENEWAL CRITERIA

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: scaly, itchy dry skin patches)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
C. You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq

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Commercial Effective: 05/01/20

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BUDESONIDE

Generic	Brand				
BUDESONIDE	ORTIKOS				

GUIDELINES FOR USE

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

A. You have mild to moderate Crohn's Disease (inflammation of the digestive tract that affects a part of your small intestines and/or the beginning of the colon which can lead to stomach pain, diarrhea, weight loss, or malnutrition)
B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
   1. You are 8 years of age or older
   2. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product
C. **If you have mild to moderate Crohn's Disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
   3. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

Commercial Effective: 01/01/21

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C1 ESTERASE INHIBITOR

Generic	Brand				
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE HAEGARDA				
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST				

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

CINRYZE

Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for approval:

G. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
H. Your diagnosis is confirmed by documented complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
I. You are 6 years of age or older
J. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
K. The requested medication is being used for prevention of hereditary angioedema attacks
L. You will not be using Cinryze together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, danazol, berotralstat)

HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. You are 6 years of age or older

(Initial HAEGARDA criteria continued on the next page)

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C1 ESTERASE INHIBITOR

INITIAL CRITERIA - HAEGARDA (CONTINUED)

D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Haegarda together with an alternative preventive agent for HAE (such as Takhzyro, Cinryze, danazol, berotralstat)

BERINERT

Our guideline named **C1 ESTERASE INHIBITOR (Berinert)** requires the following rule(s) be met for approval:
A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

RUCONEST

Our guideline named **C1 ESTERASE INHIBITOR (Ruconest)** requires the following rule(s) be met for approval:
A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

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C1 ESTERASE INHIBITOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For requests of Berinert or Ruconest, please refer to the initial criteria section.

CINRYZE

Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for renewal:

C. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
D. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

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Commercial Effective: 01/01/21

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CABOZANTINIB S-MALATE

Generic	Brand			
CABOZANTINIB S-MALATE	COMETRIQ, CABOMETYX			

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

GUIDELINES FOR USE

COMETRIQ

Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:

A. You have a diagnosis of progressive, metastatic (disease that has spread) medullary thyroid cancer (MTC).

CABOMETYX

Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:

A. You have a diagnosis of advanced renal cell carcinoma (type of kidney cancer) OR hepatocellular carcinoma (type of liver cancer)
B. **If you have hepatocellular carcinoma (type of kidney cancer), approval also requires:**
   1. You have previously been treated with Nexavar (sorafenib)

Commercial Effective: 07/01/20

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CANNABIDIOL

Generic	Brand			
CANNABIDIOL	EPIDIOLEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
   2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
   3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

B. **If you have seizures associated with Dravet syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried clobazam AND valproic acid derivative, unless there is a medical reason why you cannot (contraindication)

C. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried TWO of the following, unless there is a medical reason why you cannot (contraindication): clobazam, valproic acid derivative, topiramate, lamotrigine

D. **If you have seizures associated with tuberous sclerosis complex, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried TWO anti-epileptic medications (drugs to treat seizures) such as clobazam, valproic acid derivative, topiramate, lamotrigine, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule to be met for renewal:

A. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
   2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
   3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

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Commercial Effective: 01/01/21

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CAPECITABINE

Generic	Brand			
CAPECITABINE	XELODA			

GUIDELINES FOR USE

Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:

A. You have ONE of the following diagnoses:
   1. Stage III (Duke's C) colon cancer (cancer has spread to lymph nodes)
   2. Metastatic colorectal cancer (colon cancer that has spread)
   3. Metastatic breast cancer (breast cancer that has spread)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. Capecitabine is being used by itself OR in combination with oxaliplatin (CapeOX or XELOX regimen)

C. **If you have metastatic breast cancer, approval also requires ONE of the following:**
   1. You have previously failed a trial of both paclitaxel AND an anthracycline -containing regimen
   2. You have previously failed a trial of an anthracycline-containing regimen and capecitabine is being used in combination with docetaxel

Note: Required alternative regimens listed above may require prior authorization and may be covered under the medical benefit.

Commercial Effective: 07/01/20

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CAPLACIZUMAB-YHDP

Generic	Brand			
CAPLACIZUMAB-YHDP	CABLIVI			

GUIDELINES FOR USE

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi**) requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP- a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
D. You have NOT experienced more than two recurrences of acquired thrombotic thrombocytopenia purpura, while on Cablivi therapy. For example there's a new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (process of replacing a liquid part of the blood) and up to 28 days of extended therapy
E. You also meet ONE of the following:
    1. Your request is for continuation of Cablivi therapy from inpatient (hospital) setting and you previously received plasma exchange and immunosuppressive therapy (treatment that weakens your immune system) within the inpatient setting
    2. Your request is for continuation of Cablivi therapy from the initial 30 days treatment course (no break in therapy) AND:
        a. You are receiving immunosuppressive therapy, and
        b. You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13: type of blood clot disorder] activity level remain present)

Commercial Effective: 07/01/20

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CAPMATINIB

Generic	Brand				
CAPMATINIB	TABRECTA				

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

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Commercial Effective: 10/01/20

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CAPSAICIN

Generic	Brand			
CAPSAICIN 8% PATCH	QUTENZA			

GUIDELINES FOR USE

Our guideline named **CAPSAICIN (Qutenza)** requires the following rule be met for approval:

A. You have a diagnosis of neuropathic pain associated with ONE of the following conditions:
- Postherpetic neuralgia (PHN) (painful condition that affects the nerve fibers and skin after having shingles)
- Diabetic peripheral neuropathy (DPN) of the feet (numbness of the feet that is caused by diabetes)

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

Commercial Effective: 08/24/20

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CARBIDOPA-LEVODOPA

Generic	Brand			
CARBIDOPA/LEVODOPA	DUOPA			

GUIDELINES FOR USE

Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:

A. You have a diagnosis of advanced Parkinson's disease (nerve system disorder that affects movement)

Commercial Effective: 07/01/20

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CENEGERMIN-BKBJ

Generic	Brand			
CENEGERMIN-BKBJ	OXERVATE			

GUIDELINES FOR USE

Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:

A. You have a diagnosis of neurotrophic keratitis (an eye disease due to a damaged eye nerve)
B. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor)
C. You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) such as herpes zoster infection (shingles virus), multiple sclerosis (disorder where immune system attacks nerves), diabetes, ocular surgical (eye surgery) damage
D. You have loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
E. You are refractory (not fully responsive) to conservative management that includes artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses

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Commercial Effective: 09/04/20

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CERITINIB

Generic	Brand			
CERITINIB	ZYKADIA			

GUIDELINES FOR USE

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

A. You have a diagnosis of metastatic non-small cell lung cancer (type of lung cancer that has spread)
B. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration-approved test

Commercial Effective: 07/01/20

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CERTOLIZUMAB PEGOL

Generic	Brand			
CERTOLIZUMAB PEGOL	CIMZIA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

(Initial criteria continued on next page)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in the digestive system)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

(Initial criteria continued on next page)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

G. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried the following preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx

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

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CERTOLIZUMAB PEGOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS) OR non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
   1. You have 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: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy

E. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy

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CHENODIOL

Generic	Brand			
CHENODIOL	CHENODAL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
B. **If you have radiolucent gallstones, approval also requires:**
   1. You have tried ursodiol, unless there is a medical reason why you cannot (contraindication)
   2. You have not received previous chenodiol therapy for more than a total of 24 months

RENEWAL CRITERIA

Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for renewal:

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
B. **If you have radiolucent gallstones, renewal also requires:**
   1. You have **NOT** had chenodiol therapy for more than a total of 24 months
   2. You do **NOT** have complete or no gallstone dissolution (disappearance) seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
   3. You have partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
C. **If you have cerebrotendinous xanthomatosis, renewal also requires you have experienced an improvement** in **ONE** of the following:
   1. Normalization of elevated serum or urine bile alcohols
   2. Normalization of elevated serum cholestanol levels
   3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

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CHOLIC ACID

Generic	Brand			
CHOLIC ACID	CHOLBAM			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:

A. You show signs of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins that occur from ONE of the following conditions:
   1. Bile acid synthesis disorders (your body has a problem making bile acid)
   2. Peroxisomal disorders (Zellweger spectrum disorders) (problems with a part of a cell that contains enzymes)

RENEWAL CRITERIA

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:

A. You have experienced an improvement in your liver function as defined by at least ONE of the following criteria:
   1. ALT (alanine aminotransferase) or AST (aspartate transaminase) (types of liver enzymes) values have been lowered to less than 50 U/L or baseline levels reduced by 80%
   2. Total bilirubin values reduced to less than 1 mg/dL
   3. No evidence of cholestasis (condition where bile cannot flow from liver) on liver biopsy

Commercial Effective: 07/01/20

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CLADRIBINE

Generic	Brand			
CLADRIBINE	MAVENCLAD			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for renewal:

A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. You have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
D. You have not received a total of two years of treatment with Mavenclad

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Commercial Effective: 07/01/20

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CLASCOTERONE

Generic	Brand				
CLASCOTERONE	WINLEVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
B. You are 12 years of age or older
C. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have previously tried BOTH of the following unless there is a medical reason why you cannot (contraindication):
    1. ONE oral acne agent (such as oral antibiotics or oral isotretinoin)
    2. TWO topical acne agents (such as topical retinoids, topical antibiotics, benzoyl peroxide)

RENEWAL CRITERIA

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

A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
B. You had improvement of acne lesions

Commercial Effective: 01/01/21

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CLOBAZAM-SYMPAZAN

Generic	Brand			
CLOBAZAM	SYMPAZAN			

GUIDELINES FOR USE

Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for approval:

A. You have Lennox-Gastaut Syndrome (type of severe seizure)
B. The requested medication will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome (type of severe seizure) such as in combination with lamotrigine or topiramate
C. You are 2 years of age or older
D. You are unable to take tablets or suspension
E. You had a trial of or contraindication to (medical reason why you cannot use) generic/branded clobazam products (Onfi)

Commercial Effective: 07/01/20

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COBIMETINIB

Generic	Brand			
COBIMETINIB FUMARATE	COTELLIC			

GUIDELINES FOR USE

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

A. You have unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
B. You are positive for BRAF V600E OR V600K (types of genes) mutation
C. Cobimetinib will be used in combination with vemurafenib (Zelboraf)

Commercial Effective: 07/01/20

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

Generic	Brand				
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER	DEXCOM G4, DEXCOM G5, DEXCOM G6				
FLASH GLUCOSE SCANNING READER, CONTINUOUS BLOOD-GLUCOSE RECEIVER	FREESTYLE LIBRE 14/10, FREESTYLE LIBRE 2				
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, DEXCOM G6, EVERSENSE SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER				
BLOOD-GLUCOSE SENSOR	DEXCOM G6, DEXCOM G5-G4 SENSOR, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3				
FLASH GLUCOSE SENSOR, CONTINUOUS BLOOD GLUCOSE SENSOR	FREESTYLE LIBRE SENSOR, FREESTYLE LIBRE 2 SENSOR				

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for approval:

A. You have type 1, type 2, or gestational (during pregnancy) diabetes (too much sugar in your blood)
B. You meet ONE of the following:
   1. You are performing at least 4 finger-stick glucose (blood sugar) tests daily
   2. You are being treated with insulin and meet ONE of the following:
      a. You are using a continuous subcutaneous (injection under the skin) insulin infusion pump
      b. You use 3 or more injections of insulin daily
      c. You are on an insulin treatment plan that requires frequent adjustment of insulin dosing
   3. You meet ALL of the following:
      a. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)
      b. You have either tried (without adequate results or continuous need is identified by your doctor) or do not have access to a professional continuous glucose monitor from your doctor's office
C. **If you are requesting Dexcom G6 system (meter, sensor, transmitter), approval also requires:**
   1. You are 2 years of age or older
D. **If you are requesting Dexcom G4 or Dexcom G5 system (meter, sensor, transmitter), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried Dexcom G6
E. **If you are requesting FreeStyle Libre System (reader, sensor), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried Dexcom G6
F. **If you are requesting FreeStyle Libre 2.0 System (reader, sensor), approval also requires:**
   1. You are 4 years of age or older
   2. You have previously tried Dexcom G6
G. **If you are requesting Medtronic Guardian Connect (sensor, transmitter), approval also requires:**
   1. You are between 14 to 75 years of age
   2. You have previously tried Dexcom G6
H. **If you are requesting Eversense Smart Transmitter, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried Dexcom G6

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CONTRACEPTIVE ZERO COST SHARE OVERRIDE

Generic	Brand				
CONTRACEPTIVES, ORAL					
CONTRACEPTIVES, TRANSDERMAL					
CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC					
INTRA-UTERINE DEVICES (IUD'S)					
CONTRACEPTIVES, INJECTABLE					
CONTRACEPTIVES, IMPLANTABLE					
CONTRACEPTIVE, INTRAVAGINAL					
DIAPHRAGMS/CERVICAL CAP					

GUIDELINES FOR USE

Our guideline named **CONTRACEPTIVE ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

A. **If the request is for a single-source brand (no generic available) contraceptive medication that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:**
   1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to appropriate use)

B. Your doctor has provided documentation supporting ONE of the following criteria:
   1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
   3. The requested medication is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

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CORTICOTROPIN

Generic	Brand				
CORTICOTROPIN	ACTHAR				

GUIDELINES FOR USE

Our guideline named **CORTICOTROPIN (Acthar Gel)** requires the following rule(s) be met for approval:

A. You have infantile spasms (type of seizure disorder in young children)
B. You are less than 2 years of age

For all other indications, consider the use of intravenous (IV) corticosteroids.

Other approved indications include:

1. Acute exacerbation (sudden worsening of symptoms) of multiple sclerosis
2. Rheumatic disorders (disease affecting joints in the body)
   a. Psoriatic arthritis (joint pain and swelling with red scaly skin patches)
   b. Rheumatoid arthritis (including juvenile rheumatoid arthritis)
   c. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
3. Collagen disease (diseases associated with defects in collagen)
   a. Systemic lupus erythematosus (condition where immune system attacks healthy tissue)
   b. Systemic dermatomyositis (polymyositis; inflammatory disease with muscle weakness and skin rash)
4. Dermatologic disease (diseases relating to the skin)
   a. Severe erythema multiforme (disorder affecting skin, mucous membranes, genitals and eyes)
   b. Stevens-Johnson syndrome (rare, serious skin disorder)
5. Allergic disease
   a. Serum sickness (immune system reaction to non-human proteins)
6. Ophthalmic disease (diseases involving the eye)
   a. Severe acute and chronic allergic and inflammatory processes involving the eye and its parts (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)
7. Respiratory disease (disease involving the lungs)
   a. Symptomatic sarcoidosis (abnormal collections of inflammatory cells in the lungs, skin or lymph nodes)
8. Edematous state (accumulation of excessive amount of fluid)
   a. To induce a diuresis (increase urine production) or a remission (reduction) of proteinuria (protein in urine) in the nephrotic syndrome (kidney disorder that causes the body to pass too much protein in the urine) without uremia of the idiopathic type (high levels of waste products in the blood with no known cause), or that due to lupus erythematosus

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CRIZOTINIB

Generic	Brand			
CRIZOTINIB	XALKORI			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Metastatic non-small cell lung cancer (type of lung cancer that has spread) with anaplastic lymphoma kinase (ALK; a type of enzyme)-positive tumors
   2. Metastatic non-small cell lung cancer with ROS1 (a type of enzyme) -positive tumors.

Commercial Effective: 07/01/20

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CYSTEAMINE BITARTRATE

Generic	Brand			
CYSTEAMINE BITARTRATE	PROCYSBI			

GUIDELINES FOR USE

Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:

A. You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
B. You are 1 year of age or older
C. You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

Commercial Effective: 07/01/20

CYSTEAMINE HYDROCHLORIDE

Generic	Brand			
CYSTEAMINE HCL	CYSTARAN			

GUIDELINES FOR USE

Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:

A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
B. You require treatment for corneal cystine crystal accumulation or deposits (build up of cysteine in the eye)

Commercial Effective: 10/01/20

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DABRAFENIB

Generic	Brand			
DABRAFENIB MESYLATE	TAFINLAR			

GUIDELINES FOR USE

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

A. You have unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread), metastatic non-small cell lung cancer, melanoma (skin cancer), or locally advanced or metastatic anaplastic thyroid cancer.
B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used as a single agent (by itself)
C. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mekinist (trametinib)
D. **If you have melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication has not previously been used for more than one year
   3. The medication will be used in combination with Mekinist (trametinib) for adjuvant (add-on) treatment
   4. There is involvement of lymph node(s) following complete resection (removal of a tumor and normal tissue around it)
E. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mekinist (trametinib)
F. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

DACLATASVIR

Generic	Brand			
DACLATASVIR DIHYDROCHLORIDE	DAKLINZA			

GUIDELINES FOR USE

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

A. You have hepatitis C, with genotype 1 or genotype 3 infection
B. You are 18 years of age or older
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. You have documentation showing at least ONE detectable HCV (hepatitis C virus) RNA level (amount of virus in your blood) within the past 6 months as evidence of a current and chronic HCV infection.
E. You must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi
F. **For Genotype 1 infection we also require:**
    1. *Patients without cirrhosis (liver scarring):*
        a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
        b. You have previously tried Epclusa, Harvoni or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
    2. *Patients with decompensated cirrhosis (you have symptoms related to liver scarring):*
        a. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
        b. Concurrent (used at the same time with) ribavirin use required
    3. *Patients status post liver transplant:*
        a. You have previously tried Harvoni or Mavyret and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
        b. Concurrent (used at the same time with) ribavirin use required

(Criteria continued on next page)

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

G. **For Genotype 3 infection we also require:**
   1. *Patients without cirrhosis:*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa or Mavyret and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (Child-Pugh B or C; you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required
   3. *Post-liver transplant, without cirrhosis:*
      a. Previous trial of Mavyret required and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required
   4. *Post-liver transplant, with compensated cirrhosis*
      a. Previous trial of Epclusa or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

Daklinza will not be approved if you meet ANY of the following:
- You are using any of the following medications at the same time while on Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
- You are using any of the following medications at the same time while on Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
- You have compensated cirrhosis (Child-Pugh A; you have no symptoms related to liver damage) and are not status post liver transplant (you have not had a liver transplant)

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DACOMITINIB

Generic	Brand			
DACOMITINIB	VIZIMPRO			

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (type of cancer that has spread)
B. You have epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
C. The requested medication will be used as first-line treatment

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Commercial Effective: 07/01/20

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DALFAMPRIDINE

Generic	Brand			
DALFAMPRIDINE	AMPYRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have multiple sclerosis (disease in which the immune system eats away at the protective covering of nerves)
B. The medication is prescribed by or recommended by a neurologist (doctor who specializes in disorders of the nervous system)
C. You have symptoms of a walking disability

RENEWAL CRITERIA

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:

A. You have experienced or maintained at least a 15% improvement in walking ability.

Commercial Effective: 07/01/20

DAROLUTAMIDE

Generic	Brand			
DAROLUTAMIDE	NUBEQA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)
B. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)
C. You meet ONE of the following:
    1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
    2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
    3. Your blood testosterone levels are less than 50 ng/dL

RENEWAL CRITERIA

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:

A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)

Commercial Effective: 01/01/21

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DASATINIB

Generic	Brand			
DASATINIB	SPRYCEL			

GUIDELINES FOR USE

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

A. You have Philadelphia chromosome-positive (Ph+; type of gene mutation) chronic myeloid leukemia (CML; slowly progressing type of blood-cell cancer that begins in the bone marrow) in chronic, accelerated, or myeloid or lymphoid blast phase, OR Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL; type of cancer of the blood and bone marrow that affects white blood cells).

B. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND are newly diagnosed
   2. You are between 1 and 17 years of age

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance or intolerance to prior therapy including imatinib (Gleevec)
   3. You have had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that you do not have the following mutations: T315I, V299L, T315A, or F317L/V/I/C

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance or intolerance to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are newly diagnosed, between 1 and 17 years of age, AND using Sprycel in combination with chemotherapy

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DECITABINE/CEDAZURIDINE

Generic	Brand				
DECITABINE/ CEDAZURIDINE	INQOVI				

GUIDELINES FOR USE

Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Myelodysplastic syndromes (MDS: type of blood cancer)
   2. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)
B. You are 18 years of age or older
C. **If you have myelodysplastic syndromes (MDS), approval also requires:**
   1. You meet ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
      a. Intermediate-1
      b. Intermediate-2
      c. High-risk

Commercial Effective: 01/01/21

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DEFERASIROX

Generic	Brand			
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for approval:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
C. **If you have chronic iron overload due to blood transfusions, approval also requires:**
   1. You are 2 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values taken within the previous 3 months)
D. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:**
   1. You are 10 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater
E. Requests for Jadenu sprinkle packets require a trial of equivalent generic Exjade or Jadenu tablets

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DEFERASIROX

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (we need at least 2 lab values taken within the previous 3 months)
C. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

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Commercial Effective: 09/07/20

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DEFERIPRONE

Generic	Brand			
DEFERIPRONE	FERRIPROX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
C. You have tried Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
D. You meet ONE of the following:
    1. You are experiencing intolerable toxicities, clinically significant adverse effects, or have a contraindication to (medical reason why you cannot use) current chelation therapy (process of removing metals from the blood) with Exjade, Jadenu, or Desferal
    2. Chelation therapy (with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough as shown by ONE of the following:
        a. Serum ferritin levels (amount of iron-containing blood cell proteins) stay above 2500mcg/L (at least 2 lab values in the previous 3 months)
        b. You have evidence of cardiac iron accumulation (iron build up in your heart) as defined by: cardiac T2* MRI less than 10 milliseconds, iron induced cardiomyopathy (heart disease), fall in left ventricular ejection fraction (LVEF: amount of blood your heart pumps out), arrhythmia indicating inadequate chelation (irregular heartbeat because iron was not lowered enough in body)

RENEWAL CRITERIA

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:

A. You have transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

Commercial Effective: 10/12/20

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DEFEROXAMINE

Generic	Brand			
DEFEROXAMINE MESYLATE	DESFERAL, DEFEROXAMINE MESYLATE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
C. You are 3 years of age or older
D. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 1000mcg/L (shown by at least 2 lab values in the previous 3 months)

RENEWAL CRITERIA

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rules be met for renewal:

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

Commercial Effective: 07/01/20

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DEFLAZACORT

Generic	Brand			
DEFLAZACORT	EMFLAZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that gets worse)
B. You are 2 years of age or older
C. You doctor confirms your diagnosis with genetic testing
D. The drug is prescribed by or recommended by a neurologist (nerve system doctor) specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
E. You have tried prednisone or prednisolone for at least 6 months and meet one of the following:
    1. Prednisone or prednisolone did not work and you meet ALL of the following criteria:
        a. You are not in Stage 1: pre-symptomatic phase
        b. There is no steroid myopathy (muscle disease due to steroid)
        c. You have documentation that your disease is advanced– you cannot walk, cannot function, cannot breathe using standard measures over time, consistent with advancing disease (stage 2 or higher). Acceptable standard measures include: 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower'smaneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA), pulmonary function (forced vital capacity, lung function tests), upper limb strength (propelling a wheelchair 30 feet)
    2. You had adverse side effects while on prednisone or prednisolone and there is documentation of literature-based evidence provided supporting Emflaza's decreased effect for that side effect
       Note: Requests due to side effects while on prednisone or prednisolone that are named or listed in the prescribing information of Emflaza will not be approved

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DEFLAZACORT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that worsens)
B. You meet ONE of the following criteria:
   i. **If you are currently ambulatory (can walk), renewal also requires:**
      a. You have shown function, stabilization or improvement in a standard set of ambulatory or functional status measures since being on Emflaza. These measures must be monitored, tracked, and documented consistently. Acceptable standard measures include: 6-minute walk distance, time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, North Star Ambulatory Assessment, Physician Global Assessments
   ii. **If you are currently non-ambulatory (cannot walk), renewal also requires:**
      a. You have maintained or have a less than expected decrease in pulmonary (breathing) function and/or upper limb strength assessed by standard measures since being on Emflaza. These measures must be monitored, tracked, and documented consistently. Acceptable standard measures include: pulmonary function (force vital capacity, pulmonary function tests), upper limb strength measures (propelling a wheelchair 30 feet), Physician Global Assessments

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Commercial Effective: 07/01/20

DELAFLOXACIN

Generic	Brand			
DELAFLOXACIN	BAXDELA			

GUIDELINES FOR USE

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

A. You meet **ONE** of the following:
   1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist or
   2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI); **OR** community-acquired bacterial pneumonia (CABP: type of lung infection)

B. **If you have an acute bacterial skin or skin structure infection, approval also requires:**
   1. You are at least 18 years of age
   2. The infection is caused by any of the following bacteria: Staphylococcus aureus (including methicillin-resistant [MRSA] *and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa*
   3. You do not have a diagnosis of animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitis ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum
   4. You meet **ONE** of the following criteria:
      i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to **ONE** standard of care agent for acute bacterial skin or skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin), **AND** b) delafloxacin will work against the bacteria
      ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial of or contraindication to (a medical reason why you cannot use) **ONE** of the following agents: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)

(Criteria continued on next page)

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

C. **If you have community-acquired bacterial pneumonia (CABP: type of lung infection), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae*
   3. You meet **ONE** of the following criteria:
      i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) AND b) delafloxacin will work against the bacteria
      ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (a medical reason why you cannot use) **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Commercial Effective: 04/01/20

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DESIRUDIN

Generic	Brand			
DESIRUDIN	IPRIVASK			

GUIDELINES FOR USE

Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

Commercial Effective: 07/01/20

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DEUTETRABENAZINE

Generic	Brand			
DEUTETRABENAZINE	AUSTEDO			

GUIDELINES FOR USE

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

A. You have chorea (involuntary movements) associated with Huntington's disease or moderate to severe tardive dyskinesia (involuntary, repetitive body movements)
B. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system) or movement disorder specialist
C. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. Moderate to severe tardive dyskinesia has been present for at least 3 months
   2. You are at least 18 years of age
   3. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system), movement disorder specialist, or psychiatrist (mental health doctor)
   4. You have a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in the prescription claims history

Commercial Effective: 07/01/20

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DEXTROMETHORPHAN with QUINIDINE

Generic	Brand			
DEXTROMETHORPHAN/ QUINIDINE	NUEDEXTA			

GUIDELINES FOR USE

Our guideline named **DEXTROMETHORPHAN with QUINIDINE (Nuedexta)** requires you have a pseudobulbar affect (sudden, uncontrollable laughter) for approval.

Commercial Effective: 07/01/20

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DIABETIC TEST STRIPS

Generic	Brand			
BLOOD SUGAR DIAGNOSTIC BLOOD SUGAR DIAGNOSTIC, DISC BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS			

GUIDELINES FOR USE

Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:

A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott
B. You require a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment (problems with sight and/or memory and thinking)
C. You require a non-preferred blood glucose test strip because you use another manufacturer's companion insulin pump

Request for non-preferred test strips will not be approved if due to a need for data management software. Please note that data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

Commercial Effective: 06/01/20

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DICHLORPHENAMIDE

Generic	Brand			
DICHLORPHENAMIDE	KEVEYIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), or Paramyotonia Congenita (disorder that causes muscles stiffness)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a neurologist (nerve system doctor)
D. You do not have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow, or a health condition that warrants concurrent use of high-dose aspirin
E. **If you have primary hypokalemic periodic paralysis, approval also requires:**
    1. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
F. **If you have primary hyperkalemic periodic paralysis or Paramyotonia Congenita, approval also requires:**
    1. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)

RENEWAL CRITERIA

Our guideline named **DICHLORPHENAMIDE (Keveyis)** requires that you have experienced at least two fewer attacks per week from baseline (measurement before you started treatment) for renewal.

Commercial Effective: 07/01/20

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DICLOFENAC ORAL PACKET

Generic	Brand				
DICLOFENAC POTASSIUM	CAMBIA				

GUIDELINES FOR USE

Our guideline named **DICLOFENAC ORAL PACKET (Cambia)** requires the following rule(s) be met for approval:

A. The request is for acute treatment of migraine attacks
B. You are unable to swallow pills
C. You had a previous trial of generic diclofenac AND over the counter (OTC) or generic aspirin, ibuprofen, or naproxen

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Commercial Effective: 04/01/20

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DICLOFENAC TOPICAL

Generic	Brand			
DICLOFENAC SODIUM 3%	SOLARAZE			

GUIDELINES FOR USE

Our guideline named **DICLOFENAC TOPICAL (Solaraze)** requires the following rule(s) be met for approval:

A. You have actinic keratosis (rough, scaly patch on the skin caused by years of sun exposure)
B. You had a previous trial of topical fluorouracil (such as Efudex, Fluoroplex, Carac), unless there is a medical reason why you cannot (contraindication)
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor) or oncologist (cancer/tumor doctor)

Commercial Effective: 07/01/20

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DIMETHYL FUMARATE

Generic	Brand			
DIMETHYL FUMARATE	TECFIDERA			

GUIDELINES FOR USE

Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. If you are requesting brand Tecfidera, you must have previously tried generic dimethyl fumarate

Commercial Effective: 10/19/20

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DIROXIMEL FUMARATE

Generic	Brand			
DIROXIMEL FUMARATE	VUMERITY			

GUIDELINES FOR USE

Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 04/01/20

DORNASE ALFA

Generic	Brand			
DORNASE ALFA	PULMOZYME			

GUIDELINES FOR USE

Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: an inherited disorder that damages lung and digestive system with fluid build up)
B. If you are requesting twice daily dosing, we require that you have tried and failed once daily dosing

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Commercial Effective: 07/01/20

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DROXIDOPA

Generic	Brand			
DROXIDOPA	NORTHERA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DROXIDOPA (Northera)** requires the following rules be met for approval:

A. You have neurogenic orthostatic hypotension
B. You are 18 years of age or older
C. You have a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency (you are missing a type of enzyme), or non-diabetic autonomic neuropathy (nerve pain/damage)
D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
E. The medication was prescribed or given in consultation with a neurologist (nerve doctor) or cardiologist (heart doctor)
F. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'
G. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
H. You have a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position

RENEWAL CRITERIA

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:

A. You have neurogenic orthostatic hypotension (NOH)
B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

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Commercial Effective: 07/01/20

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DUPILUMAB

Generic	Brand			
DUPILUMAB	DUPIXENT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
   2. Moderate to severe asthma
   3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You meet at least ONE of the following for disease severity:
      a. Atopic dermatitis involving at least 10% of body surface area (BSA)
      b. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc)
   2. You have at least TWO of the following:
      a. Intractable pruritus (severe itching)
      b. Cracking and oozing/bleeding of affected skin
      c. Impaired activities of daily living
   3. The medication is prescribed by or given in consultation with a dermatologist (skin doctor) or allergist/immunologist (allergy doctor)
   4. You are 6 years of age or older
   5. You had an inadequate response or contraindication to (a medical reason why you cannot use) ONE of the following: topical corticosteroids, topical calcineurin inhibitors [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [Eucrisa (crisaborole)], or phototherapy (light therapy)

C. **If you have moderate to severe asthma, approval also requires:**
   1. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) with a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months **OR** oral corticosteroid-dependent asthma
   2. You are 12 years of age or older

(Initial criteria continued on next page)

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

3. You had prior therapy with medium, high-dose, or maximally tolerated inhaled corticosteroid [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
4. You have experienced at least ONE 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)
5. Dupixent will be used as an add-on maintenance treatment
6. You are not being concurrently treated with Xolair or an anti-IL5 asthma biologic such as Nucala, Cinqair, Fasenra
7. The medication is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/breathing) or allergy medicine

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
1. You are 18 years of age or older
2. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
3. You have inadequately controlled disease as determined by **ONE** of the following:
   a. Use of systemic steroids in the past 2 years
   b. Endoscopic sinus surgery (using a small camera to help in surgery)
4. Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
5. The medication is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist

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DUPILUMAB

GUIDELINE FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
   2. Moderate to severe asthma
   3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have experienced or maintained improvement in at least two of the following:
      a. Intractable pruritus (severe itching)
      b. Cracking and oozing/bleeding of affected skin
      c. Impaired activities of daily living
   2. You are 6 years of age or older

C. **If you have moderate to severe asthma, renewal also requires:**
   1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
   2. You have shown a clinical response as evidenced by ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      b. Decreased use of rescue medications
      c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
      d. Reduction in severity or frequency of asthma-related symptoms such as less wheezing, shortness of breath, coughing, etc.

D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

Commercial Effective: 07/13/20

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DUVELISIB

Generic	Brand			
DUVELISIB	COPIKTRA			

GUIDELINES FOR USE

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

A. You have relapsed or refractory chronic lymphocytic leukemia (CLL: blood and bone marrow cancer that does not fully respond to treatment), small lymphocytic lymphoma (SLL: a type of white blood cell cancer), or follicular lymphoma (FL: type of cancer with abnormal immune system cells)
B. You are 18 years of age or older
C. **If you have relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
   1. You have received at least two prior therapies for CLL or SLL
D. **If you have relapsed or refractory follicular lymphoma (FL), approval also requires:**
   1. You have received at least two prior systemic therapies for FL

Commercial Effective: 07/01/20

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EFINACONAZOLE

Generic	Brand			
EFINACONAZOLE	JUBLIA			

GUIDELINES FOR USE

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

A. You have onychomycosis of the toenail(s) (toenail fungus)
B. You have previously tried the following unless contraindicated (a medical reason why you cannot use): ciclopirox topical solution AND either oral terbinafine OR oral itraconazole
C. You have at least ONE of the following conditions:
   1. Diabetes, peripheral vascular disease (narrowed blood vessels reduce blood flow to the limbs), or immunosuppression (weakened immune system)
   2. Pain surrounding the nail or soft tissue involvement

Commercial Effective: 07/01/20

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ELAGOLIX

Generic	Brand			
ELAGOLIX	ORILISSA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
D. You had a previous trial of or contraindication to (a medical reason why you cannot use) a nonsteroidal anti-inflammatory drug (NSAID; such as ibuprofen, meloxicam, naproxen) **AND** a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
E. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

RENEWAL CRITERIA

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Requests will not be approved if you meet ONE of the following conditions:
A. You have received a 6-month course of Orilissa 200mg twice daily
B. You have received a 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
C. You have received a 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

Commercial Effective: 10/08/20

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

Generic	Brand				
ELAGOLIX AND ESTRADIOL AND NORETHINDRONE	ORIAHNN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You are 18 years of age or older
C. You are a premenopausal woman
D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
E. You have not received a total of 24 months cumulative treatment with Oriahnn

RENEWAL CRITERIA

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You had improvement of heavy menstrual bleeding on therapy
C. You have not received a total of 24 months cumulative treatment with Oriahnn

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Commercial Effective: 01/01/21

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ELAPEGADEMASE-LVLR

Generic	Brand			
ELAPEGADEMASE-LVLR	REVCOVI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system) as shown by ONE of the following:
   1. Confirmatory generic test
   2. Suggestive laboratory findings such as elevated deoxyadenosine nucleotide levels or lymphopenia (not enough of a type of white blood cell) AND you have hallmark signs/symptoms such as recurrent infections, failure to thrive, persistent diarrhea
B. The requested medication is prescribed by or given in consultation with an immunologist (immune system doctor), hematologist/oncologist (blood/cancer doctor), or physician specializing in inherited metabolic disorders
C. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow), OR the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

RENEWAL CRITERIA

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system)
B. You have documentation of trough plasma adenosine deaminase activity greater than or equal to 30 mmol/hr/L AND trough deoxyadenosine nucleotide levels less than 0.02 mmol/L
C. You have improvement in/maintenance of immune function from baseline (such as decrease in number and severity of infections), AND you have not received successful hematopoietic cell transplantation (HCT) or gene therapy

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ELBASVIR/GRAZOPREVIR

Generic	Brand			
ELBASVIR/GRAZOPREVIR	ZEPATIER			

GUIDELINES FOR USE

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have hepatitis C (type of liver inflammation caused by a virus)
B. You have genotype 1 or genotype 4 hepatitis C
C. You are 18 years of age or older
D. You have previously tried the following, unless there is a medical reason why you cannot: Epclusa, Harvoni or Mavyret (patients with previous failure of a full treatment of Epclusa, Harvoni or Mavyret will not be approved)
E. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
F. You have documentation of HCV (hepatitis C virus) infection that shows at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
G. If you have genotype 1a infection, we require testing for baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)
H. If you are treatment-experienced patients OR treatment naïve (never previously treated) with genotype 1a infection and baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein), we require that you use ribavirin
I. Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4; previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection)

Zepatier will not be approved if you meet any of the following:

A. You are using any of the following interacting medications at the same time while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
B. You are taking Sovaldi (sofosbuvir) with Zepatier
C. You have moderate or severe hepatic impairment (Child-Pugh B or C)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

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ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

Generic	Brand				
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You are 12 years of age or older
C. Documentation that you have at least one *F508del* mutation (a permanent change in your DNA that make up your gene) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
D. The medication is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert

RENEWAL CRITERIA

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

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ELIGLUSTAT TARTRATE

Generic	Brand			
ELIGLUSTAT TARTRATE	CERDELGA			

GUIDELINES FOR USE

Our guideline named **ELIGLUSTAT TARTRATE (Cerdelga)** requires the following rule(s) be met for approval:

A. You have type 1 (non-neuronopathic) Gaucher disease (genetic disorder where a type of fatty substance builds up in the body but does not affect the brain or spinal cord)
B. You are 18 years of age or older
C. Twice daily dosing will be approved if you are an extensive or immediate metabolizer of CYP2D6 (cytochrome P450 2D6; a type of enzyme) inhibitors
D. Once daily dosing will be approved if you are a poor metabolizer of CYP2D6 (cytochrome P450 2D6; a type of enzyme)

Commercial Effective: 07/01/20

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ELTROMBOPAG

Generic	Brand			
ELTROMBOPAG	PROMACTA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have one of the following diagnoses:
   1. Chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
   2. Thrombocytopenia (low blood platelet count) due to chronic hepatitis C
   3. Severe aplastic anemia (type of blood disorder)

B. **If you are greater than 12 years of age and the request is for Promacta packets, approval also requires:**
   1. You previously had a trial of Promacta tablets
   2. You have a medical need for powder packets

C. **If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 1 year of age or older
   2. You have tried corticosteroids or immunoglobulins, or did not have a good enough response to a splenectomy (removal of spleen) - unless there is a medical reason why you cannot (contraindication)
   3. The medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)

D. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

E. **If you have severe aplastic anemia, approval also requires ONE of the following:**
   1. You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
   2. You did not have a good enough response to immunosuppressive therapy

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ELTROMBOPAG

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

Our guideline named **ELTROMBOPAG (Promacta) requires the following rules be met for renewal:**

A. You have chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
B. You have a clinical response, as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter)

Commercial Effective: 04/20/20

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ELUXADOLINE

Generic	Brand			
ELUXADOLINE	VIBERZI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have irritable bowel syndrome with diarrhea (an intestinal problem causing pain in the belly, gas, diarrhea, and constipation)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
D. You had a trial of Xifaxan (rifaximin) AND either tricyclic anti-depressants (such as amitriptyline, desipramine) OR dicyclomine, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for renewal:

1. You have irritable bowel syndrome with diarrhea (an intestinal problem causing pain in the belly, gas, diarrhea, and constipation)
2. You had at least 30% decrease in abdominal pain (stomach pain) on a 0-10 point pain scale
3. You had at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

Commercial Effective: 07/01/20

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EMICIZUMAB-KXWH

Generic	Brand			
EMICIZUMAB-KXWH	HEMLIBRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:

A. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
B. The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor)
D. Patients with Factor VIII inhibitors must have a history of a high titer (concentration) of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
E. Patients without Factor VIII inhibitors must meet one of the following criteria:
    1. You have severe hemophilia A defined as less than 1% factor VIII activity compared to normal
    2. You have *mild* or *moderate* hemophilia A and a history of 2 or more bleeds per year

RENEWAL CRITERIA

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:

A. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
B. You had a clinical benefit after using the medication compared to baseline

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Commercial Effective: 07/01/20

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ENASIDENIB

Generic	Brand			
ENASIDENIB	IDHIFA			

GUIDELINES FOR USE

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

A. You have relapsed or refractory acute myeloid leukemia (a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
B. You are 18 years of age or older
C. You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

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Commercial Effective: 07/01/20

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ENCORAFENIB

Generic	Brand			
ENCORAFENIB	BRAFTOVI			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that has spread or cannot be completely removed with surgery)
   2. Metastatic colorectal cancer (a type of cancer that affects the colon and the rectum and has spread to other parts of the body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mektovi (binimetinib)

C. **If you have metastatic colorectal cancer, approval also requires:**
   1. You have a BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Erbitux (cetuximab)
   3. You have previously received treatment

Commercial Effective: 05/01/20

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ENDOTHELIN RECEPTOR ANTAGONISTS

Generic	Brand			
BOSENTAN	TRACLEER			
AMBRISENTAN	LETAIRIS			
MACITENTAN	OPSUMIT			

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

LETAIRIS

Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    a. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    b. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    c. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a classification system of heart failure symptoms)
E. You do not have idiopathic pulmonary fibrosis (scarring of the lungs for an unknown reason)

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ENDOTHELIN RECEPTOR ANTAGONISTS

INITIAL CRITERIA (CONTINUED)

TRACLEER

Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Tracleer)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. You are 3 years of age and older
C. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
D. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
   a. Mean pulmonary artery pressure greater than or equal to 25 mmHg
   b. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
   c. Pulmonary vascular resistance greater than 3 Wood units
E. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a classification system of heart failure symptoms)
F. You do not have idiopathic pulmonary fibrosis (scarring of the lungs for an unknown reason)
G. You are not concurrently taking cyclosporine A or glyburide

OPSUMIT

Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Opsumit)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
   a. Mean pulmonary artery pressure greater than or equal to 25 mmHg
   b. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
   c. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a classification system of heart failure symptoms)

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ENDOTHELIN RECEPTOR ANTAGONISTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis, Tracleer, Opsumit)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. **If you are requesting Tracleer (for patients 18 years of age or older), Letairis or Opsumit, renewal also requires ONE of the following:**
    1. You show improvement from baseline in the 6-minute walk distance
    2. You have a stable 6-minute walk distance with a stable or improved Word Health Organization (WHO) functional class
C. **If you are requesting Tracleer and are age 3-17 years old, renewal also requires ONE of the following:**
    1. You have improvement in pulmonary vascular resistance
    2. You have remained stable or shown improvement in exercise ability (such as 6-minute walk test, World Health Organization [WHO] functional class symptoms)

Commercial Effective: 07/01/20

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ENTRECTINIB

Generic	Brand			
ENTRECTINIB	ROZLYTREK			

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of body) OR a solid tumor
B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. You have *ROS1*-positive tumors (you have a type of gene mutation)
C. **If you have a solid tumor, approval also requires:**
   1. You are 12 years of age or older
   2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (you have a type of gene mutation that doesn't have any known resistance)
   3. The tumor is metastatic (has spread to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (disease)
   4. There are no satisfactory alternative treatments, or you have progressed (gotten worse) after treatment

Commercial Effective: 07/01/20

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ENZALUTAMIDE

Generic	Brand			
ENZALUTAMIDE	XTANDI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

B. You have ONE of the following diagnoses:
   1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

C. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

D. **If you have non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have a high-risk prostate cancer (rapidly increasing prostate specific antigen levels)

E. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have previously tried Zytiga (abiraterone acetate) unless there is a medical reason why you cannot take it (contraindication)

RENEWAL CRITERIA

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

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ERDAFITINIB

Generic	Brand			
ERDAFITINIB	BALVERSA			

GUIDELINES FOR USE

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

A. You have locally advanced or metastatic urothelial carcinoma (type of bladder cancer that has spread)
B. You are 18 years of age or older
C. You have susceptible fibroblast growth factor receptor (FGFR3 or FGFR2) genetic alterations (abnormalities) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
D. You meet ONE of the following:
    1. You have progressed (worsened disease) during or following at least one line of prior platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. You have progressed within 12 months of neoadjuvant (treatment given before main therapy) or adjuvant (add-on) platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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ERENUMAB-AOOE

Generic	Brand			
ERENUMAB-AOOE	AIMOVIG			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

RENEWAL CRITERIA

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:

A. Aimovig is being prescribed for preventive treatment of migraines.
B. You meet **ONE** of the following criteria:
   1. You have experienced less migraines or headache attacks by at least 2 days per month with Aimovig therapy
   2. You have experienced a lessening in migraine severity with Aimovig therapy
   3. You have experienced a lessening in migraine duration with Aimovig therapy

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ERLOTINIB

Generic	Brand			
ERLOTINIB	TARCEVA			

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread) OR locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)
B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test
C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Commercial Effective: 07/01/20

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ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand				
DARBEPOETIN	ARANESP				
EPOETIN ALFA	EPOGEN PROCRIT				
EPOETIN ALFA-EPBX	RETACRIT				
METHOXY PEG-EPOETIN BETA	MIRCERA				

GUIDELINES FOR USE

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

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
   1. You have a hemoglobin level of less than 11g/dL
   2. Your hemoglobin level has decreased at least 2g/dL below your baseline level.

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   2. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

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

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried Procrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. You have a hemoglobin of less than 10g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

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

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy,** approval also requires:
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 11g/dL **OR** your hemoglobin has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa,** approval also requires:
   1. You have tried Procrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 13g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

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

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried Procrit
   2. You have tried a lower ribavirin dose, unless there is a medical reason why you cannot (contraindication)
   3. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 13g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

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

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older, approval also requires**:
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
C. **If you are between 5 and 17 years of age, approval also requires:**
   1. You are on hemodialysis
   2. You are changing from another erythropoiesis-stimulating agent (ESA; epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR PROCRIT

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are NOT on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR ARANESP

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR EPOGEN

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR RETACRIT

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR MIRCERA

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for renewal:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older and are currently receiving dialysis treatment, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
    2. The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
C. **If you are 18 years of age or older and are NOT receiving dialysis treatment, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
    2. You have a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
D. **If you are between 5 and 17 years of age, renewal also requires:**
    1. You are currently receiving dialysis treatment
    2. You have ONE of the following:
        a. A hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
        b. A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

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Commercial Effective: 01/01/21

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ETANERCEPT

Generic	Brand			
ETANERCEPT	ENBREL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial criteria continued on next page)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

RENEWAL CRITERIA

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires**:
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

(Renewal criteria continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have 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.

F. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have 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.

Commercial Effective: 09/07/20

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EVEROLIMUS

Generic	Brand			
EVEROLIMUS	AFINITOR			
EVEROLIMUS	AFINITOR DISPERZ			

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

GUIDELINES FOR USE

AFINITOR DISPERZ

Our guideline named **EVEROLIMUS (Afinitor Disperz)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Subependymal giant cell astrocytoma (SEGA; a type of brain tumor) with tuberous sclerosis complex (TSC; genetic disorder with many non-cancer tumors)
   2. Tuberous sclerosis complex (TSC)-associated partial-onset seizures

B. **If you have subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC), approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

C. **If you have tuberous sclerosis complex (TSC)-associated partial-onset seizures, approval also requires:**
   1. You are 2 years of age or older
   2. The medication will be used as adjunctive (add-on) treatment

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EVEROLIMUS

GUIDELINES FOR USE (CONTINUED)

AFINITOR

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

A. You meet ONE of the following:
   1. You have advanced renal cell carcinoma (type of kidney cancer) after failure of or contraindication to (medical reason why you cannot use) treatment with sunitinib (Sutent) or sorafenib (Nexavar) (which may also require prior authorization), AND you are 18 years of age or older
   2. You have subependymal giant cell astrocytoma (SEGA; a type of brain tumor) with tuberous sclerosis complex (TSC; genetic disorder with many non-cancer tumors) that requires therapeutic intervention but cannot be curatively resected (completely removed with surgery), AND you are 1 year of age or older
   3. You have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, either neuroendocrine tumors of pancreatic origin (PNET) OR well-differentiated, non-functional neuroendocrine tumors of gastrointestinal (GI) or lung origin, AND you are 18 years of age or older
   4. You have renal angiomyolipoma (type of kidney tumor) and tuberous sclerosis complex (TSC) that does not require immediate surgery, AND you are 18 years of age or older
   5. You are a postmenopausal woman with advanced hormone receptor-positive, HER2 (human epidermal growth factor receptor 2: a gene/protein in breast cancer) - negative breast cancer (defined as IHC scores less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0), AND the requested medication will be used in combination with Aromasin (exemestane) after failure of or contraindication (medical reason why you cannot use) to treatment with Femara (letrozole) or Arimidex (anastrozole).

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EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

Generic	Brand			
EXCLUDED DRUGS				

GUIDELINES FOR USE

Our guideline named **EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA** (reviewed for <insert drug name>) requires that ALL of the following rule(s) be met for approval:

A. The requested medication is being used for the treatment of ONE of the following:
   1. A Food and Drug Administration (FDA)-approved indication
   2. A medically accepted indication and it is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.

B. You meet one of the following criteria (1, 2, or 3):
   1. If the request is for a combination product and the individual components with the same route of administration are commercially available and are covered by your plan, you must meet the following (a, b, and c):
      a. You have previously tried <insert individual components> together
      b. Your doctor provided a medical rationale that the requested combination product would be safer and/or more efficacious than using the individual components together
      c. You have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents
   2. If the request is for a medication that has clinically appropriate covered alternative(s) with the same active ingredient and same route of administration, you must meet the following (a and b):
      a. You have previously tried at least three clinically appropriate covered alternatives with the same active ingredients and same route of administration (if available), including but not limited to <insert formulary agents>, OR there is a medical rationale why the covered alternatives cannot be tried.
      b. You have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents

(Criteria continued on next page)

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EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

3. If the requested medication does NOT have clinically appropriate covered alternatives with the same active ingredient and same route of administration, you must have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents.

Effective: 12/17/20

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FEDRATINIB

Generic	Brand			
FEDRATINIB	INREBIC			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
B. You are 18 years of age or older
C. You previously had a trial of or contraindication (medical reason why you cannot use) to Jakafi (ruxolitinib)

RENEWAL CRITERIA

Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:

A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
B. You had symptom improvement by **ONE** of the following:
    1. You have a spleen volume reduction of 35% or greater from baseline after 6 months of therapy
    2. You have a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
    3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

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Commercial Effective: 07/01/20

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FENFLURAMINE

Generic	Brand				
FENFLURAMINE	FINTEPLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
B. You are 2 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spine, and nerves)
D. You had a previous trial of clobazam AND valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

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

A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

Commercial Effective: 08/01/20

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FENTANYL NASAL SPRAY

Generic	Brand			
FENTANYL NASAL SPRAY	LAZANDA			

GUIDELINES FOR USE

Our guideline named **FENTANYL NASAL SPRAY (Lazanda)** requires the following rule(s) to be met for approval:

A. You have a diagnosis of cancer-related pain
B. You are currently taking a maintenance dose of a controlled-release pain medication (such as MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
E. You had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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FENTANYL SUBLINGUAL SPRAY

Generic	Brand			
FENTANYL SUBLINGUAL SPRAY	SUBSYS			

GUIDELINES FOR USE

Our guideline named **FENTANYL SUBLINGUAL SPRAY (Subsys)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. You had a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
E. You had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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FENTANYL TRANSDERMAL PATCH

Generic	Brand			
FENTANYL	DURAGESIC			

GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
B. The requested medication is not prescribed on an 'as needed' basis
C. Requests for dosing every 48 hours requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

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Commercial Effective: 07/01/20

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FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand			
FENTANYL CITRATE	ACTIQ, ABSTRAL, FENTORA			

GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq, Fentora, Abstral)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)
C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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FINGOLIMOD

Generic	Brand			
FINGOLIMOD	GILENYA			

GUIDELINES FOR USE

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

A. You have a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease
B. You are 10 years of age or older.
C. You do not have any of the following contraindications (medical reason why you cannot use) to Gilenya:
   1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker
   3. A baseline QTC interval 500 msec or above (a measure of the speed of electrical conduction in the heart)
   4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Commercial Effective: 07/01/20

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FLIBANSERIN

Generic	Brand			
FLIBANSERIN	ADDYI			

GUIDELINES FOR USE

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

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

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are not currently using Vyleesi (bremelanotide)

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FLIBANSERIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You are not currently using Vyleesi (bremelanotide)
E. You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

Commercial Effective: 07/01/20

FLUOROURACIL 0.5% CREAM

Generic	Brand			
FLUOROURACIL 0.5%	CARAC			

GUIDELINE FOR USE

Our guideline named **FLUOROURACIL 0.5% CREAM (Carac)** requires the following rule(s) be met for approval:

A. You have actinic or solar keratosis (rough, scaly patch on the skin caused by years of sun exposure)
B. You have previously tried at least **ONE** of the following:
   1. Generic topical (applied to skin) agents (such as imiquimod 5%, diclofenac 3%, fluorouracil 5%)
   2. Preferred topical (applied to skin) agents (such as Picato)

Commercial Effective: 07/01/20

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FOSTAMATINIB

Generic	Brand			
FOSTAMATINIB	TAVALISSE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
D. You had a splenectomy (surgical removal of spleen) **OR** a previous trial of or contraindication to (medical reason why you cannot use) at least **TWO** of the following treatments:
    1. Corticosteroids
    2. IVIG (intravenous immunoglobulin)
    3. Rhogam
    4. Rituxan (rituximab)
    5. Thrombopoietin receptor agonist such as Promacta (eltrombopag), Nplate (romiplostim)

RENEWAL CRITERIA

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You had clinically significant prevention of bleeds while on therapy
C. Your AST (aspartate transaminase) and ALT (alanine transaminase) levels (types of liver enzymes) have remained under 3 times the upper limits of normal per reference range
D. Your total bilirubin level has remained under 2 times the upper limits of normal per reference range
E. Your absolute neutrophil count (ANC; a measure of the number of neutrophils which are a type of white blood cell) has remained within normal limits per reference range
F. Your platelets have reached a level between 50 and 450 x 10(9)/L

FOSTEMSAVIR

Generic	Brand				
FOSTEMSAVIR	RUKOBIA				

GUIDELINES FOR USE

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

A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
B. You are 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
D. You are treatment experienced (previously treated)
E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
F. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

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Commercial Effective: 08/01/20

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FREMANEZUMAB-VFRM

Generic	Brand			
FREMANEZUMAB-VFRM	AJOVY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
   4. You have previously tried Aimovig AND Emgality
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
   4. You have previously tried Aimovig AND Emgality

RENEWAL CRITERIA

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:

A. Ajovy is prescribed for the preventive treatment of migraines
B. You meet **ONE** of the following:
   1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
   2. You have experienced a reduction in migraine severity with Ajovy therapy
   3. You have experienced a reduction in migraine duration with Ajovy therapy

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GALCANEZUMAB-GNLM

Generic	Brand			
GALCANEZUMAB-GNLM	EMGALITY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:

A. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
D. **If you have episodic cluster headaches, approval also requires:**
   1. You are 18 years of age or older

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GALCANEZUMAB-GNLM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
B. **If you have migraines, renewal also requires ONE of the following:**
    1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
    2. You have experienced a reduction in migraine severity with Emgality therapy
    3. You have experienced a reduction in migraine duration with Emgality therapy
C. **If you have episodic cluster headaches, renewal also requires:**
    1. You had improvement in episodic cluster headache frequency as compared to baseline

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Commercial Effective: 01/01/21

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GEFITINIB

Generic	Brand			
GEFITINIB	IRESSA			

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (NSCLC; type of lung cancer that has spread)
B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of permanent changes in your DNA that make up your gene) as detected by an FDA (Food and Drug Administration)-approved test

Commercial Effective: 07/01/20

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GILTERITINIB

Generic	Brand			
GILTERITINIB FUMARATE	XOSPATA			

GUIDELINES FOR USE

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

A. You have relapsed or refractory acute myeloid leukemia (AML: type of white blood cell cancer)
B. You are 18 years of age or older
C. You have FMS-like tyrosine kinase 3 (type of gene) mutation (change in the DNA gene) as detected by a Food and Drug Administration-approved test

Commercial Effective: 07/01/20

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GLASDEGIB

Generic	Brand			
GLASDEGIB MALEATE	DAURISMO			

GUIDELINES FOR USE

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

A. You have newly-diagnosed acute myeloid leukemia (AML: type of white blood cell cancer)
B. The requested medication will be used in combination with low-dose cytarabine
C. You are 75 years of age or older, **OR** you have comorbidities (having more than one disease) that prevents the use of intensive induction chemotherapy

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Commercial Effective: 07/01/20

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GLATIRAMER ACETATE

Generic	Brand			
GLATIRAMER ACETATE	COPAXONE, GLATOPA, GLATIRAMER ACETATE			

GUIDELINES FOR USE

Our guideline named **GLATIRAMER ACETATE (Copaxone, Glatopa)** requires the following rule(s) be met for approval:

1. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
2. You are 18 years of age or older

Commercial Effective: 01/01/21

GLECAPREVIR/PIBRENTASVIR

Generic	Brand			
GLECAPREVIR/ PIBRENTASVIR	MAVYRET			

GUIDELINES FOR USE

Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

1. You have a diagnosis of genotype 1, 2, 3, 4, 5, or 6 hepatitis C
2. You are at least 12 years old or weigh at least 45 kilograms
3. The medication is prescribed by or recommended by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist (doctor who specializes in treatment of infections), physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
4. You have documentation of HCV (hepatitis c virus) infection. We require at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
5. You have compensated cirrhosis (no symptoms related to liver damage) or no cirrhosis (no liver damage) and meet ONE of the following:
   a. You are treatment naïve (never been treated) (genotype 1-6)
   b. You are treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir (genotype 1-6)
   c. You are treatment experienced with NS5A (Nonstructural protein 5A) inhibitor or NS3/4A protease inhibitor (genotype 1)
   d. You had a kidney transplant or liver transplant and are treatment naïve or treatment experienced (genotype 1-6)

The medication will not be approved if you meet any of the following:

A. You are concurrently taking (alone or in combination): rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
B. You have moderate or severe liver impairment (Child-Pugh B or C)
C. You have prior failure of a direct-acting antiviral (DAA) regimen that contains NS5A inhibitor AND NS3/4A protease inhibitor (for example, Technivie, Viekira, Vosevi, Zepatier) or you had previous concurrent (used at the same time) treatments containing a NS5A inhibitor AND NS3/4A protease inhibitor
D. Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

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GLYCEROL PHENYLBUTYRATE

Generic	Brand			
GLYCEROL PHENYLBUTYRATE	RAVICTI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
B. Documentation of confirmation of urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
C. You are 2 months of age or older
D. Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
E. The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
F. The patient does **NOT** have a deficiency of N-acetylglutamate synthetase (type of enzyme) or acute hyperammonemia (short and sudden high ammonia levels)
G. You have previously tried Buphenyl (sodium phenylbutyrate), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
B. You had clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

Commercial Effective: 07/01/20

GLYCOPYRRONIUM TOPICAL

Generic	Brand			
GLYCOPYRRONIUM 2.4% CLOTH	QBREXZA			

GUIDELINES FOR USE

Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:

A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You had a trial of a prescription strength aluminum chloride product such as Drysol

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Commercial Effective: 10/01/20

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GOLIMUMAB - SQ

Generic	Brand			
GOLIMUMAB - SQ	SIMPONI - SQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/ extended release)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/ extended release), Otezla

(Initial criteria continued on next page)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara, Xeljanz (immediate release/ extended release)

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

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)

(Renewal criteria continued on next page)

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have moderate to severe ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (diagnostic test to determine the effectiveness of drug therapy) while on therapy

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Commercial Effective: 04/01/20

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

Generic	Brand			
LEUPROLIDE ACETATE	ELIGARD			
LEUPROLIDE ACETATE (GENERIC)	LEUPROLIDE ACETATE			
NAFARELIN ACETATE	SYNAREL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, leuprolide acetate, Synarel)** requires the following rule(s) be met for approval:

A. You have advanced prostate cancer, moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus), central precocious puberty (CPP; early sexual development in girls and boys), or gender dysphoria (you're distressed because your assigned sex/gender do not match your gender identity)

B. **If you have moderate to severe pain associated with endometriosis, approval also requires:**
   1. The request is for Synarel
   2. You are 18 years of age or older
   3. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
   4. You have previously tried a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation), unless there is a medical reason why you cannot (contraindication)

C. **If you are female and have central precocious puberty, approval also requires:**
   1. The request is for Synarel or Leuprolide (generic)
   2. You are 2 years of age or older
   3. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are/were younger than 8 years of age when your condition started
   6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

(Initial criteria continued on next page)

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. The request is for Synarel or Leuprolide (generic)
   2. You are 2 years of age or older
   3. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are/were younger than 9 years of age when your condition started
   6. Documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

RENEWAL CRITERIA

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, leuprolide acetate, Synarel)** requires the following rule(s) be met for renewal:

A. You have advanced prostate cancer, moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus), central precocious puberty (CPP; early sexual development in girls and boys), or gender dysphoria (you're distressed because your assigned sex/gender do not match your gender identity)
B. **If you have moderate to severe pain associated with endometriosis, renewal also requires:**
   1. The request is for Synarel
   2. You had improvement of pain related to endometriosis while on therapy
   3. You are receiving add-back therapy at the same time (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
   4. You have NOT received a total course of Synarel therapy exceeding 12 months
C. **If you have central precocious puberty, renewal also requires:**
   1. The request is for Synarel or Leuprolide (generic)
   2. Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   3. You have not reached actual age which corresponds to current pubertal age

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GRANULOCYTE COLONY-STIMULATING FACTORS

Generic	Brand			
FILGRASTIM-SNDZ	ZARXIO			
FILGRASTIM	NEUPOGEN			
PEGFILGRASTIM	NEULASTA			
PEGFILGRASTIM-JMDB	FULPHILA			
PEGFILGRASTIM-CBQV	UDENYCA			
TBO-FILGRASTIM	GRANIX			
FILGRASTIM-AAFI	NIVESTYM			
PEGFILGRASTIM-BMEZ	ZIEXTENZO			
PEGFILGRASTIM-APGF	NYVEPRIA			

GUIDELINES FOR USE

Our guideline named **GRANULOCYTE COLONY-STIMULATING FACTORS (GCSF)** requires the following rule(s) be met for approval:

A. The requested medication is prescribed by or recommended by a hematologist (blood doctor) or oncologist (cancer/tumor doctor)

B. **Requests for Zarxio also require ONE of the following:**
   1. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) undergoing induction or consolidation chemotherapy treatment (you're starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   2. You have a nonmyeloid malignancy and are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical symptoms such as febrile neutropenia
   3. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   4. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia
   5. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and you are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect the bone marrow and cause low levels of a type of white blood cell) with fever. If you are 1 month of age or older, you must also have previously tried Granix for this indication.

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

C. **Requests for Neupogen also require ONE of the following:**
   1. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   2. You have a nonmyeloid malignancy and are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation (BMT) and you are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical symptoms such as febrile neutropenia)
   3. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   4. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia
   5. You are using the requested drug for increasing survival if you have been acutely exposed to myelosuppressive doses of radiation (you have radiation that affects your blood and bone marrow such as Hematopoietic Syndrome of Acute Radiation Syndrome)
   6. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever. If you are 1 month of age or older, you must have previously tried Granix for this indication

D. **Requests for Neulasta also requires ONE of the following:**
   1. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
   2. You are using the requested drug for increasing survival if you have been acutely exposed to myelosuppressive doses of radiation (you have radiation that affects your blood and bone marrow such as Hematopoietic Syndrome of Acute Radiation Syndrome

E. **Requests for Fulphila, Nyvepria, Udenyca, or Ziextenzo also requires the following:**
   1. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

F. **Requests for Granix also requires the following:**
   1. You are 1 month of age or older
   2. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever

G. **Requests for Nivestym also requires ONE of the following:**
   1. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   2. You have a nonmyeloid malignancy and are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical sequelae (symptoms such as febrile neutropenia)
   3. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   4. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia
   5. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever. If you are 1 month of age or older, you must also have previously tried Granix for this indication

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Commercial Effective: 01/01/21

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GUSELKUMAB

Generic	Brand			
GUSELKUMAB	TREMFYA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine, unless there is a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

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GUSELKUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 01/01/21

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HYDROMORPHONE ER

Generic	Brand			
HYDROMORPHONE HCL	EXALGO, HYDROMORPHONE ER			

GUIDELINES FOR USE

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Commercial Effective: 07/01/20

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IBRUTINIB

Generic	Brand			
IBRUTINIB	IMBRUVICA			

GUIDELINES FOR USE

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

A. You have mantle cell lymphoma (type of white blood cell cancer), chronic lymphocytic leukemia (type of blood and bone marrow cancer), small lymphocytic lymphoma (type of white blood cell cancer), Waldenström's macroglobulinemia (type of cancer affecting two white cell types of B cells), marginal zone lymphoma (type of cancer of B-cells), or chronic graft versus host disease (donor bone marrow or stem cells attack the receiving person)
B. You are 18 years of age or older
C. Requests for Ibrutinib 140mg or 280mg tablets requires you had a trial of Ibrutinib 140mg capsules, unless there is a medical reason why you cannot (contraindication)
D. **If you have mantle cell lymphoma, approval also requires:**
   2. You have received at least one prior therapy for mantle cell lymphoma
E. **If you have marginal zone lymphoma, approval also requires:**
   1. You need systemic (treatment spreads through the blood) therapy
   2. You have received at least one prior anti-CD20-based therapy (such as Rituxan)
F. **If you have chronic graft versus host disease, approval also requires:**
   1. You have failed one or more lines of systemic therapy (treatment spread through the blood, such as corticosteroids)

Commercial Effective: 07/01/20

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ICATIBANT

Generic	Brand			
ICATIBANT	FIRAZYR			

GUIDELINES FOR USE

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

A. You have hereditary angioedema (HAE: an inherited condition of severe swelling attacks)
B. You are 18 years of age or older
C. Your diagnosis is confirmed via complement testing (blood test that measures the activity of a group of immune system proteins in the bloodstream)
D. The medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
E. The medication is prescribed by or given in consultation with an allergist/immunologist (doctor who specializes in allergies and immune disorders) or hematologist (blood doctor)

Commercial Effective: 07/01/20

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IDELALISIB

Generic	Brand			
IDELALISIB	ZYDELIG			

GUIDELINES FOR USE

Our guideline named **IDELALISIB (Zydelig)** requires you meet **ONE** of the following rules for approval:

A. You have relapsed chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer) and will use the requested medication with rituximab at the same time
B. You have relapsed follicular B-cell non-Hodgkin lymphoma (FL: type of immune system cancer) and you have received at least **TWO** prior systemic therapies (treatment that travels through the blood stream)
C. You have relapsed small lymphocytic lymphoma (SLL: type of immune system cancer) and you have received at least TWO prior systemic therapies (treatment that travels through the blood stream)

Commercial Effective: 07/01/20

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ILOPROST

Generic	Brand			
ILOPROST	VENTAVIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symtpom)

RENEWAL CRITERIA

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH; type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable in the 6-minute walk distance test AND your World Health Organization functional class has remained stable or improved (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

Commercial Effective: 07/01/20

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IMATINIB

Generic	Brand			
IMATINIB MESYLATE	GLEEVEC, IMATINIB MESYLATE			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia positive chronic myeloid leukemia (type of blood cell cancer that begins in bone marrow with an abnormal gene) in chronic phase
   2. Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
   3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer that has returned or did not respond to treatment)
   4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   5. Myelodysplastic/myeloproliferative disease (a group of diseases where the bone marrow makes too many white blood cells) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
   6. Aggressive systemic mastocytosis (a type of cell accumulates in internal tissues and organs) without D816V c-Kit mutation or with c-Kit mutational status unknown
   7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (type of inflammatory cancer)
   8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (type of rare skin tumor that cannot be completely removed by surgery or returns/ spreads)
   9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (tumor in stomach/intestines that spreads or cannot be removed by surgery) with a Kit (CD117) positive
   10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor

B. **If you are newly diagnosed with Philadelphia positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

(Criteria continued on next page)

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

D. **If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older

E. **If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. The requested medication will be used in combination with chemotherapy

F. **If you have myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, approval also requires:**
   1. You are 18 years of age or older

G. **If you have aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, approval also requires:**
   1. You are 18 years of age or older

H. **If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:**
   1. You are 18 years of age or older

I. **If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:**
   1. You are 18 years of age or older

J. **If the request is for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older

K. **If you have gastrointestinal stromal tumor, approval also requires:**
   1. For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 (type of gene) mutation (a permanent change in your DNA that make up your gene)

IMMUNE GLOBULIN

Generic	Brand			
IMMUNE GLOBULIN	BIVIGAM, CARIMUNE NF NANOFILTERED, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA			
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED			
IMMUNE GLOBULIN / MALTOSE	OCTAGAM			
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA			
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU			
IMMUN GLOB G(IGG)-IFAS/GLYCINE	PANZYGA			
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG			
IMMUNE GLOBULIN (HUMAN)-KLHW	XEMBIFY			
IMMUNE GLOBULIN (HUMAN)-SLRA	ASCENIV			

GUIDELINES FOR USE

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

A. **For Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Carimune NF Nanofiltered, Flebogamma DIF, Gammagard S-D, Gammaplex, Privigen, Octagam, or Panzyga for intravenous (IV) injection**, approval requires you to have ONE of the following diagnoses:
   1. Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
   2. Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
   3. Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
   4. Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)

(Criteria continued on next page)

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

5. Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
6. B-cell Chronic Lymphocytic Leukemia (blood and bone marrow cancer of immune cells) with Autoimmune Hemolytic Anemia (body destroys red blood cells more rapidly than it produces them), Immune Thrombocytopenic Purpura (decreased number of blood cells that prevent bleeding with increased easy bruising) OR Pure Red Cell Blood Aplasia (bone marrow stops making red blood cells)
7. Guillain-Barre Syndrome (immune system attacks the nerves)
8. Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
9. Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
10. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation) related to a solid organ transplant
11. Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)-infected child
12. Reduction of secondary infections in pediatric HIV infections
13. Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
14. Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
15. Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
16. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
17. Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
18. Neonatal sepsis (blood infection in infants)
19. Rotaviral enterocolitis (severe diarrhea among infants and young children)
20. Toxic shock syndrome (life-threatening complication of certain bacterial infections)
21. Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
22. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
23. Autoimmune Mucocutaneous Blistering Disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita

(Criteria continued on next page)

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

B. **For Asceniv, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)
   2. You are 12 years of age or older
   3. You have tried any other TWO immunoglobulin products

C. **For Gamastan S-D, approval requires:**
   1. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella

D. **For Hizentra, approval requires:**
   1. The medication is only for subcutaneous (under the skin) use
   2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak) OR chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

E. **For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:**
   - The medication is only for subcutaneous (under the skin) use
   - You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

F. **For Gammagard Liquid, Gamunex-C, or Gammaked for subcutaneous use, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

Commercial Effective: 04/01/20

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INDOMETHACIN RECTAL

Generic	Brand			
INDOMETHACIN	INDOCIN			

GUIDELINES FOR USE

Our guideline named **INDOMETHACIN RECTAL (Indocin)** requires that you meet ONE of the following rule(s) for approval:

A. You have dysphagia (difficulty swallowing), difficulty swallowing capsules, or have a feeding tube placed (such as a G-tube, J-tube)
B. You had a previous trial of at least two prescription strength oral NSAIDs (non-steroidal anti-inflammatory drugs such as ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

Commercial Effective: 07/01/20

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INHALED INSULIN

Generic	Brand			
INSULIN REGULAR, HUMAN	AFREZZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:

A. You have type 1 or type 2 diabetes
B. You are 18 years of age or older
C. You have a baseline spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume)
D. **If you have type 1 diabetes, approval also requires:**
   1. You are using a long-acting insulin with the requested medication and that you have tried a formulary rapid acting insulin: Humalog
E. **If you have type 2 diabetics, approval also requires:**
   1. You tried a formulary rapid acting insulin: Humalog
   2. Your prescriber has indicated that you are physically unable or unwilling to use injectable insulin

RENEWAL CRITERIA

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have type 1 or type 2 diabetes
B. You have documentation of follow up spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume in one second) after 6 months of treatment and annually thereafter
C. Your FEV1 has NOT declined 20% or more from baseline
D. **If you have type 1 diabetes,** approval requires that you are using a long acting insulin at the same time with the requested medication

Commercial Effective: 07/01/20

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INOTERSEN

Generic	Brand			
INOTERSEN SODIUM	TEGSEDI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), hATTR specialist, or medical geneticist
D. You have stage 1 or 2 polyneuropathy
E. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
    1. Biopsy (surgical sample) of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR (Transthyretin) protein
    2. DNA genetic sequencing to confirm hATTR mutation

RENEWAL CRITERIA

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
B. You have not progressed to stage 3 polyneuropathy (widespread nerve pain/damage) as shown by functional decline such as being wheelchair-bound or bedridden

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INTERFERON ALFA-2B

Generic	Brand			
INTERFERON ALFA-2B	INTRON A			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires **ONE** of the following rule(s) be met for approval:

A. The requested medication is being used to treat one of the following:
   1. Chronic hepatitis C (type of liver inflammation)
   2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
   3. Condylomata acuminate (genital warts)
   4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
   5. Chronic hepatitis B (type of liver inflammation)
   6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
   7. Malignant melanoma (serious type of skin cancer)
   8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
   9. Follicular lymphoma (type of lymphatic system cancer)
   10. Angioblastoma (certain blood-vessel tumors of the brain)
   11. Carcinoid (cancer) tumor
   12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
   13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)
   14. Multiple myeloma (plasma cell cancer)
   15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
   16. Ovarian cancer
   17. Polycythemia vera (cancer where bone marrow makes too many red blood cells)
   18. Renal cell carcinoma (type of kidney cancer)
   19. Skin cancer, thrombocytosis (your body makes too many platelets)
   20. Thrombocytosis (high level of platelets (cells that helps blood clot and stop bleeding) in your blood)
   21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic hepatitis C, approval also requires:**
   1. You are infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C
   2. Therapy is being supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist or a physician specializing in the treatment of hepatitis (such as a hepatologist)
   3. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of greater than or equal to 50 IU/mL
   4. The requested medication will be used with ribavirin or you have a medical reason why you cannot (contraindication)
   5. You had a previous trial of or contraindication to (medical reason why you cannot use) a peginterferon product

RENEWAL CRITERIA

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:

A. The request is for continuation of current therapy or renewal with Intron A therapy
B. **If you are being treated for chronic hepatitis C (type of liver inflammation), renewal also requires:**
   1. Therapy is being supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist or a physician specializing in the treatment of hepatitis (such as a hepatologist)
   2. You have a HCV (hepatitis C virus) RNA level (amount of virus in your blood) undetectable (less than 50 IU/mL) at 24 weeks

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Commercial Effective: 07/01/20

INTERFERONS FOR MULTIPLE SCLEROSIS

Generic	Brand			
INTERFERON BETA-1A	AVONEX, AVONEX PEN			
INTERFERON BETA-1A/ALBUMIN	AVONEX, REBIF, REBIF REBIDOSE			
INTERFERON BETA-1B	BETASERON, EXTAVIA			
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN			

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

GUIDELINES FOR USE

PLEGRIDY, AVONEX, REBIF, BETASERON

Our guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS (Plegridy, Avonex, Rebif, Betaseron)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

EXTAVIA

Our guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS (Extavia)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried any TWO of the following preferred formulary drugs, unless there is a medical reason why you cannot (contraindication): Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta
(**Please note:** other MS agents may also require prior authorization)

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INTERFERON GAMMA-1B, RECOMB

Generic	Brand				
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
   2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

B. **If you have chronic granulomatous disease, approval also requires:**
   1. The medication is prescribed by or given in consultation with a hematologist (blood doctor), infectious disease specialist (doctor that specializes in treating infections), or immunologist (doctor that specializes in treating and managing allergies, asthma and immunologic disorders)

C. **If you have severe malignant osteopetrosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (doctor that specializes in all things relating to our hormones)

RENEWAL CRITERIA

Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
   2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

B. You have shown clinical (medical) benefit compared to baseline (such as reduction in frequency and severity of serious infections)

C. You have not received hematopoietic cell transplantation (transplant of stem cells from bone marrow, peripheral blood, or umbilical cord blood)

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ISTRADEFYLLINE

Generic	Brand			
ISTRADEFYLLINE	NOURIANZ			

GUIDELINES FOR USE

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

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. You are 18 years of age or older
C. You are experiencing 'OFF' episodes (times when medication wears off and you have movement problems)
D. Nourianz will be used along with levodopa/carbidopa
E. You had a previous trial of or contraindication to (medical reason why you cannot use) **TWO** Parkinson's agents from **TWO** different drug classes:
    1. Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
    2. Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
    3. Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

Commercial Effective: 07/01/20

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ITRACONAZOLE - TOLSURA

Generic	Brand			
ITRACONAZOLE	TOLSURA			

GUIDELINES FOR USE

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

A. You are 18 years of age or older
B. You have **ONE** of the following fungal infections:
   1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
   3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy
C. Therapy is prescribed by or given in consultation with an Infectious Disease Specialist
D. You had a previous trial of a generic itraconazole formulation
E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

Commercial Effective: 07/01/20

IVACAFTOR

Generic	Brand			
IVACAFTOR	KALYDECO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You are 4 months of age or older
B. You have a diagnosis of cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
C. If you are between 4 months and less than 6 years of age, **Ivacaftor packets** will be approved. Documentation of your weight is required
D. You have documentation of one of the following mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene:

2789+5G→A	*D1152H*	*G1069R*	*P67L*	*S1251N*
3272-26A→G	*D1270N*	*G1244E*	*R1070Q*	*S1255P*
3849+10kbC→T	*D579G*	*G1349D*	*R1070W*	*S549N*
711+3A→G	*E193K*	*G178R*	*R117C*	*S549R*
A1067T	*E56K*	*G551D*	*R117H*	*S945L*
A455E	*E831X*	*G551S*	*R347H*	*S977F*
D110E	*F1052V*	*K1060T*	*R352Q*	
D110H	*F1074L*	*L206W*	*R74W*	

E. You are **NOT** homozygous (have 2 copies of the same gene) for the F508del mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
F. The medication is prescribed by or given in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert

RENEWAL CRITERIA

Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: life-threatening disorder that damages lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
   1. You have maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
   2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

IVOSIDENIB

Generic	Brand			
IVOSIDENIB	TIBSOVO			

GUIDELINES FOR USE

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

A. You have acute myeloid leukemia (AML: blood and bone marrow cancer with too many white blood cells)
B. **If you have relapsed or refractory acute myeloid leukemia (AML: type of blood and bone marrow cancer that returns after treatment), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You are 18 years of age or older
C. **If you have a new diagnosis of acute myeloid leukemia (AML: type of blood and bone marrow cancer), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You meet **ONE** of the following criteria:
      a. You are 75 years of age or older
      b. You are 18 years of age or older **AND** have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy

Commercial Effective: 07/01/20

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IXAZOMIB

Generic	Brand			
IXAZOMIB CITRATE	NINLARO			

GUIDELINES FOR USE

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

A. You have multiple myeloma (plasma cell cancer)
B. The requested medication will be used in combination with lenalidomide and dexamethasone
C. You have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

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Commercial Effective: 07/01/20

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IXEKIZUMAB

Generic	Brand			
IXEKIZUMAB	TALTZ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more of the following forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You meet ONE of the following:
      a. You are 6 to 11 years of age AND have previously tried the following preferred immunomodulatory (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel
      b. You are 12 to 17 years of age AND have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel AND Stelara
      c. You are 18 years of age or older AND have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Otezla, Stelara, Tremfya, Skyrizi

(Initial criteria continued on next page)

CONTINUED ON NEXT PAGE

IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Xeljanz/XR, Otezla, Stelara

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Cosentyx

E. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
   5. You have previously tried the preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx

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

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IXEKIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS) OR non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
   1. You have 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: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

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Commercial Effective: 10/01/20

LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE

Generic	Brand				
LACTIC ACID/ CITRIC ACID/ POTASSIUM BITARTRATE	PHEXXI				

GUIDELINES FOR USE

Our guideline named **LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE (Phexxi)** requires the following rule(s) be met for approval:

A. You are a female patient with reproductive potential using the requested medication for prevention of pregnancy
B. You are not using vaginal ring products (such as Annovera or Nuvaring) together with Phexxi
C. You had a previous trial of two contraceptive agents (such as an intrauterine device, hormonal implant, injection, patch, or oral products), unless there is a medical reason you cannot (contraindication)

Commercial Effective: 10/01/20

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LANADELUMAB

Generic	Brand			
LANADELUMAB-FLYO	TAKHZYRO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Takhzyro together with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

RENEWAL CRITERIA

Our guideline named **LANADELUMAB (Takhzyro)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in hereditary angioedema attacks

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Commercial Effective: 01/01/21

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LAPATINIB

Generic	Brand			
LAPATINIB DITOSYLATE	TYKERB			

GUIDELINES FOR USE

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

A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)
B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: gene/protein in breast cancer) positive
C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. The requested medication will be used in combination with Xeloda (capecitabine)
   2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
D. **If you have metastatic breast cancer, approval also requires:**
   1. Your tumor is hormone receptor-positive
   2. The requested medication will be used in combination with Femara (letrozole)
   3. You are a postmenopausal woman

Commercial Effective: 10/19/20

LAROTRECTINIB

Generic	Brand			
LAROTRECTINIB	VITRAKVI			

GUIDELINES FOR USE

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

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

Commercial Effective: 07/01/20

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LASMIDITAN

Generic	Brand			
LASMIDITAN SUCCINATE	REYVOW			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
A. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
   1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
   2. You have experienced clinical improvement as defined by ONE of the following:
      a. Ability to function normally within 2 hours of dose
      b. Headache pain disappears within 2 hours of dose
      c. Treatment works consistently in majority of migraine attacks

Commercial Effective: 12/12/20

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L-GLUTAMINE

Generic	Brand			
GLUTAMINE (L-GLUTAMINE)	ENDARI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **L-GLUTAMINE (ENDARI)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (type of red blood cell disorder)
B. You are 5 years of age or older
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
D. The patient had a trial of or contraindication to hydroxyurea
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered given into the vein, narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
    2. You are having sickle-cell associated symptoms such as pain or anemia (your blood doesn't have enough healthy red blood cells and you're tired) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

RENEWAL CRITERIA

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) bet met for renewal:

A. You have sickle cell disease (type of red blood cell disorder)
B. You have maintained or experienced a reduction in acute complications of sickle-cell disease such as number of sickle cell crises, hospitalizations, acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Commercial Effective: 04/01/20

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LEDIPASVIR/SOFOSBUVIR

Generic	Brand			
LEDIPASVIR/SOFOSBUVIR	HARVONI			

GUIDELINES FOR USE

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (type of liver inflammation)
B. You have genotype 1, genotype 4, genotype 5, or genotype 6 hepatitis C
C. You are 3 years of age or older
D. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. If you are treatment-experienced (previously treated) with no cirrhosis (liver damage) and genotype 1, previous treatment should include one of the following: 1) peginterferon and ribavirin, 2) triple therapy with HCV protease inhibitor (type of drug to treat hepatitis C), peginterferon and ribavirin, or 3) a prior non-NS5A inhibitor (type of drug to treat hepatitis C), sofosbuvir-containing regimen
G. If you are treatment-experienced (previously treated) with compensated cirrhosis (no symptoms related to liver damage) and genotype 1, previous treatment should include either 1) peginterferon and ribavirin, or 2) triple therapy with HCV protease inhibitor (type of drug to treat hepatitis C), peginterferon and ribavirin
H. **If you have decompensated cirrhosis (symptoms related to liver damage) or are post-liver transplant (without cirrhosis or with compensated cirrhosis), approval also requires:**
    1. You will be using a ribavirin-containing regimen
I. **If the request is for Harvoni 45mg/200 mg pellets, approval also requires:**
    1. You are unable to swallow tablets

Harvoni will not be approved for the following:

A. You are using any of the following medications concurrently (at the same time) while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, the combination agent Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or the combination agent tipranavir/ritonavir
B. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Commercial Effective: 07/01/20

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LEFAMULIN

Generic	Brand			
LEFAMULIN	XENLETA			

GUIDELINES FOR USE

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

A. You have community-acquired bacterial pneumonia (type of lung infection)
B. You are 18 years of age or older
C. The infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
D. You meet **ONE** of the following criteria:
    1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
    2. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with a) resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** b) susceptibility to Xenleta
    3. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of at least **TWO** standard of care agents (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) for community-acquired bacterial pneumonia, unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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LENALIDOMIDE

Generic	Brand			
LENALIDOMIDE	REVLIMID			

GUIDELINES FOR USE

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

A. You have **ONE** of the following diagnoses:
   1. Multiple myeloma (plasma cell cancer)
   2. Anemia due to a myelodysplastic syndrome (cancer that affects blood cell production)
   3. Mantle cell lymphoma (type of white blood cell cancer)
   4. Follicular lymphoma (type of slow growing white blood cell cancer)
   5. Marginal zone lymphoma (a rare type of slow growing white blood cell cancer)

B. You are 18 years of age or older

C. **If you have anemia due to a myelodysplastic syndrome, approval also requires:**
   1. You have a deletion 5q (type of gene) abnormality

D. **If you have mantle cell lymphoma, approval also requires:**
   1. You have tried two prior therapies and the cancer returns or gets worse (relapses or progresses). One of the therapies tried must be Velcade (bortezomib) (Note: Velcade may be covered under the medical benefit and/or require prior authorization).

E. **If you have follicular lymphoma, approval also requires:**
   1. You have previously been treated for follicular lymphoma
   2. The requested medication is being taken in combination with a rituximab product (type of cancer drug)

F. **If you have marginal zone lymphoma, approval also requires:**
   1. You have previously been treated for marginal zone lymphoma
   2. The requested medication is being taken in combination with a rituximab product

Commercial Effective: 07/01/20

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LENVATINIB

Generic	Brand			
LENVATINIB MESYLATE	LENVIMA			

GUIDELINES FOR USE

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

A. You have **ONE** of the following diagnoses:
   1. Differentiated thyroid cancer (cancer cells look/act like normal thyroid cells)
   2. Advanced renal cell cancer (kidney cancer)
   3. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed by surgery)
   4. Advanced endometrial carcinoma (type of cancer that starts in the uterus)

B. **If you have differentiated thyroid cancer, approval also requires:**
   1. Your thyroid cancer is locally recurrent or metastatic (cancer that has spread to other parts of the body)
   2. Your thyroid cancer is progressive (getting worse)
   3. You have tried radioactive iodine therapy, unless there is medical reason why you cannot (contraindication)

C. **If you have advanced renal cell cancer, approval also requires:**
   1. Lenvima is used in combination with everolimus
   2. You have tried one prior anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
   3. You have experienced disease progression following prior systemic therapy (disease has worsened after previous therapy)
   4. You are not a candidate for curative surgery or radiation

Commercial Effective: 07/01/20

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LETERMOVIR PO

Generic	Brand			
LETERMOVIR	PREVYMIS			

GUIDELINES FOR USE

Our guideline named **LETERMOVIR PO (Prevymis)** requires the following rule(s) be met for approval:

A. You are undergoing an allogeneic hematopoietic stem cell transplant (you have cells transplanted from a matching donor)
B. You are 18 years of age or older
C. You are CMV (Cytomegalovirus)-seropositive [R+]
D. Prevymis will be used for prophylaxis (prevention) of cytomegalovirus infection and disease
E. Prevymis will be started between Day 0 and Day 28 post-transplantation (before or after engraftment)
F. You are not receiving the medication beyond 100 days post-transplantation

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Commercial Effective: 07/01/20

LEVAMLODIPINE

Generic	Brand				
LEVAMLODIPINE MALEATE	CONJUPRI				

GUIDELINES FOR USE

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

A. You have hypertension (high blood pressure)
B. You are 6 years of age or older
C. You have tried and failed BOTH of the following unless there is a medical reason you are unable to (contraindication):
   1. TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine, nifedipine)
   2. TWO other antihypertensive agents from any of the following classes:
      a. Thiazides (such as hydrochlorothiazide, chlorothiazide)
      b. Angiotensin-converting enzyme inhibitors (such as lisinopril, enalapril)
      c. Angiotensin II receptor blockers (such as losartan, irbesartan)

Commercial Effective: 01/01/21

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LEVODOPA

Generic	Brand			
LEVODOPA	INBRIJA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
C. You are currently being treated with carbidopa/levodopa
D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

RENEWAL CRITERIA

Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

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LOFEXIDINE

Generic	Brand			
LOFEXIDINE	LUCEMYRA			

GUIDELINES FOR USE

Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:

A. Lucemyra is being used to lessen opioid withdrawal symptoms to help abrupt opioid discontinuation
B. You are 18 years of age or older
C. You are in a setting with close patient monitoring of Lucemyra (lofexidine) treatment for a maximum of 18 days
D. Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

Commercial Effective: 07/01/20

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LOMITAPIDE

Generic	Brand			
LOMITAPIDE	JUXTAPID			

GUIDELINES FOR USE

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

A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol)
B. Your diagnosis of homozygous familial hypercholesterolemia (type of inherited high cholesterol) was determined by meeting **ONE** of the following criteria:
    1. Simon Broome diagnostic criteria
    2. Dutch Lipid Network criteria with a score of at least 8
    3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein) - cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (condition where fatty growth develops under the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents
C. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
D. You have an LDL (low density lipoprotein) - cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin (drug used for cholesterol) treatment
E. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors
F. **If you are statin tolerant, approval also requires:**
    1. You meet **ONE** of the following criteria:
        a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
        b. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
    2. You will continue statin (drug used for cholesterol) treatment in combination with Juxtapid

(Criteria continued on next page)

CONTINUED ON NEXT PAGE

LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy (drug used for cholesterol) such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant, or hypersensitivity (allergic) reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measurement of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.

Commercial Effective: 07/01/20

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LOMUSTINE

Generic	Brand			
LOMUSTINE	GLEOSTINE			

GUIDELINES FOR USE

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

A. You meet **ONE** of the following:
   1. You have Hodgkin's Lymphoma (type of immune system cancer)
   2. You have primary and metastatic brain tumors (tumor that has spread to other parts of body) **AND** you have previously received appropriate surgical and/or radiotherapeutic procedures

B. **If you have primary and metastatic brain tumors, approval also requires ONE of the following:**
   1. The requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine)
   2. You have had a previous trial of intravenous (IV) carmustine

Commercial Effective: 07/01/20

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LORLATINIB

Generic	Brand			
LORLATINIB	LORBRENA			

GUIDELINES FOR USE

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

A. You have anaplastic lymphoma kinase (ALK: type of enzyme)-positive metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
B. You have experienced disease progression (disease has worsened) on at least **ONE** of the following regimens:
    1. Crizotinib and at least one other anaplastic lymphoma kinase (ALK: type of enzyme) inhibitor for metastatic disease (cancer that has spread to other parts of the body)
    2. Alectinib as the first anaplastic lymphoma kinase (ALK: type of enzyme) inhibitor therapy for metastatic disease (cancer that has spread to other parts of the body)
    3. Ceritinib as the first anaplastic lymphoma kinase (ALK: type of enzyme) inhibitor therapy for metastatic disease (cancer that has spread to other parts of the body)

Commercial Effective: 07/01/20

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LUMACAFTOR/IVACAFTOR

Generic	Brand			
LUMACAFTOR/IVACAFTOR	ORKAMBI			

GUIDELINES FOR USE

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

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:

A. You are 2 years of age or older
B. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
C. Documentation that you are homozygous (have 2 copies of the same gene) for the F508del-CFTR (type of gene: Cystic fibrosis transmembrane conductance regulator) mutation
D. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert

RENEWAL CRITERIA

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

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LUSUTROMBOPAG

Generic	Brand			
LUSUTROMBOPAG	MULPLETA			

GUIDELINES FOR USE

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

A. You have thrombocytopenia (low number of platelets in the blood)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist), gastroenterologist (digestive tract doctor), hepatologist (liver doctor), immunologist, or endocrinologist (hormone doctor)
D. You have chronic liver disease
E. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
F. You have a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
G. You are not receiving other thrombopoietin receptor agonist therapy (drugs that help make more blood platelets) such as avatrombopag, romiplostim, eltrombopag

Commercial Effective: 07/01/20

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MEBENDAZOLE

Generic	Brand			
MEBENDAZOLE	EMVERM			

GUIDELINES FOR USE

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

A. Emverm is being used for the treatment of *Enterobius vermicularis* (pinworm), *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm)
B. You are 2 years of age or older
C. **If you have *enterobius vermicularis* (pinworm), approval also requires:**
   1. You previously had a trial of over-the-counter (OTC) pyrantel pamoate, unless there is a medical reason why you cannot (contraindication)
D. **If you have trichuris trichiura (whipworm) or ascaris lumbricoides (common roundworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication)
E. **If you have ancylostoma duodenale (common hookworm) or necator americanus (American hookworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication) OR you had a trial of over-the-counter (OTC) pyrantel pamoate

Commercial Effective: 10/01/20

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MECAMYLAMINE HYDROCHLORIDE

Generic	Brand			
MECAMYLAMINE HCL	VECAMYL			

GUIDELINES FOR USE

Our guideline named **MECAMYLAMINE HYDROCHLORIDE (Vecamyl)** requires the following rule(s) be met for approval:

A. The requested medication will be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension
B. You have had a trial of at least three of the following, unless there is a medical reason why you cannot (contraindication): angiotensin converting enzyme inhibitor (ACE-I) or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

Commercial Effective: 07/01/20

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MECASERMIN

Generic	Brand			
MECASERMIN	INCRELEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
   2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone
B. You are 2 years to less than 18 years of age
C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)
D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]
E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

RENEWAL CRITERIA

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:

A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

Commercial Effective: 04/01/20

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MECHLORETHAMINE GEL

Generic	Brand			
MECHLORETHAMINE HCL	VALCHLOR			

GUIDELINES FOR USE

Our guideline named **MECHLORETHAMINE GEL (Valchlor)** requires the following rule(s) be met for approval:

A. You have stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (type of immune system cancer)
B. You had prior skin-directed therapy such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy

Commercial Effective: 07/01/20

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MEPOLIZUMAB

Generic	Brand			
MEPOLIZUMAB	NUCALA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Severe asthma with an eosinophilic phenotype (inflammatory type)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
   3. Hypereosinophilic syndrome (HES) (a rare blood disorder)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/ breathing) medicine or allergy medicine
   3. Nucala will be used as add-on maintenance treatment
   4. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
   5. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   6. You have experienced at least ONE asthma exacerbation (worsening of symptoms) 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
   7. You are not being treated on the requested medication concurrently (at the same time) with Xolair, Dupixent, or another anti-IL-5 asthma biologic (such as Cinqair, Fasenra)

C. **If you have eosinophilic granulomatosis with polyangiitis (EGPA), approval also requires:**
   1. You are 18 years of age or older

D. **If you have hypereosinophilic syndrome (HES), approval also requires:**
   1. You are 12 years of age or older
   2. You had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

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MEPOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA, Churg-Strauss syndrome) OR hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

Commercial Effective: 10/12/20

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METHYLNALTREXONE

Generic	Brand			
METHYLNALTREXONE BROMIDE	RELISTOR			

GUIDELINES FOR USE

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

A. You have opioid (type of pain medication)-induced constipation with chronic non-cancer pain, OR you have an advanced illness or pain caused by active cancer and you require opioid dosage increase for palliative care (treatment of symptoms)
B. You are 18 years of age or older
C. **If you have advanced (terminal) illness, or pain caused by active cancer and** you require opioid dosage increase for palliative care (treatment of symptoms), only Relistor injection may be approved
D. **If you have chronic non-cancer pain, approval also requires:**
    1. You have been taking opioids for at least four weeks
    2. You had a previous trial of naloxegol (Movantik), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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METOCLOPRAMIDE

Generic	Brand				
METOCLOPRAMIDE	GIMOTI				

GUIDELINES FOR USE

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

A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (disorder that causes delayed emptying of food from the stomach)
B. You are 18 years of age or older
C. You have previously tried or have a contraindication (medical reason why you cannot take) to metoclopramide ODT (orally disintegrating tablet)

Commercial Effective: 01/01/21

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MIDOSTAURIN

Generic	Brand			
MIDOSTAURIN	RYDAPT			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Newly diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
   2. Aggressive systemic mastocytosis (ASM: condition with a build up of a type of white blood cell)
   3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
   4. Mast cell leukemia (MCL: type of white blood cell cancer)

B. **If you have newly diagnosed acute myeloid leukemia (AML), approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

Commercial Effective: 07/01/20

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MIFEPRISTONE

Generic	Brand			
MIFEPRISTONE	KORLYM			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have endogenous Cushing's syndrome (CS: condition that occurs after having high levels of cortisol hormone in the body for a long time)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. Your diagnosis has been confirmed by ONE of the following:
    1. 24-hour urine free cortisol test (at least 2 or more tests to confirm)
    2. Overnight 1mg dexamethasone test
    3. Late night salivary cortisol (at least 2 or more tests to confirm)
E. Your hypercortisolism (high levels of cortisol) is not a result of chronic glucocorticoids (class of drugs that consist of steroids)
F. You have type 2 diabetes mellitus (too much sugar in your blood) OR glucose intolerance (term for a group of conditions that result in elevated blood sugar)
G. You have failed surgical treatment for Cushing's syndrome OR you are not a candidate for surgery

RENEWAL CRITERIA

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:

A. You have endogenous Cushing's syndrome (condition that occurs after having high levels of cortisol hormone in the body for a long time)
B. You continue to have improvement of glucose tolerance and/or stable glucose tolerance (such as reduced hemoglobin A1C [average amount of sugar in your blood over the last 2 to 3 months], improved fasting glucose)
C. You continue to tolerate Korlym
D. You are not a candidate for surgery or have failed surgery for Cushing's syndrome

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MIGALASTAT

Generic	Brand			
MIGALASTAT	GALAFOLD			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have confirmed Fabry disease (rare genetic disease)
B. You are 18 years of age or older
C. You have an amenable (responsive) galactosidase alpha gene (GLA) variant based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by clinical genetics professional as the cause of disease (pathogenic/likely pathogenic)
D. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
E. You are NOT concurrently using enzyme replacement therapy (Fabrazyme)
F. You are symptomatic OR have evidence of injury from GL-3 (a type of cell that builds up) to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR (measurement of how well your kidneys are working) for age, persistent albuminuria (buildup of a type of protein), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. You meet ONE of the following:
    1. If you are a female patient: Confirmation of Fabry disease (rare genetic disease) via genetic test documenting galactosidase alpha gene (GLA) mutation
    2. If you are a male patient: Confirmation of Fabry disease via enzyme assay (lab test) showing you have a low amount of alpha galactosidase A (a-Gal -A) OR genetic test documenting galactosidase alpha gene (GLA) mutation

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MIGALASTAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:

A. You have Fabry disease (rare genetic disease)
B. You have demonstrated improvement or maintenance/stabilization while on therapy in at least ONE of the following areas:
    1. Symptoms such as pain, hypohidrosis/anhidrosis (little to no sweat), exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas (condition with small, dark spots on the skin), abnormal cornea, tinnitus (ringing in the ears), or hearing loss
    2. Imaging such as brain/cardiac MRI (Magnetic resonance imaging), DEXA (Dual-energy X-ray absorptiometry: scan that measures bone density), or renal (kidney) ultrasound
    3. Laboratory or histological testing such as GL-3 (type of cell that builds up) in plasma/urine or renal biopsy

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Commercial Effective: 07/01/20

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MIGLUSTAT

Generic	Brand			
MIGLUSTAT	ZAVESCA			

GUIDELINES FOR USE

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

A. You have mild to moderate type 1 Gaucher disease (rare genetic disorder that affects organs and tissues)
B. You are 18 years of age or older
C. The requested medication will be used as monotherapy (used alone)
D. Enzyme replacement therapy is not a therapeutic option for this patient (due to allergy, hypersensitivity, or poor venous access)

Commercial Effective: 07/01/20

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MILTEFOSINE

Generic	Brand			
MILTEFOSINE	IMPAVIDO			

GUIDELINES FOR USE

Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:

A. You are 12 years of age or older
B. You have Leishmaniasis (type of parasite disease) with ONE of the following types of infection:
    1. Visceral leishmaniasis (affects your organs) caused by *Leishmania donovani*
    2. Cutaneous leishmaniasis (affects your skin layers) caused by ALL of the following:
        a. *Leishmania braziliensis*
        b. *Leishmania guyanensis*
        c. *Leishmania panamensis*
    3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by *Leishmania braziliensis*
C. Species identification must be confirmed via ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
    1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
    2. Culture medium
    3. Polymerase chain reaction (lab method to make copies of genes)
    4. Serologic testing (testing your blood and body fluids such as rK39 Rapid Test)

Commercial Effective: 07/01/20

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MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand			
MINOCYCLINE HCL MICROSPHERES	ARESTIN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have documentation of confirmed periodontitis (inflammation and infection of the gums)
B. You are age 18 years or older
C. The medication is prescribed by or given in consultation with an oral health care professional
D. You do not have a history of minocycline or tetracycline sensitivity or allergy
E. You do not have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. The requested medication will be administered by an oral health professional
G. The requested medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. The requested medication is not being used for acutely abscessed periodontal pocket (not used for short-term and sudden infection with pus-filled pocket)
I. The medication is not being used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus
    2. Chemotherapy
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. The medication is not being used in the regeneration of alveolar bone (bone that has tooth sockets), either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

RENEWAL CRITERIA

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:

A. You have documentation of periodontitis (inflammation and infection of the gums)
B. The medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planning

MIPOMERSEN SODIUM

Generic	Brand			
MIPOMERSEN SODIUM	KYNAMRO			

GUIDELINES FOR USE

Our guideline named **MIPOMERSEN SODIUM (Kynamro)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol) which was determined by meeting **ONE** of the following criteria:
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of at least 8
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein)-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (fatty growths underneath the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

C. The medication is prescribed by or recommended by a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management specialist)

D. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment

E. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

F. **If you are statin tolerant, approval also requires:**
   1. You meet ONE of the following:
      i. You have been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
      ii. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and you cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You will continue statin treatment in combination with Kynamro

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant or hypersensitivity reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measure of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

Commercial Effective: 07/01/20

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MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand			
MOMETASONE FUROATE	SINUVA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

RENEWAL CRITERIA

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Commercial Effective: 10/01/20

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MONOMETHYL FUMARATE

Generic	Brand				
MONOMETHYL FUMARATE	BAFIERTAM				

GUIDELINES FOR USE

Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried or have a contraindication to (medical reason why you cannot take) dimethyl fumarate AND ONE of the following: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta

(**Please note:** Other multiple sclerosis medications may also require prior authorization)

Commercial Effective: 01/01/21

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NERATINIB

Generic	Brand			
NERATINIB	NERLYNX			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Early stage (stage I-III) breast cancer
   2. Advanced or metastatic breast cancer

B. **If you have early stage (stage I-III) breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
   3. The tumor is hormone-receptor positive
   4. The requested medication will be used as extended adjuvant therapy following Herceptin-(trastuzumab-) based therapy
   5. The medication is being requested within 2 years of completing the last trastuzumab dose

C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
   3. The requested medication will be used in combination with capecitabine
   4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

Commercial Effective: 04/01/20

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NILOTINIB

Generic	Brand			
NILOTINIB HCL	TASIGNA			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML: a type of blood cell cancer) in chronic phase
   2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase

B. **If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (type of blood cell cancer) in chronic phase, approval also requires:**
   1. You are 1 year of age or older

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia (type of blood cell cancer) in chronic or accelerated phase, approval also requires:**
   1. You are 18 years of age or older
   2. You are resistant or intolerant to prior therapy including Gleevec (imatinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (a type gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

D. **If you have Philadelphia chromosome-positive chronic myeloid leukemia (a type of blood cell cancer) in chronic phase, approval also requires:**
   1. You are 1 to 17 years of age
   2. You are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (type of gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

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NIMODIPINE SOLUTION

Generic	Brand			
NIMODIPINE	NYMALIZE			

GUIDELINES FOR USE

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:

A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
B. You are 18 years of age or older
C. You are unable to swallow nimodipine oral capsules

Commercial Effective: 05/25/20

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NINTEDANIB

Generic	Brand			
NINTEDANIB	OFEV			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
   2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. **If you have idiopathic pulmonary fibrosis (IPF), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
   3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
   4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
   5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline

(Initial criteria continued on next page)

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

C. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:**
   1. You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40% of predicted value
   6. Other causes of interstitial lung disease are ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype (PF-ILD), approval also requires:**
   1. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (ILD) (not caused by comorbidities such as infection, heart failure)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45% of predicted value

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NINTEDANIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
   2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

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Commercial Effective: 01/01/21

NIRAPARIB

Generic	Brand			
NIRAPARIB TOSYLATE	ZEJULA			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Recurrent (returning) epithelial ovarian cancer (cancer that forms on the surface of the ovary), fallopian tube cancer, or primary peritoneal cancer (type of abdominal cancer)
   2. Advanced ovarian, epithelial ovarian, fallopian tube, or primary peritoneal cancer

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to your most recent platinum-based chemotherapy
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*
   4. The requested medication will be used as monotherapy (used by itself for treatment)
   5. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (treatment)
   6. You have completed at least 2 or more lines of platinum-based chemotherapy

C. **If you have advanced ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have been treated with three or more prior chemotherapy regimens (treatments)
   3. Your cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:
      a. Deleterious (harmful) or suspected deleterious BRCA mutation (type of gene mutation)
      b. Genomic instability and have progressed more than six months after response to the last platinum-based chemotherapy
   4. You were selected for treatment based on an Food and Drug Administration-approved companion diagnostic test for Zejula

D. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum based-chemotherapy
   3. The requested medication will be used for maintenance treatment

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NITISINONE

Generic	Brand			
NITISINONE	ORFADIN, NITYR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have previously tried generic nitisinone capsules unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

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OBETICHOLIC ACID

Generic	Brand			
OBETICHOLIC ACID	OCALIVA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following criteria:
   1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
   2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
   3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age and older
C. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor) or hepatologist (liver doctor)
D. You meet ONE of the following:
   1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
   2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
E. You do not have complete biliary obstruction (blockage of bile ducts)

RENEWAL CRITERIA

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:

A. You have primary biliary cholangitis (type of liver disease)
B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) are less than 1.67-times the upper limit of normal or have decreased by at least 15% from baseline while on treatment with obeticholic acid
C. You have not developed complete biliary obstruction (blockage of bile ducts)

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OCTREOTIDE - ORAL

Generic	Brand				
OCTREOTIDE	MYCAPSSA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
B. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
C. You have responded to and are currently stable on an injectable somatostatin analog therapy (such as octreotide, lanreotide, or pasireotide)

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE (Mycapssa)** requires the following rule(s) be met for renewal:

A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
B. You have had reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
C. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

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Commercial Effective: 09/07/20

OCTREOTIDE - SQ

Generic	Brand				
OCTREOTIDE ACETATE	BYNFEZIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   a. You are 18 years of age or older
   b. You had an inadequate response to or cannot be treated with **ALL** of the following:
      i. Surgical resection (removal by surgery)
      ii. Pituitary irradiation (radiation therapy directed at the pituitary)
      iii. Bromocriptine mesylate at maximally tolerated doses

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:**
   a. You are 18 years of age or older

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas), approval also requires:**
   a. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. You have had improvement or sustained remission of your symptoms

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OFATUMUMAB-SQ

Generic	Brand				
OFATUMUMAB	KESIMPTA				

GUIDELINES FOR USE

Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 01/01/21

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OLAPARIB

Generic	Brand			
OLAPARIB	LYNPARZA			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Advanced ovarian cancer
   2. Recurrent or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal (abdomen) cancer
   3. HER2-negative (you do not have a certain gene mutation) metastatic breast cancer (breast cancer that has spread to other parts of the body)
   4. Metastatic pancreatic adenocarcinoma (cancer of the pancreas that has spread to other parts of the body)
   5. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have advanced ovarian cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as monotherapy (used alone for treatment)
   3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with at least three prior lines of chemotherapy (such as, paclitaxel, docetaxel, cisplatin, carboplatin)

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be started no later than 8 weeks after your most recent platinum-containing regimen
   3. You are in complete or partial response to your most recent platinum-based chemotherapy
   4. You have completed at least two or more lines of platinum-based chemotherapy
   5. The requested medication will be used alone for maintenance treatment

(Criteria continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used for maintenance treatment
   3. You are in complete or partial response to first-line platinum-based chemotherapy
   4. You meet ONE of the following:
      a. You have a deleterious or suspected deleterious germline or somatic BRCA mutation (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
      b. Your cancer is homologous recombination deficiency (HRD: type of gene mutation) positive
         i. HRD status is defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
         ii. Lynparza will be used in combination with bevacizumab

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (disease that has spread to other parts of the body)
   4. If you have hormone receptor (HR)-positive breast cancer, you must have had prior treatment with endocrine (hormone) therapy or be considered inappropriate for endocrine therapy

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used for maintenance treatment
   3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

(Criteria continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

G. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
1. You are 18 years of age or older
2. You have a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation that causes a change in your DNA that make up your gene) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. Your disease has worsened following prior treatment with enzalutamide or abiraterone
4. You meet ONE of the following:
   a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
   b. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)
   c. Your blood testosterone levels are less than 50 ng/dL

Commercial Effective: 10/01/20

OMACETAXINE MEPESUCCINATE

Generic	Brand			
OMACETAXINE MEPESUCCINATE	SYNRIBO			

GUIDELINES FOR USE

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

A. You have chronic myeloid leukemia (CML: type of blood cell cancer)
B. **If the request is for induction therapy, approval also requires:**
   1. You have previously tried or have a contraindication (a medical reason why you cannot) to two of the following therapies: Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig
   2. You have received less than 6 fills of Synribo
C. **If the request is NOT for induction therapy, approval also requires:**
   1. You have achieved a hematologic response (your blood tests show you have improvement), defined as an absolute neutrophil count [ANC] greater than or equal to 1.5 x 10(9)/L, AND platelets greater than or equal to 100 x 10(9)/L, AND no blood blasts; OR bone marrow blasts less than 5 percent)

Commercial Effective: 07/01/20

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OMADACYCLINE

Generic	Brand			
OMADACYCLINE	NUZYRA			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Community-acquired bacterial pneumonia (CABP: type of lung infection)
   2. Acute (severe and sudden) bacterial skin or skin structure infection (ABSSSI)

B. **If you have community-acquired bacterial pneumonia, approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

(Criteria continued on next page)

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (*Includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of or contraindication to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

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OMBITASVIR/PARITAPREVIR/RITONAVIR

Generic	Brand			
OMBITASVIR/PARITAPREVIR/ RITONAVIR	TECHNIVIE			

GUIDELINES FOR USE

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR (Technivie)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 4 without cirrhosis (liver damage) or with compensated cirrhosis (you do not have symptoms related to liver damage; Child-Pugh A)
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. The requested medication will be used with ribavirin, unless you are treatment naïve without cirrhosis (you have never been previously treated and do not have liver damage) and you have an intolerance or contraindication to (medical reason why you cannot use) ribavirin
D. You are 18 years of age or older
E. You have previously failed a short trial of Harvoni or Epclusa or Mavyret. Reasons for failure may include adverse effect, intolerance to therapy, or contraindication to (medical reason why you cannot use) all 3 drugs (**NOTE:** If you completed a full course of therapy with Mavyret and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
F. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
G. You have evidence of current hepatitis C virus infection and chronic hepatitis C virus infection as documented by at least one detectable HCV RNA levels (amount of virus in your blood) within the past 6 months

A total of 12 weeks of therapy will be approved.

The medication will NOT be approved for the following:

A. You are using any of the following medications at the same time while on Technivie: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have moderate or severe liver impairment (Child Pugh B or Child Pugh C)
C. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

E. You have previously used (failed a full course of therapy) or are currently using any of the following regimens:
   1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
   2. A combination NS5B polymerase inhibitor/NS5A inhibitor (type of hepatitis C drug) including Harvoni (ledipasvir/sofosbuvir)
   3. Any HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)
   4. Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir) or Viekira XR

Commercial Effective: 07/01/20

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

Generic	Brand			
OMBITASVIR/PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA PAK			
OMBITASVIR/PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA XR			

GUIDELINES FOR USE

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR/ DASABUVIR (Viekira Pak or Viekira XR)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 1
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. You will be using ribavirin with the requested medication, unless you have genotype 1b
D. You are 18 years of age or older
E. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
F. You have previously failed a short trial with Epclusa, Harvoni or Mavyret. Reasons for failure include adverse effect early in therapy, intolerance to therapy, or if you have a medical reason why you cannot use (contraindication) all 3 drugs. (**NOTE:** If you completed a full course of therapy with Epclusa, Harvoni or Mavyret and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
G. You have documentation of a recent hepatitis C virus infection shown by at least one HCV RNA level (amount of virus in the blood) within the past 6 months

The medication will not be approved for the following patients:

A. You are using any of the following medications at the same time while on Viekira: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have decompensated cirrhosis (symptoms related to liver damage)
C. You have moderate liver impairment (Child Pugh B) or severe liver impairment (Child Pugh C)
D. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

E. You have a limited life expectancy (less than 12 months) due to other conditions not related to the liver
F. You have previously used/failed a full course of therapy, or currently using any of the following regimens:
   1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
   2. A combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
   3. A hepatitis C virus protease inhibitor (type of hepatitis drug) including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

A total of 12 weeks of therapy will be approved except 24 weeks of therapy for 1) genotype 1a with cirrhosis if patient is treatment experienced, previous null responder or 2) a liver transplant recipient.

Commercial Effective: 03/16/20

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OPICAPONE

Generic	Brand				
OPICAPONE	ONGENTYS				

GUIDELINES FOR USE

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

A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
B. You are 18 years of age or older
C. You are experiencing 'OFF' episodes (times when you have symptoms return due to medication wearing off)
D. You are currently being treated with carbidopa/levodopa
E. You have tried or failed or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
    1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
    2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
    3. Adenosine receptor antagonist A2A (such as istradefylline)
    4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

Commercial Effective: 01/01/21

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

Generic	Brand			
N/A	N/A	N		

GUIDELINES FOR USE

Our guideline named **OPIOID-ANTIPSYCHOTIC CONCURRENT USE** allows an approval for use of an opioid with an antipsychotic medication (type of mental health drug) together when one of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care or end-of-life care (care focused on treating symptoms of illness)
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that the use of an opioid and an antipsychotic medication together is intended and clinically appropriate for you

Commercial Effective: 07/01/20

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OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms (attests) to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication

Commercial Effective: 07/01/20

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OPIOID-BUPRENORPHINE CONCURRENT USE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility
E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

Commercial Effective: 07/01/20

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OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

A claim for a pain medication will be denied when there are two or more providers prescribing opioid agents for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You have active cancer
   2. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   3. You are enrolled in a hospice
   4. You are a resident of a long-term care facility
   5. You have sickle cell disease (type of blood disorder)

B. Your prescriber is aware that there is more than one provider prescribing opiates for you, and you meet **TWO** of the following:
   1. You have documentation showing your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do not have a history of substance abuse or addiction
   5. Your provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record.

This safety edit allows for an override for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine milligram equivalent (MME)) or hard-stop threshold (200 mg morphine milligram equivalent (MME)). Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

Commercial Effective: 07/01/20

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID LONG ACTING DUPLICATIVE THERAPY** allows approval of the requested drug taken together with other long-acting opioid drug(s) from different prescribers when ONE of the following conditions are met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that they are aware that you are concurrently receiving more than one long-acting opioid medication

Commercial Effective: 07/01/20

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OPIOID-NAIVE CUMULATIVE DOSING (ONCD)

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

The guideline named **OPIOID-NAIVE CUMULATIVE DOSING** allows approval of a higher quantity of an opioid medication if at least ONE of the following conditions is met:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care (care focused on treating symptoms of illness)
- Enrolled in hospice
- Resident of a long-term care facility
- Diagnosis of sickle cell disease (type of red blood cell disorder)
- You are not opioid naive

If none of these conditions apply, BOTH of the following criteria must be met:

- The provider has indicated that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

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Commercial Effective: 06/01/20

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OPIOID-NAIVE DAY SUPPLY LIMITATION

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for a longer day supply when you are opioid-naïve and meet at least **ONE** of the following conditions:

A. You have active cancer
B. You are enrolled in hospice
C. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
D. You are a resident of a long-term care facility
E. You have sickle cell disease (type of blood disorder)
F. You are NOT opioid naïve (you have been consistently using opioid pain medications)
G. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary

Commercial Effective: 07/01/20

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OPIOID NAIVE FILL LIMIT

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID NAIVE FILL LIMIT** allows an approval of the requested drug when it exceeds the fill limit for an initially opioid-naïve patient (those who have not used opioid drugs within the past 60 days) when ONE of the following conditions is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that the additional fill of the requested opioid analgesic (pain-relieving) medication is intended and clinically appropriate for you

Commercial Effective: 07/01/20

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Generic	Brand			
OPIOIDS	OPIOIDS			

GUIDELINES FOR USE

Our guideline named **OPIOID SINGLE CLAIM DOSING AT POS** allows for an override of an opioid product equal to or exceeding the soft-stop threshold (50 morphine milligram equivalent [MME]) at the pharmacy or by a prior authorization. The hard-stop threshold (90 MME) is not overridable and requires a prior authorization. An override will be provided if ONE (A or B) of the following rule(s) are met:

A. You meet ONE of the following conditions:
   1. You have active cancer
   2. You are receiving treatment for palliative care (treatment for comfort from symptoms)
   3. You have sickle cell disease (type of blood disorder)
   4. You are enrolled in a hospice
   5. Your doctor is a pain management specialist
B. Your physician confirms that the requested high dose is considered medically necessary.
   1. If the requested dose is lower than 300 MME, your prescriber must provide a maximum opioid threshold. If your prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding 90 MME, the claim will be approved up to 25 percent greater than the previously approved MME or up to 112.5 MME.
   2. If the requested dose is equal to or greater than 300 MME, approval will be granted if you are stable on the dose.

Commercial Effective: 07/01/20

OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility
E. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you

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Commercial Effective: 07/01/20

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OSILODROSTAT

Generic	Brand				
OSILODROSTAT	ISTURISA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
E. You previously had a trial of oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:

A. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
C. You continue to tolerate treatment with Isturisa

Commercial Effective: 10/01/20

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OSIMERTINIB

Generic	Brand			
OSIMERTINIB MESYLATE	TAGRISSO			

GUIDELINES FOR USE

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

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread throughout the body)
B. You meet ONE of the following:
   1. You are positive for an epidermal growth factor receptor (EGFR) T790M (type of gene) mutation as confirmed by a FDA (Food and Drug Administration)-approved test AND meet all of the following:
      a. You have progressed (your condition has worsened) while on or after EGFR tyrosine kinase-inhibitor therapy. Examples of EGFR tyrosine kinase-inhibitor therapy include Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
      b. You are not currently receiving therapy with an EGFR tyrosine kinase-inhibitor such as Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
   2. You are positive for epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (types of genes) mutations as confirmed by a FDA - approved test AND you have not received prior systemic treatment (therapy that travels through the blood) for metastatic non-small cell lung cancer

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OZANIMOD

Generic	Brand				
OZANIMOD	ZEPOSIA				

GUIDELINES FOR USE

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

A. You have a relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You had a previous trial of ONE sphingosine-1-phosphate receptor modulator (such as Gilenya or Mayzent) AND any ONE agent indicated for the treatment of multiple sclerosis (**Please note:** Other multiple sclerosis agents may also require prior authorization)

Commercial Effective: 06/15/20

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PALBOCICLIB

Generic	Brand			
PALBOCICLIB	IBRANCE			

GUIDELINES FOR USE

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

A. You have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (cancer that is in the advanced stage or that has spread to other parts of the body)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. The requested medication will be used with an aromatase inhibitor (type of cancer drug such as anastrozole, letrozole, or exemestane) AND you meet ALL of the following:
      i. You are a postmenopausal female OR a male
      ii. You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      iii. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancer by preventing the cancer cells from multiplying)
   2. The requested medication will be used in combination with Faslodex (fulvestrant) AND you meet ALL of the following:
      i. Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      ii. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancers by preventing the cancer cells from multiplying)

Commercial Effective: 07/01/20

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PANOBINOSTAT

Generic	Brand			
PANOBINOSTAT	FARYDAK			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have multiple myeloma (cancer that forms in a type of white blood cell)
B. You have been treated with at least 2 prior regimens including:
    1. Velcade (bortezomib)
    2. Immunomodulatory medication such as Thalomid, Revlimid, or Pomalyst. (These drugs adjust immune responses)
C. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone

RENEWAL CRITERIA

Our guideline named **PANOBINOSTAT (Farydak)** requires the following rule(s) be met for renewal:

A. You have tolerated the first 8 weeks of therapy without experiencing any severe or medically significant toxicity

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Commercial Effective: 07/01/20

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PARATHYROID HORMONE

Generic	Brand			
PARATHYROID HORMONE	NATPARA			

GUIDELINES FOR USE

Our guideline for **PARATHYROID HORMONE** requires the following rule(s) be met for approval:

A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
B. You have previously tried activated vitamin D (calcitriol) and calcium
C. Your hypoparathyroidism (low levels of a type of hormone) is not due to a calcium sensing receptor (CSR) mutation (changes in your DNA that make up your gene)
D. Your hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery in past 30 days)
E. Therapy is prescribed by or given in consultation with an endocrinologist (hormone specialist)

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PASIREOTIDE

Generic	Brand			
PASIREOTIDE	SIGNIFOR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. You have undergone pituitary (a major hormone gland) surgery OR pituitary surgery is not an option
E. You have previously tried oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for renewal:

A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
B. You continue to have improvement of Cushing’s disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
C. You continue to tolerate treatment with Signifor

Commercial Effective: 10/01/20

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PATIROMER

Generic	Brand			
PATIROMER CALCIUM SORBITEX	VELTASSA			

GUIDELINES FOR USE

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

A. You have hyperkalemia (high levels of potassium in blood)
B. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor) or cardiologist (heart doctor)
C. The requested medication is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
D. You are NOT currently receiving dialysis
E. You have tried ONE of the following to lower the risks for hyperkalemia:
    1. Limit to taking no more than one of the following drugs at any given time:
        i. Angiotensin converting enzyme inhibitor (ACE-I such as lisinopril, benazepril)
        ii. Angiotensin receptor blocker (ARB such as valsartan, losartan)
    2. Lowering the dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (such as ACE-I's, ARB's, aldosterone antagonists like spironolactone) has been considered
F. **If your estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2), approval also requires:**
    1. You have tried to treat hyperkalemia with loop diuretics such as bumetanide, ethacrynic acid, furosemide, torsemide
G. **If your estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m(2) or above approval also requires:**
    1. You have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide, OR a thiazide diuretic such as chlorthalidone, hydrochlorothiazide, metolazone
H. You have previously tried Lokelma (sodium zirconium cyclosilicate)

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PAZOPANIB

Generic	Brand			
PAZOPANIB	VOTRIENT			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Advanced soft tissue sarcoma (STS: cancer that starts in soft tissues like muscle, tendons, fat, lymph vessels, blood vessels, and nerves)

B. **If you have advanced soft tissue sarcoma (STS), approval also requires:**
   1. You had a trial of chemotherapy (cancer treatment such as anthracycline treatment), unless there is a medical reason why you cannot (contraindication)
   2. You do NOT have adipocytic soft tissue sarcoma (type of cancer in fat cells) or gastrointestinal stromal tumors (GIST: type of cancer that starts in a type of cell in the digestive system)

Commercial Effective: 07/01/20

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Generic	Brand			
SILDENAFIL	REVATIO			
TADALAFIL	ADCIRCA, ALYQ			

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group I: a way to classify the severity of disease)
B. The medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documentation showing you have pulmonary arterial hypertension based on the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
E. You are NOT concurrently or intermittently taking oral erectile dysfunction agents (such as Cialis, Viagra) or any organic nitrates in any form
F. You are NOT concurrently taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas)
G. In addition to the above requirements, the following criteria apply to the specific agents listed:
    1. Request for REVATIO (Sildenafil) ORAL SUSPENSION requires that you are unable to swallow pills and you have tried crushed sildenafil tablets

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RENEWAL CRITERIA

Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO) Group 1 (a way to classify the severity of disease)
B. You meet ONE of the following criteria:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have a stable 6-minute walk distance test with a stable or improved World Health Organization functional class

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PEANUT ALLERGEN POWDER-DNFP

Generic	Brand				
PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-DNFP	PALFORZIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:

A. You have a peanut allergy confirmed by ONE of the following:
   1. If you have undergone a purposeful food challenge: you have documentation of a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
   2. If you have NOT undergone a purposeful food challenge: you have documentation of a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
B. You are 4 to 17 years of age
C. Therapy is prescribed by given in consultation with an allergist/immunologist (allergy/immune system doctor)
D. You have a clinical history of allergic reaction to peanuts
E. The medication is to be used in conjunction with a peanut-avoidance diet
F. You are not currently on peanut-specific immunotherapy (such as Viaskin Peanut)

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PEANUT ALLERGEN POWDER-DNFP

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:

A. You have an allergy to peanuts
B. Therapy is prescribed by or given in consultation with an allergist/immunologist (allergy/immune system doctor)
C. Palforzia will be used together with a peanut-avoidance diet
D. You are not currently on peanut-specific immunotherapy (such as Viaskin Peanut)
E. You meet ONE of the following:
    1. You have a persistent peanut allergy (your peanut allergy has not gone away)
    2. If you have undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
    3. If you have NOT undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months

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PEG-INTERFERON ALFA-2B

Generic	Brand			
PEG-INTERFERON ALFA-2B	SYLATRON, SYLATRON 4-PACK			

GUIDELINES FOR USE

Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
   2. You have melanoma (skin cancer) with the presence of cancer cells in your lymph nodes (microscopic or gross nodal involvement), within 84 days of surgical removal of the cancer

Commercial Effective: 10/01/20

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PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

Generic	Brand			
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK			
PEGINTERFERON ALFA-2B	PEGINTRON			

GUIDELINES FOR USE

Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 (type of liver inflammation caused by hepatitis C virus). Requests for Pegasys will also be approved for a diagnosis of chronic hepatitis B

B. **If you have chronic hepatitis B (type of liver inflammation caused by hepatitis B virus), approval also requires:**
   1. You are 3 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specializing in disorders caused by viruses, bacteria, fungi and parasites), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   3. You do not have cirrhosis (liver damage)
   4. You have tested positive for HBeAg (hepatitis B e-antigen)
   5. You have evidence of viral replication (the virus has multiplied in your body) with high serum ALT (high amount of a type of liver enzymes)

C. **If you have chronic hepatitis C (type of liver inflammation caused by hepatitis C virus), approval also requires:**
   1. You are between 3 and 11 years old
   2. The medication is prescribed by or given in a consultation with a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specializing in disorders caused by viruses, bacteria, fungi and parasites), or a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor)
   3. You have other symptoms of hepatitis C (extrahepatic manifestations) such as cryoglobulinemia (abnormal proteins in the blood), rashes, and glomerulonephritis (inflammation in your kidneys) AND you have advanced fibrosis (scar tissue in the liver) that requires urgent treatment to lower your risks of getting worse or dying
   4. Peginterferon is being used with ribavirin, unless there is a medical reason why you cannot use ribavirin (contraindication)
   5. You have a detectable pretreatment HCV RNA level/viral load (amount of virus in your blood). The level varies by lab assay (test) but is a level typically greater than or equal to 25 IU/mL

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PEGVALIASE

Generic	Brand			
PEGVALIASE-PQPZ	PALYNZIQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for approval:

A. You have phenylketonuria (PKU) (a type of birth defect that causes buildup of a chemical called phenylalanine)
B. You are 18 years of age or older
C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
D. You have previously tried Kuvan (sapropterin)
E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

RENEWAL CRITERIA

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for renewal:

B. You have a diagnosis of phenylketonuria (PKU: type of birth defect that causes buildup of a chemical called phenylalanine)
C. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

Commercial Effective: 12/12/20

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PEMIGATINIB

Generic	Brand				
PEMIGATINIB	PEMAZYRE				

GUIDELINES FOR USE

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

A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have previously been treated
D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test

Commercial Effective: 10/01/20

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PENICILLAMINE

Generic	Brand			
PENICILLAMINE	CUPRIMINE			
PENICILLAMINE	DEPEN			
PENICILLAMINE	D-PENAMINE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:

A. You have a known family history of Wilson's disease (a genetic disorder in which copper builds up in the body) or physical examination consistent with Wilson's disease, cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)
B. **If you have Wilson's disease, approval also requires:**
    1. The drug is prescribed by or given in consultation with a hepatologist (a liver doctor); and
    2. You have maintained a low copper diet (less than 2mg copper per day); and
    3. If you are requesting Cuprimine, you must have tried to Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)
    4. You meet ONE of the following:
        a. You have blood levels of the copper-protein ceruloplasmin less than 20mg/dL; or
        b. Your liver biopsy (sample cells taken from your liver) shows you have an abnormally high amount of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (rings around the iris of your eye); or
        c. Your diagnosis has been confirmed by genetic testing for ATP7B (type of gene) mutations

(Initial criteria continued on next page)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you have cystinuria, approval also requires:**
   1. You have nephrolithiasis (kidney stones) and one (1) or more of the following:
      a. Kidney stone analysis shows that there is cystine (an amino acid);
      b. Urine analysis shows there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria with positive tests results in the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body);
   2. You have a daily cystine output greater than 300mg per 24 hours after a urine cystine excretion testing
   3. You have failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following, unless there is a medical reason why you cannot (contraindicated):
      a. Increased fluid intake
      b. Modest reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   4. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor)
   5. For Cuprimine requests, you must have a previous trial of Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin), unless there is a medical reason why you cannot (contraindication)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. The medication is prescribed by or given in consultation with a rheumatologist (joint disease doctor)
   2. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you must have tried Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)

E. **If you have an active prior authorization approval for Depen,** D-Penamine will be approved without meeting additional criteria during the period of Depen shortage.

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PENICILLAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of Wilson's disease (a genetic disorder in which copper builds up in the body), cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)
B. **If you have Wilson's disease, approval also requires:**
    1. You have achieved free serum copper of less than 10 mcg/dL
C. **If you have cystinuria, approval also requires:**
    1. You have achieved cystine excretion of less than 200 mg/day
D. **If you have active rheumatoid arthritis, approval also requires:**
    1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
    2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

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Commercial Effective: 07/01/20

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PENTOSAN POLYSULFATE

Generic	Brand				
PENTOSAN POLYSULFATE SODIUM	ELMIRON				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:

A. You have a diagnosis of interstitial cystitis/bladder (painful bladder condition) pain syndrome ongoing for at least six weeks

RENEWAL CRITERIA

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:

A. You have experienced clinical improvement from baseline secondary to treatment

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Commercial Effective: 04/01/20

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PEXIDARTINIB

Generic	Brand			
PEXIDARTINIB	TURALIO			

GUIDELINES FOR USE

Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:

A. You have symptomatic tenosynovial giant cell tumor (TGCT: type of non-cancerous growth in or around a joint causing tissue damage and reducing function)
B. TGCT is associated with severe morbidity (disease) or functional limitations
C. TGCT is NOT responsive to improvement with surgery
D. You are 18 years of age or older

Commercial Effective: 07/01/20

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PHENOXYBENZAMINE

Generic	Brand			
PHENOXYBENZAMINE	DIBENZYLINE			

GUIDELINES FOR USE

Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:

A. You have pheochromocytoma (tumor in your adrenal gland)
B. The requested drug is used to treat pheochromocytoma before pheochromocytoma surgery to remove the tumor
C. The requested drug is prescribed by an endocrinologist (hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist/oncologist (cancer doctor)
D. You must have tried an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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PIMAVANSERIN

Generic	Brand			
PIMAVANSERIN	NUPLAZID			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named drug named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:

A. You have a diagnosis of psychosis associated with Parkinson's disease (a mental disorder that causes you to have false beliefs or to hear or see things that are not really there and is related to a movement disorder)
B. You are at least 18 years old; and
C. The drug is prescribed by a doctor specializing in one of the following areas: neurology (brain doctor), geriatric medicine (specialty that focuses on health care of elderly people), or behavioral health (such as a psychiatrist).

RENEWAL CRITERIA

Our guideline named **PIMAVANSERIN (Nuplazid)** requires that you have experienced an improvement in psychosis symptoms (mental issues such as false beliefs or hearing or seeing things that are not really there) from baseline during the past 12 months of therapy and you show a continued need for treatment.

Commercial Effective: 07/01/20

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PIRFENIDONE

Generic	Brand			
PIRFENIDONE	ESBRIET			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (an inflammatory disease that affects multiple organs in the body, but mostly the lungs and lymph glands), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (condition that weakens your immune system), viral hepatitis (liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

RENEWAL CRITERIA

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:

A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

Commercial Effective: 01/01/21

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PITOLISANT

Generic	Brand			
PITOLISANT HCL	WAKIX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have one of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
   2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. You have narcolepsy that is confirmed by **ONE** of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
   3. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have cataplexy with narcolepsy, approval also requires:**
   1. Wakix is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

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PITOLISANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
   2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. You meet ONE of the following:
   1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
   2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline

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Commercial Effective: 11/09/20

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POMALIDOMIDE

Generic	Brand			
POMALIDOMIDE	POMALYST			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Multiple myeloma (MM: cancer that forms in your white blood cells)
   2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)

B. **If you have multiple myeloma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is used in combination with dexamethasone
   3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

C. **If you have Kaposi sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
      b. You are human immunodeficiency virus (HIV)-negative

Commercial Effective: 07/01/20

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PONATINIB

Generic	Brand			
PONATINIB HCL	ICLUSIG			

GUIDELINES FOR USE

Our guideline for the drug named **PONATINIB (Iclusig)** requires you to meet ONE of the below rules for approval:

A. A diagnosis of T315I-positive (a genetic mutation) chronic myeloid leukemia (CML; type of blood cell cancer that starts in bone marrow);
B. A diagnosis of T315I-positive Philadelphia chromosome positive (a genetic mutation) acute lymphoblastic leukemia (Ph+ ALL; a type of cancer of the blood and bone marrow that affects white blood cells);
C. A diagnosis of chronic myeloid leukemia (CML; type of blood cell cancer that starts in bone marrow) AND you have tried Gleevec, Sprycel, Tasigna, or Bosulif. Gleevec, Sprycel, Tasigna, or Bosulif which may also require prior authorization;
D. A diagnosis of Philadelphia chromosome positive (a genetic mutation) acute lymphoblastic leukemia (Ph+ ALL; a type of cancer of the blood and bone marrow that affects white blood cells) AND you have tried Gleevec, Sprycel, Tasigna, or Bosulif. Gleevec, Sprycel, Tasigna, or Bosulif which may also require prior authorization.

Commercial Effective: 07/01/20

PRALSETINIB

Generic	Brand				
PRALSETINIB	GAVRETO				

GUIDELINES FOR USE

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

E. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (MTC: thyroid cancer that started in the center of the thyroid and has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

F. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor that has been detected by an Food and Drug Administration (FDA)-approved test

G. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) mutant tumor
   3. You need systemic therapy (medicine that goes into the entire body)

H. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor
   3. You need systemic therapy (medicine that goes into the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is appropriate)

Commercial Effective: 01/01/21

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PREDNISONE DELAYED-RELEASE TABS

Generic	Brand			
PREDNISONE	RAYOS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for approval:

A. The request is for a Food and Drug Administration-approved indication
B. You had a previous trial of **ONE** of the following, unless there is a medical reason why you cannot (contraindication): generic prednisone, prednisolone, or methylprednisolone
C. You have had a subclinical response (not a full response) or treatment failure of generic prednisone, prednisolone, or methylprednisolone

RENEWAL CRITERIA

Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for renewal approval:

A. The request is for a Food and Drug Administration-approved indication
B. You have had a clinical benefit from using Rayos (such as improvement in inflammatory condition from baseline)
C. You cannot be tapered off (slowly lowering the dose to stop use) corticosteroid (Rayos)

Commercial Effective: 07/01/20

PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE

Generic	Brand				
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA				
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY				
TENOFOVIR DISOPROXIL FUMARATE	VIREAD				
EMTRICITABINE	EMTRIVA				

GUIDELINES FOR USE

Our guideline named **PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE** requires the following rule(s) be met for approval:

A. The requested pre-exposure prophylaxis (PrEP) medication is FDA (Food and Drug Administration) approved for PrEP or recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines
B. If the request is for a single-source brand (no generic available) PrEP medication that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:
    1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)
C. Your doctor has provided documentation supporting ONE of the following:
    1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
    2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
    3. The requested medication is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)

Commercial Effective: 07/01/20

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PYRIMETHAMINE

Generic	Brand			
PYRIMETHAMINE	DARAPRIM			

GUIDELINES FOR USE

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

Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:

A. The request is ONE of the following:
   1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
   2. Chronic maintenance therapy for toxoplasmosis
   3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)

B. **If you are being treated for acute toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV)
   2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
   3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm(3)

E. **If you have congenital toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

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PYRIMETHAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:

A. The request is ONE of the following:
   1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
   2. Chronic maintenance therapy for toxoplasmosis
   3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)

B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
   1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm(3)
   3. You are currently taking ART (anti-retroviral therapy)

REGORAFENIB

Generic	Brand			
REGORAFENIB	STIVARGA			

GUIDELINES FOR USE

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

A. You have a diagnosis of metastatic colorectal cancer (colon cancer that has spread in the body), **OR** locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (type of growth in the digestive system tract, most commonly in the stomach or small intestine), OR hepatocellular carcinoma (type of liver cancer).
B. **If you have metastatic colorectal cancer (CRC), approval also requires:**
   1. If colorectal cancer is **wild type KRAS** (a type of unmutated gene), you must have tried an anti-EGFR therapy (treatment that stops a protein from helping cancer cells grow) such as Erbitux [cetuximab] or Vectibix [panitumumab], unless there is a medical reason why you cannot use these agents (contraindication).
   2. If colorectal cancer is **NOT wild type KRAS,** you must have tried **ALL** of the following preferred therapies unless there is a medical reason why you cannot (contraindication):
      a. An anti-VEGF therapy (group of medicines that reduce new blood vessel growth) such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept].
      b. A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine.
C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had a trial with Gleevec (imatinib) and Sutent (sunitinib) unless there is a medical reason why you cannot use these agents (contraindication).
D. **If you have hepatocellular carcinoma (HCC), approval also requires:**
   1. You had a previous treatment with Nexavar (sorafenib).

These prior therapies may be covered under the medical benefit and/or may require prior authorization.

Commercial Effective: 07/01/20

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RIBOCICLIB

Generic	Brand			
RIBOCICLIB SUCCINATE	KISQALI			
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI FEMARA CO-PACK			

GUIDELINES FOR USE

Our guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (cancer that has spread throughout the body and has a type of hormone with no gene mutation).
B. **For Kisqali-Femara Co-Pack, approval also requires:**
   a. You are female
   b. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   c. You have **NOT** experienced disease progression (worsening of disease) after previously using CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
   d. You meet **ONE** of the following:
      i. You are pre/perimenopausal
      ii. You are post-menopausal and had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)
C. **For Kisqali, approval also requires ONE of the following:**
   1. Kisqali will be used in combination with an aromatase inhibitor and you meet all of the following:
      a. You are female
      b. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      c. You have **NOT** experienced disease progression (worsening of disease) following prior CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
      d. You meet ONE of the following:
         i. You are pre/perimenopausal
         ii. You are post-menopausal and had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

(Criteria continued on next page)

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RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

2. Kisqali will be used in combination with Faslodex (fulvestrant) and you meet all of the following:
   a. You are female and post-menopausal
   b. You have **NOT** experienced disease progression (worsening of disease) following prior CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
   c. You meet **ONE** of the following:
      i. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      ii. You have experienced disease progression on endocrine therapy **AND** had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

Commercial Effective: 07/01/20

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RIFAXIMIN

Generic	Brand			
RIFAXIMIN	XIFAXAN			

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

XIFAXAN 550MG TABLETS

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses: reduction of risk of overt hepatic encephalopathy recurrence (loss of brain function when your liver cannot remove toxins from the blood) or irritable bowel syndrome with diarrhea (a condition of stomach pain with many periods of diarrhea)

B. **For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a hepatologist (doctor who specializes in treating the liver)
   3. You have previously tried lactulose or you are currently taking lactulose monotherapy (drug used alone for treatment)

C. **If you have irritable bowel syndrome with diarrhea, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have tried tricyclic anti-depressants (such as amitriptyline, nortriptyline, etc.) or dicyclomine, unless there is a medical reason why you cannot (contraindication)

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RIFAXIMIN

INITIAL CRITERIA (CONTINUED)

XIFAXAN 200MG TABLETS

Our guideline named **RIFAXIMIN (Xifaxan 200 mg tablets)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses: travelers' diarrhea, *Clostridium difficile* infection (a type of bacterial infection) or for the treatment of overt hepatic encephalopathy (loss of brain function when your liver cannot remove toxins from the blood)

B. **If you have traveler's diarrhea, approval also requires:**
   1. You are 12 years of age or older
   2. You have previously tried oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin, unless there is a medical reason why you cannot (contraindication)

C. **For the treatment of overt hepatic encephalopathy, approval also requires:**
   1. The requested medication will be used in combination with lactulose

D. **If you have *Clostridium difficile* infection, approval also requires:**
   1. You had at least one previous occurrence of *Clostridium difficile* infection
   2. The requested medication will be used in combination with vancomycin
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

RENEWAL CRITERIA

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses: Reduction of risk of overt hepatic encephalopathy recurrence (loss of brain function when your liver cannot remove toxins from the blood) or irritable bowel syndrome with diarrhea (a condition of stomach pain with many periods of diarrhea)

B. If you have irritable bowel syndrome with diarrhea, renewal also requires:
   1. At least 10 weeks have passed since your last treatment course of rifaximin
   2. You have experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   3. You have experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

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RILUZOLE SUSPENSION

Generic	Brand			
RILUZOLE	TIGLUTIK			

GUIDELINES FOR USE

Our guideline named **RILUZOLE SUSPENSION (Tiglutik)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
B. You are 18 years of age or older
C. You have tried riluzole tablets
D. You are unable to take riluzole tablet formulation

Commercial Effective: 07/01/20

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RIMEGEPANT

Generic	Brand				
RIMEGEPANT	NURTEC ODT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

A. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You had a trial of ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
    1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
    2. You have experienced clinical improvement as defined by ONE of the following:
        a. Ability to function normally within 2 hours of dose
        b. Headache pain disappears within 2 hours of dose
        c. Treatment works consistently in majority of migraine attacks

Commercial Effective: 01/01/21

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RIOCIGUAT

Generic	Brand			
RIOCIGUAT	ADEMPAS			

GUIDELINES FOR USE (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

INITIAL CRITERIA

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

A. You have a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension World Health Organization Group 4 (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) or a diagnosis of pulmonary arterial hypertension World Health Organization Group 1 (PAH: type of high blood pressure affecting lungs and arteries)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)
C. **If you have pulmonary arterial hypertension, approval also requires:**
    1. You have a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
        a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
        b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
        c. Pulmonary vascular resistance (PVR) greater than 3 Wood units
    2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
    3. You had a previous trial of a phosphodiesterase-5 inhibitor such as Revatio or Adcirca, unless there is a medical reason why you cannot (contraindication)
    4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)
D. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
    1. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
    2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
    3. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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RIOCIGUAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   i. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
   ii. Pulmonary arterial hypertension (PAH) (WHO Group 1)

B. You show improvement from baseline in the 6-minute walk distance **OR** have a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class.

Commercial Effective: 04/01/20

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RIPRETINIB

Generic	Brand				
RIPRETINIB	QINLOCK				

GUIDELINES FOR USE

Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:

A. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
B. You are 18 years of age or older
C. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

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Commercial Effective: 10/01/20

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RISANKIZUMAB-RZAA

Generic	Brand			
RISANKIZUMAB-RZAA	SKYRIZI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rules be met for approval:

A. You are 18 years of age or older
B. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have previously tried one or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

RENEWAL CRITERIA

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

Commercial Effective: 07/01/20

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RISDIPLAM

Generic	Brand				
RISDIPLAM	EVRYSDI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. **If you are presymptomatic (symptoms have not yet appeared), approval also requires:**
    1. There is documentation showing you have up to three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
E. **If you are symptomatic (symptoms have appeared), approval also requires:**
    1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
    2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
    3. If you previously had gene therapy, you had less than expected clinical benefit

RENEWAL CRITERIA

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

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RUCAPARIB

Generic	Brand			
RUCAPARIB	RUBRACA			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   5. Epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that affects the abdomen or a woman's sex organs)
   6. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer returns and affects the abdomen or a woman's sex organs)
   7. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic) confirmed by Food and Drug Administration (FDA)-approved test for Rubraca
   3. You have been treated with two or more chemotherapies such as paclitaxel, docetaxel, cisplatin, carboplatin

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in a complete or partial response to platinum based-chemotherapy
   3. The requested medication will be used for maintenance treatment

D. **If you have metastatic castration-resistant prostate cancer (mCRPC), approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic)
   3. You have been treated with androgen receptor-directed therapy AND a taxane-based chemotherapy
   4. You meet ONE of the following:
      i. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      ii. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)
      iii. Your blood testosterone level is less than 50 ng/dL

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RUXOLITINIB

Generic	Brand			
RUXOLITINIB PHOSPHATE	JAKAFI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera
   3. Steroid -refractory acute graft-versus-host disease
B. **If you have intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
   1. You are 18 years of age or older
C. **If you have polycythemia vera, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)
D. **If you have steroid -refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

RENEWAL CRITERIA

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for renewal:

A. You have intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
B. You have experienced or maintained symptom improvement [such as a 50 percent or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0], 50 percent or greater reduction in palpable spleen length, or spleen reduction of 35 percent or greater from baseline spleen volume after 6 months of therapy

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SACROSIDASE

Generic	Brand			
SACROSIDASE	SUCRAID			

GUIDELINES FOR USE

Our guideline named **SACROSIDASE (Sucraid)** requires a diagnosis of genetically determined sucrose deficiency (you have a genetic disorder that will not allow your body to process a type of sugar), or congenital sucrase-isomaltase deficiency (CSID: disorder that affects your ability to digest certain sugars due to absent or low levels of two digestive enzymes).

Commercial Effective: 07/01/20

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SAPROPTERIN DIHYDROCHLORIDE

Generic	Brand			
SAPROPTERIN DIHYDROCHLORIDE	KUVAN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SAPROPTERIN DIHYDROCHLORIDE (Kuvan)** requires the following rule(s) be met for approval:

A. You have hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You follow a phenylalanine-restricted diet

RENEWAL CRITERIA

Our guideline named **SAPROPTERIN DIHYDROCHLORIDE (Kuvan)** requires the following rule(s) be met for renewal:

A. You hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You experienced at least a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride)
C. You continue to follow a phenylalanine-restricted diet

Commercial Effective: 07/01/20

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SARGRAMOSTIM

Generic	Brand			
SARGRAMOSTIM	LEUKINE			

GUIDELINES FOR USE

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

A. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor), **OR** you meet **ONE** of the following:
   1. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer) and are using the requested medication to shorten time to neutrophil (a type of white blood cell) recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND you are 55 years of age or older
   2. You are undergoing autologous transplantation (your own blood-forming stem cells are collected) and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (to collect blood sample and separate white blood cells in a lab test) AND you are 18 years of age or older
   3. You have non-Hodgkin's lymphoma (NHL: type of cancer), acute lymphoblastic leukemia (ALL: type of white blood cell cancer) or Hodgkin's lymphoma (type of cancer) and are using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation (to help your blood and bone marrow recover) AND you are 2 years of age or older
   4. The requested medication is being used for the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors (to help your blood and bone marrow recover after using a lab test to match you to the correct donors) AND you are 2 years of age or older
   5. The requested medication is being used for the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND you are 2 years of age or older
   6. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase your survival

Commercial Effective: 07/01/20

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SARILUMAB

Generic	Brand			
SARILUMAB	KEVZARA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You are 18 years of age or older
B. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
C. The medication is prescribed by or given in consultation with a rheumatologist (joint inflammation doctor)
D. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease modifying antirheumatic drug, unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
E. You have previously tried the following unless there is a medical reason why you cannot (contraindication):
    a. Any TWO of the following preferred immunomodulators (class of drugs): Enbrel, Humira, Rinvoq, Xeljanz (immediate-release/extended-release) AND
    b. Actemra (Note: Approval for Actemra first requires trial of two of the above preferred immunomodulators)

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

RENEWAL CRITERIA

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Commercial Effective: 09/01/20

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SATRALIZUMAB-MWGE

Generic	Brand				
SATRALIZUMAB-MWGE	ENSPRYNG				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
E. You have at least ONE of the following core clinical characteristics:
    a. Optic neuritis (inflammation that damages an eye nerve)
    b. Acute myelitis (sudden and severe inflammation of the spinal cord)
    c. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    d. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    e. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. You will NOT use rituximab, inebilizumab, or eculizumab together with Enspryng

RENEWAL CRITERIA

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You had a reduction in relapse frequency from baseline

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SECUKINUMAB

Generic	Brand			
SECUKINUMAB	COSENTYX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age and older
   2. The requested medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

RENEWAL CRITERIA

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy.

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
   1. You have 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: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy.

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SELEXIPAG

Generic	Brand			
SELEXIPAG	UPTRAVI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. The medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into right side of heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) of 25 mmHg or greater
    2. Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms (a way to classify how limited you are during physical activity)

RENEWAL CRITERIA

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance
    2. You have a stable 6-minute walk distance from baseline AND your World Health Organization (WHO) functional class (way to classify how limited you are during physical activity) has remained stable or improved

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SELINEXOR

Generic	Brand			
SELINEXOR	XPOVIO			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Relapsed or refractory multiple myeloma (RRMM: cancer of a type of white blood cells called plasma cells, that has return or did not respond to treatment)
   2. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of cancer that starts in the immune system), including DLBCL arising from follicular lymphoma

B. You are 18 years of age or older

C. **If you have relapsed or refractory multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with dexamethasone
   2. You have received at least four prior therapies for the treatment of RRMM)
   3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
      i. Two proteasome inhibitors (such as bortezomib, carfilzomib)
      ii. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
      iii. One anti-CD38 monoclonal antibody (such as daratumumab)

D. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), approval also requires:**
   1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

Commercial Effective: 07/13/20

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SELPERCATINIB

Generic	Brand				
SELPERCATINIB	RETEVMO				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Metastatic (disease has spread to other parts of the body) *RET* (type of gene) fusion-positive non-small cell lung cancer (NSCLC: type of lung cancer)
   2. Advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC: type of thyroid cancer)
   3. Advanced or metastatic *RET* fusion-positive thyroid cancer

B. **If you have metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC), approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy (treatment that travels through the bloodstream to the entire body)

D. **If you have advanced or metastatic *RET* fusion-positive thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy
   3. You are radioactive iodine-refractory (your tumor is resistant to treatment with radioactive iodine), if radioactive iodine is appropriate

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Commercial Effective: 10/01/20

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SELUMETINIB

Generic	Brand				
SELUMETINIB	KOSELUGO				

GUIDELINES FOR USE

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

A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
B. You are 2 to 17 years of age
C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

Commercial Effective: 10/01/20

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SIMEPREVIR

Generic	Brand			
SIMEPREVIR	OLYSIO			

GUIDELINES FOR USE

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

A. You have chronic hepatitis C, genotype 1 (type of liver inflammation)
B. You are 18 years of age or older
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. You must have documentation of a recent hepatitis c virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the past 6 months
E. You will be using Olysio with Sovaldi taken at the same time
F. You have previously failed a short trial of Harvoni, Mavyret or Epclusa and stopped due to reasons such as adverse effect or intolerance early in therapy, unless there is a medical reason why you cannot (contraindication) take all 3 agents. The medication will not be approved for an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response)
G. You are treatment naïve (never previously treated) or treatment-experienced with prior treatment with peginterferon/ribavirin

Olysio will not be approved for the following patients:

A. You have failed a full course of treatment with 1) any HCV protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek] or boceprevir [Victrelis]) **OR** 2) a regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
B. You have compensated cirrhosis (no symptoms related to liver damage) or decompensated cirrhosis (you have symptoms related to liver damage)
C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
D. You are using Olysio with ribavirin and peginterferon alfa

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SIMEPREVIR

GUIDELINES FOR USE (CONTINUED)

E. You are taking any of the following medications that are not recommended for concurrent use with Olysio:
   - Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
   - Any cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost)
   - Delavirdine, etravirine, nevirapine, or efavirenz
   - Any HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

Commercial Effective: 07/01/20

SIMVASTATIN ORAL SUSPENSION

Generic	Brand			
SIMVASTATIN	FLOLIPID			

GUIDELINES FOR USE

Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:

A. You had a previous trial of simvastatin tablets, unless there is a medical reason why you cannot (contraindication)
B. Your prescriber provides documentation showing that you have dysphagia (general swallowing difficulties), difficulty swallowing tablets, or a feeding tube such as a G-tube or J-tube
C. Requests for zero dollar cost share also requires that you are between 40-75 years of age without a history of cardiovascular disease (relating to heart and blood vessels) and you have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
    1. Aspirin/dipyridamole (Aggrenox)
    2. Clopidogrel (Plavix)
    3. Dipyridamole
    4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
    5. Prasugrel (Effient)
    6. Praluent Pen
    7. Repatha
    8. Ticagrelor (Brilinta)
    9. Ticlopidine
    10. Vorapaxar sulfate (Zontivity)

Commercial Effective: 07/01/20

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SIPONIMOD

Generic	Brand			
SIPONIMOD	MAYZENT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have relapsing forms of multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

RENEWAL CRITERIA

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:

A. You have a relapsing form of multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. You meet ALL of the following:
    1. You have demonstrated a clinical benefit compared to pre-treatment baseline
    2. You do not have lymphopenia (low levels of a type of white blood cell)
C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

Commercial Effective: 07/01/20

SODIUM/CALCIUM/MAG/POT OXYBATE

Generic	Brand				
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   2. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

B. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

C. **If you have excessive daytime sleepiness (EDS) in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. You had a trial of ONE amphetamine derivative (such as amphetamine sulfate, methylphenidate, etc.) AND modafinil, armodafinil, solriamfetol or pitolisant - unless there is a medical reason why you cannot (contraindication)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

This medication will not be approved for patients currently being treated with sedative hypnotic agents (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant)).

RENEWAL CRITERIA

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal approval:

A. You have narcolepsy (uncontrollable daytime sleepiness)
B. You meet **ONE** of the following:
    1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
    2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

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Commercial Effective: 01/01/21

SODIUM OXYBATE

Generic	Brand			
SODIUM OXYBATE	XYREM			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:

D. You have ONE of the following diagnoses:
   1. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   2. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

E. **If you have cataplexy in narcolepsy, approval also requires:**
   4. You are 7 years of age or older
   5. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   6. You have tried **TWO** of the following: venlafaxine, fluoxetine, or a tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

F. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   6. You are 7 years of age or older
   7. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   8. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   9. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      C. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   10. You had a trial of ONE amphetamine derivative (such as amphetamine sulfate, methylphenidate) AND modafinil, armodafinil, solriamfetol or pitolisant, unless there is a medical reason why you cannot (contraindication)

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

This medication will not be approved for patients currently being treated with sedative hypnotic agents (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant)).

RENEWAL CRITERIA

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

C. You have narcolepsy (uncontrollable daytime sleepiness)
D. You meet **ONE** of the following:
   3. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   4. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

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Commercial Effective: 01/01/21

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SODIUM PHENYLBUTYRATE

Generic	Brand			
SODIUM PHENYLBUTYRATE	BUPHENYL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires the following rule(s) be met for approval:

A. You have urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. There is documentation confirming you have urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
C. Buphenyl will be used as adjunctive (add-on) therapy along with dietary protein restriction
D. Your condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone

RENEWAL CRITERIA

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced clinical benefit from baseline (such as you are having normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity).

Commercial Effective: 07/01/20

SOFOSBUVIR

Generic	Brand			
SOFOSBUVIR	SOVALDI			

GUIDELINES FOR USE

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

A. You have chronic hepatitis C (long term type of liver inflammation)
B. You are 18 years of age or older with genotype 1 or 3, **OR** you are 3 to 17 years old with genotype 2 or 3
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is evidence showing you have current and chronic hepatitis c virus infection documented by one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
    2. You will be using Sovaldi with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
    3. You had a short trial of the preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (medical reason why you cannot use) to therapy with the preferred formulary agents as specified below. An individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved
        a. If you have genotype 1 infection, you had a short trial of Epclusa, Harvoni or Mavyret or you have a contraindication to all three agents
        b. If you have genotype 3 infection, you had a short trial of Epclusa or Mavyret or you have a contraindication to both agents
F. **If you are a pediatric patient (under age 18) approval also requires:**
    1. The request must meet the Food and Drug Administration (FDA)-approved indication [treatment naive (never previously treated) or treatment experienced patient with compensated cirrhosis (no symptoms related to liver damage) (Child-Pugh A) or without cirrhosis (liver scarring)]
    2. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following:

A. You have severe renal (kidney) impairment (Glomerular filtration rate less than 30 mL/min/1.73m2), end stage renal disease and/or those requiring dialysis
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (additional diseases)
C. You are an adult with compensated cirrhosis (no symptoms related to liver damage)
D. You are using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
E. You are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
F. You are an adult who is taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin

For requests for Sovaldi/Olysio regimen for genotype 1, the following must also be met:

A. You are 18 years of age or older
B. You do not have cirrhosis (liver scarring)
C. You have not previously failed a full course of therapy with 1) any hepatitis c virus protease inhibitor (type of Hep C drug such as Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir] **OR** 2) a regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
D. You will not be using the requested medication together with any of the following medications as they are contraindicated (there is a medical reason why you cannot use the drug) or not recommended by the manufacturer:
    1. Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
    2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
    3. A cobicistat-containing medication such as Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost
    4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

For patients using Sovaldi with Daklinza, the following must also be met:

A. You are 18 years of age or older
B. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
C. You will not be using the requested medication together with any of the following medications because they are contraindicated (medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
D. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (you have symptoms related to liver damage) or you are post-liver transplant

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Commercial Effective: 06/15/20

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SOFOSBUVIR/VELPATASVIR

Generic	Brand			
SOFOSBUVIR/VELPATASVIR	EPCLUSA			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6
B. You are 6 years of age or older OR weighs at least 17 kg
C. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires:**
    1. The requested medication will be used with ribavirin
F. **If you do not have cirrhosis (liver damage) or you have compensated cirrhosis (a condition where liver is extensively scarred, but you do not have symptoms of liver damage), approval also requires ONE of the following:**
    1. You are treatment naive (never previously treated)
    2. You are treatment experienced (have previously been treated) with peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio, Incivek or Victrelis with peginterferon/ribavirin)
    3. You have genotype 1b or genotype 2 infection AND you are treatment experienced with a Sovaldi (sofosbuvir)-containing regimen that does not include NS5A inhibitor (type of hepatitis drug) such as Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio
G. **If you have hepatitis C genotype 1 and are treatment-naive (never treated before) with a pretreatment HCV RNA level (amount of virus in your blood) of less than 6 million IU/mL, and do not have cirrhosis (liver scarring) or HIV (human immunodeficiency virus), and you are not of African descent, approval also requires:**
    1. You have tried Harvoni (8-week regimen) unless there is a medical reason why you cannot (contraindication)

Epclusa will not be approved in the following condition(s):

- You are using any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
- You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Commercial Effective: 05/11/20

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand			
SOFOSBUVIR/VELPATASVIR/ VOXILAPREVIR	VOSEVI			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You have a diagnosis of chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6 infection
C. Documentation of hepatitis C virus infection with at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (liver inflammation) such as a hepatologist, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. You have failed a full course of therapy with a DAA (direct-acting antiviral) regimen that includes NS5A inhibitor (class of hepatitis C drug such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) OR you have genotype 1a or genotype 3 and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (class of hepatitis C drug such as Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other hepatitis c virus protease inhibitor in combination with Sovaldi))

The medication will not be approved for the following:

A. You are concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
B. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
C. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (other diseases)

Commercial Effective: 04/01/20

Drugs listed in this document does not ensure coverage. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is intended for informational use only and is not intended to replace professional medical advice or treatment, or diagnose, treat, cure, or prevent any disease or medical condition. This document is subject to change.

SOLRIAMFETOL

Generic	Brand			
SOLRIAMFETOL	SUNOSI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
    1. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
        i. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
        ii. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** one (1) early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** one (1) SOREMP (within about 15 minutes) on a sleep study (polysomnography) the night before the MSLT, with the sleep study ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
        iii. You have low orexin levels on a cerebrospinal fluid (CSF) assay (a test to determine the amount of a type of chemical for wakefulness in your brain)
    2. You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
    3. Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
    4. ou have tried one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)

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SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

C. **If you have excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval also require:**
   1. Your diagnosis of OSA is confirmed by a sleep study (polysomnography), home sleep apnea testing devices, or hospital-based bedside monitoring
   2. You have had Excessive Daytime Sleepiness (EDS) for at least 3 months and your Epworth Sleepiness Scale (ESS) score is more than 10
   3. You have tried modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)
   4. You have been on a treatment for the obstructive causes of OSA, for at least one month since initiation, and you have been counseled on weight-loss intervention [if your BMI (Body Mass Index: a measure of body fat based on height and weight) is greater than 30]

RENEWAL CRITERIA

Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:

A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
B. You have sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

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Commercial Effective: 07/01/20

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SOMATROPIN

Generic	Brand			
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON, ZORBTIVE			

GUIDELINES FOR USE

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

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

SEROSTIM

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

A. You have HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
C. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), nutritional support specialist OR infectious disease specialist
D. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
E. You have had an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
F. You have had an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
G. Alternative causes of wasting have been ruled out. Alternative causes may include:
    1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    2. Diarrhea
    3. Inadequate energy (caloric) intake
    4. Malignancies (tumors)
    5. Opportunistic infections (an infection that can occur because of a weakened immune system)

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

H. You meet ONE of the following criteria for weight loss:
   1. 10% unintentional weight loss over 12 months
   2. 7.5% unintentional weight loss over 6 months
   3. 5% body cell mass (BCM) loss within 6 months
   4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
   5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
   6. BMI less than 18.5 kg per meter squared

I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
   1. You meet one of the following criteria for low testosterone:
      a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
      b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
      c. A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
   2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

ZORBTIVE

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

A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly)

B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes

C. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences

D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

GENOTROPIN

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

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)

B. **If you have pediatric growth hormone deficiency (GHD), approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

D. **If you have growth failure due to Prader-Willi syndrome (PWS), approval also requires:**
   1. You have a confirmed genetic diagnosis of Prader-Willi syndrome
   2. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   3. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)

E. **If you have growth failure and are a child born small for gestational age (SGA)**, **approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph of the wrist and hand
   4. You had no catch-up growth by age 2 years
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

HUMATROPE

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

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature or growth failure in short stature homebox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

D. **If you have short stature or growth failure in short stature homeobox-containing gene deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   5. You had no catch-up growth by age 2 to 4 years

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

NORDITROPIN FLEXPRO

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you are a child with short stature born small for gestational age, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You had no catch-up growth by age 2 to 4 years
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have confirmed genetic diagnosis of Prader-Willi syndrome
   2. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

NUTROPIN AQ NUSPIN

Our guideline named **SOMATROPIN (Nutropin AQ Nuspin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure secondary to chronic kidney disease (CKD)
   3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   4. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. If **you have pediatric growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least **ONE** of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have growth failure secondary to chronic kidney disease, approval also requires:**
   1. You have NOT undergone a renal (kidney) transplantation
   2. The medication is prescribed by or in consultation with a nephrologist (kidney specialist)
   3. Your height or growth velocity is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   4. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

D. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

OMNITROPE

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

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   3. Growth failure in children born small for gestational age (SGA)
   4. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (unknown cause of short height)

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least **ONE** of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have confirmed genetic diagnosis of Prader-Willi Syndrome
   3. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)

D. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You had no catch-up growth by age 2 years
   3. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

E. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

SAIZEN

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

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

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SOMATROPIN

INITIAL CRITERIA - SAIZEN (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least **ONE** of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

ZOMACTON

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

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature in children born small for gestational age (SGA)
   4. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   5. Adult growth hormone deficiency

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least **ONE** of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you are a child with short stature born small for gestational age**, **approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You had no catch-up growth by age 2 to 4 years
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

E. **If you have short stature or growth failure in children with SHOX deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease, surgery (disease of a small area of the brain important for hormone production and body processes), radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

RENEWAL CRITERIA

SEROSTIM

Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal:

A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
B. You have **NOT** received more than 24 weeks of therapy within the plan year
C. The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
D. You have shown clinical benefit in muscle mass and weight as indicated by at least a 10% increase in weight or BCM (body cell mass) from baseline (Note: current and baseline weight must be documented including dates of measurement)
E. You are on HIV anti-retroviral therapy

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SOMATROPIN

GUIDELINES FOR USE (CONTINUED)

ZORBTIVE

Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for renewal:

A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly)
B. You have not been on the requested medication for 4 weeks

GENOTROPIN

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

   This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)
B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height
C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

D. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement in body composition

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

HUMATROPE

Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature or growth failure in short stature homebox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature or growth failure in children with SHOX deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

NORDITROPIN FLEXPRO

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

E. **If you are a child with short stature born small for gestational age, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement in body composition

NUTROPIN AQ NUSPIN

Our guideline named **SOMATROPIN (Nutropin AQ Nuspin)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure secondary to chronic kidney disease (CKD)
   3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   4. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

C. **If you have growth failure secondary to chronic kidney disease, renewal also requires:**
   1. You have not had a renal (kidney) transplantation
   2. Your growth velocity is 2 cm or more compared with what was observed from the previous year or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

OMNITROPE

Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   3. Growth failure in children born small for gestational age (SGA)
   4. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

C. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. The mediation is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement in body composition

D. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have growth failure associated with Turner syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

SAIZEN

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal:

A. You have pediatric growth hormone deficiency (GHD) or adult growth hormone deficiency.

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - SAIZEN (CONTINUED)

C. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

ZOMACTON

Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature in children born small for gestational age (SGA)
   4. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature or growth failure in children with SHOX deficiency, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - ZOMACTON (CONTINUED)

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. The medication is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

Commercial Effective: 10/01/20

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SONIDEGIB

Generic	Brand			
SONIDEGIB	ODOMZO			

GUIDELINES FOR USE

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

A. You have a locally advanced basal cell carcinoma (BCC: type of skin cancer).
B. This is a recurrence (disease returns) of basal cell carcinoma (BCC: type of skin cancer) after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
C. Baseline serum creatine kinase (CK: type of protein that helps determine muscle damage) and serum creatinine levels have been obtained before starting therapy
D. If you are a females of reproductive potential, you must verify your pregnancy status before starting therapy

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Commercial Effective: 07/01/20

SORAFENIB

Generic	Brand			
SORAFENIB TOSYLATE	NEXAVAR			

GUIDELINES FOR USE

Our guideline for **SORAFENIB (Nexavar)** requires that you have ONE of the following diagnoses for approval:

A. Advanced renal cell carcinoma (RCC: type of kidney cancer)
B. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery))
C. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned, spread , is getting worse and is not responding to a type of treatment)

Commercial Effective: 07/01/20

STATIN ZERO COST SHARE OVERRIDE

Generic	Brand			
ROSUVASTATIN	CRESTOR, EZALLOR SPRINKLE			
PRAVASTATIN	PRAVACHOL			
SIMVASTATIN	ZOCOR			
ATORVASTATIN	LIPITOR			
LOVASTATIN, LOVASTATIN EXTENDED-RELEASE	ALTOPREV			
FLUVASTATIN, FLUVASTATIN EXTENDED-RELEASE	LESCOL, LESCOL XL			
PITAVASTATIN CALCIUM	LIVALO			
PITAVASTATIN MAGNESIUM	ZYPITAMAG			

GUIDELINES FOR USE

Our guideline named **STATIN ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

A. You are between 40 to 75 years of age without a history of cardiovascular disease (heart disease)
B. You have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
    1. Aspirin/dipyridamole (Aggrenox)
    2. Clopidogrel (Plavix)
    3. Dipyridamole
    4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
    5. Prasugrel (Effient)
    6. Praluent Pen
    7. Repatha
    8. Ticagrelor (Brilinta)
    9. Ticlopidine
    10. Vorapaxar sulfate (Zontivity)

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STATIN ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

C. **If the request is for a single-source brand (no generic available) statin that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:**
   1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)

D. Your doctor provided documentation that satisfies **ONE** of the following:
   4. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   5. You have tried or have a documented medical contraindication (medical reason why you cannot take medication) to two preferred medications (or a trial of one if only one agent is available)
   6. The requested medication is considered medically necessary for you, (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)

Commercial Effective: 06/08/20

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STIRIPENTOL

Generic	Brand			
STIRIPENTOL	DIACOMIT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
B. You are 2 years of age or older
C. You are currently being treated with clobazam (a type of seizure drug)
D. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
E. You had a trial of valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:

A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
B. You are currently being treated with clobazam (type of seizure drug)

Commercial Effective: 07/01/20

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SUNITINIB

Generic	Brand			
SUNITINIB MALATE	SUTENT			

GUIDELINES FOR USE

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

A. The requested medication is being used for one of the following:
1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
2. Gastrointestinal stromal tumor (GIST: type of growth in the digestive system)
3. Unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET: type of pancreas cancer)
4. Adjuvant (add-on) treatment of renal cell carcinoma.

B. **If you have gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You had a previous trial of imatinib mesylate (Gleevec), unless there is a medical reason why you cannot (contraindication)

C. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:**
   1. Your tumor is progressive (getting worse) and well-differentiated

D. **If you have adjuvant treatment of renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You are at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy (surgical removal of kidney)

Commercial Effective: 07/01/20

TADALAFIL

Generic	Brand			
TADALAFIL	CIALIS			

GUIDELINES FOR USE

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

A. You have benign prostatic hyperplasia (BPH: your prostate is too big causing difficulty urinating) OR erectile dysfunction (difficulty getting/keeping an erection)
B. **If you have benign prostatic hyperplasia (BPH), approval also requires:**
   1. You previously tried at least two preferred formulary alternatives, including one medication from each of the following classes:
      a. 5-alpha-reductase inhibitors: (such as finasteride or dutasteride)
      b. Alpha blockers: (such as doxazosin, terazosin, tamsulosin, or alfuzosin)
C. **If you have erectile dysfunction, approval also requires**:
   1. You have previously tried generic sildenafil (Viagra)

Commercial Effective: 09/07/20

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TAFAMIDIS

Generic	Brand			
TAFAMIDIS MEGLUMINE	VYNDAQEL			
TAFAMIDIS	VYNDAMAX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein) which is confirmed by ONE of the following:
   1. Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mtcpyp/DPD (a type of test that shows your heart absorbs a chemical for imaging)(Note: Strongly positive defined as heart to contralateral lung [H/CI] ratio of at least 1.5 or grade 2 or greater localization to the heart using the Perugini grade 1-3 scoring system
   2. Biopsy of tissue of affected organ(s) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist
D. You have New York Heart Association (NYHA) class I, II or III heart failure (classification of heart failure symptoms)

RENEWAL CRITERIA

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You have not progressed to (gotten worse to) New York Heart Association (NYHA) Class IV heart failure (classification of heart failure symptoms)

Commercial Effective: 07/01/20

TALAZOPARIB TOSYLATE

Generic	Brand			
TALAZOPARIB TOSYLATE	TALZENNA			

GUIDELINES FOR USE

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

A. You have human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (disease that is advanced or has spread throughout the body and does not have a type of protein)
B. You are 18 years of age or older
C. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an Food and Drug Administration-approved test
D. You have been treated with chemotherapy in the neoadjuvant (before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
E. **If you have hormone receptor (HR)-positive breast cancer, approval also requires:**
    1. You have previously had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

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Commercial Effective: 07/01/20

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TASIMELTEON

Generic	Brand			
TASIMELTEON	HETLIOZ, HETLIOZ LQ			

GUIDELINES FOR USE

Our guideline named **TASIMELTEON (Hetlioz)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD) (type of sleep disorder where your sleep time increasingly gets delayed)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (type of genetic disorder that causes sleeping problems)

B. **If you have non-24 hour sleep-wake disorder, approval also requires:**
   1. You are 18 years of age or older
   2. You are light-insensitive or have total blindness
   3. You have previously tried and failed maximally-tolerated melatonin therapy
   4. You are requesting Hetlioz capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz oral suspension if you are 3 to 15 years old
   3. You have previously tried and failed maximally-tolerated melatonin therapy

Commercial Effective: 01/01/21

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TAVABOROLE

Generic	Brand			
TAVABOROLE	KERYDIN, TAVABOROLE			

GUIDELINES FOR USE

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

A. You have onychomycosis of the toenails (toenail fungus infection)
B. You have complicating factors such as diabetes, peripheral vascular disease (narrowed blood vessels cause low blood flow), a suppressed immune system, or pain surrounding the nail or soft tissue
C. You have previously tried the following agents, unless there is a medical reason why you cannot (contraindication):
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

Commercial Effective: 11/09/20

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TAZEMETOSTAT

Generic	Brand				
TAZEMETOSTAT	TAZVERIK				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Metastatic or locally advanced (cancer that has spread to other parts of the body or has grown outside the organ it started in, but has not yet spread to distant parts of the body) epithelioid sarcoma (rare type of soft tissue cancer)
   2. Relapsed or refractory follicular lymphoma (cancer of the white blood cells that has returned or is resistant to previous treatment)

B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
   1. You are 16 years of age or older
   2. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years or older
   2. You meet ONE of the following:
      a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (medication/treatment that spreads throughout your body)
      b. You have no satisfactory alternative treatment options

Commercial Effective: 07/13/20

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TEDUGLUTIDE

Generic	Brand			
TEDUGLUTIDE	GATTEX			

GUIDELINES FOR USE

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

A. You have short bowel syndrome (SBS; your body is unable to absorb nutrients from the foods you eat due to a lack of a functional small intestine)
B. You are 1 year of age or older
C. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

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Commercial Effective: 07/01/20

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TELOTRISTAT

Generic	Brand			
TELOTRISTAT	XERMELO			

GUIDELINES FOR USE

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

A. You have carcinoid syndrome diarrhea (diarrhea caused by a type of tumor affecting nerves/hormones)
B. The medication will be used in combination with a somatostatin analog such as octreotide
C. You are 18 years of age or older
D. The medication is being prescribed by or given in consultation with an oncologist (cancer/tumor doctor) or gastroenterologist (digestive system doctor)
E. There is documentation showing that you have been receiving a stable dose of long-acting somatostatin analog therapy such as Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) for a minimum of 3 months – unless there is a medical reason why you cannot (contraindication)
F. You have diarrhea that is inadequately controlled as defined by the presence of at least four bowel movements per day

Commercial Effective: 07/01/20

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TEMOZOLOMIDE - PO

Generic	Brand			
TEMOZOLOMIDE - PO	TEMODAR - PO			

GUIDELINES FOR USE

Our guideline named **TEMOZOLOMIDE (Temodar) - PO** requires you have one of the following diagnoses for approval:

A. Metastatic melanoma (type of skin cancer)
B. Anaplastic astrocytoma (type of brain tumor)
C. Glioblastoma multiforme (type of tumor affecting brain or spine)
D. Small cell lung cancer (SCLC)

Commercial Effective: 07/01/20

TERIFLUNOMIDE

Generic	Brand			
TERIFLUNOMIDE	AUBAGIO			

GUIDELINES FOR USE

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

A. You have a diagnosis of a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 04/01/20

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TERIPARATIDE

Generic	Brand			
TERIPARATIDE	FORTEO			

GUIDELINES FOR USE

Our guideline named **TERIPARATIDE (Forteo, Teriparatide)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Postmenopausal osteoporosis (weak and brittle bones)
   2. Primary or hypogonadal (sex organs don't function properly) osteoporosis in a male patient
   3. Glucocorticoid (steroid)-induced osteoporosis

B. You have not received a total of 24 months or more cumulative treatment with any parathyroid hormone therapy (Forteo, Tymlos, Teriparatide)

C. You meet ONE of the following:
   1. You are at high risk for fractures defined as ONE of the following:
      a. History of osteoporotic (i.e., fragility, low trauma) fracture(s)
      b. 2 or more risk factors for fracture (such as 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 GnRH analogs such as nafarelin, etc.)
      c. No prior treatment for osteoporosis AND FRAX (test for your risk of fractures) score at least 20% for any major fracture OR at least 3% for hip fracture
   2. You are unable to use oral therapy due to reasons such as 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
   3. You had an adequate trial of or intolerance to bisphosphonates (such as alendronate, risedronate, ibandronate), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 04/13/20

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TESAMORELIN

Generic	Brand			
TESAMORELIN	EGRIFTA			

GUIDELINES FOR USE

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

A. The medication is being used for the reduction of excess abdominal fat in HIV (human immunodeficiency virus)-infected patients who have lipodystrophy syndrome (abnormal distribution of fat in the body)
B. You must be receiving treatment with a protease inhibitor (PI), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), or an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir).

Commercial Effective: 07/01/20

TESTOSTERONE

Generic	Brand			
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO			
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE			
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED			
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST			
TESTOSTERONE UNDECANOATE	JATENZO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological disorder (not due to disease)
   3. Gender dysphoria (you identify yourself as a member of the opposite sex)
   4. Female with metastatic breast cancer (cancer spreading to other areas of body)

B. **If you are a female with metastatic breast cancer or you are a male with delayed puberty not secondary to a pathological (extreme) disorder**, only intramuscular (injected into muscle) testosterone enanthate or methyltestosterone (Testred, Android, or Methitest) may be approved

C. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

(Initial criteria continued on next page)

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

D. **If you are a male with primary or secondary hypogonadism, approval requires ONE of the following:**
   1. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history OR
   2. You have ONE of the following lab values showing you have low testosterone levels:
      i. At least two morning total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state (you have not eaten)
      ii. Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

E. **If the request is for Xyosted, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for testosterone replacement therapy

F. **If the request is for Jatenzo, approval also requires:**
   1. You are 18 years of age or older

G. **If the request is for Androderm, Fortesta, Natesto or Striant, approval also requires:**
   1. You had a trial of a generic lower cost agent (e.g. AndroGel 1%, AndroGel 1.62%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate), unless there is a medical reason why you cannot (contraindication)

H. **If the request is for Android, Methitest, or Testred, approval also requires:**
   1. You had a trial of **TWO** lower cost agents (e.g. AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular (injected into the muscle) testosterone enanthate, Androderm, AndroGel 1.62%, Fortesta, Natesto, Striant, Jatenzo), unless there is a medical reason why you cannot (contraindication)

I. **If you are a male patient requesting methyltestosterone (Testred, Android or Methitest) for delayed puberty not secondary to a pathological disorder, approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that Intramuscular testosterone enanthate requires a prior authorization

J. **If you are a female patient requesting methyltestosterone (Testred, Android or Methitest) for metastatic breast cancer, approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that intramuscular testosterone enanthate requires a prior authorization.

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TESTOSTERONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological (extreme) disorder (not due to disease)
   3. Female with metastatic breast cancer (cancer spreading to other areas of body)
   4. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

C. **If you are a male patient with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Documentation of normalized serum testosterone levels and hematocrit concentrations (type of blood test) compared to baseline

D. **If you are a male patient with delayed puberty not secondary to a pathological disorder, only the following medications will be approved:**
   1 Intramuscular testosterone enanthate, Testred, Android, Methitest

E. **If you are a female patient with metastatic breast cancer, only the following medications will be approved:**
   1. Intramuscular testosterone enanthate, Testred, Android, Methitest

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Commercial Effective: 01/01/21

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TETRABENAZINE

Generic	Brand			
TETRABENAZINE	XENAZINE			

GUIDELINES FOR USE

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

A. You have chorea (involuntary movements) associated with Huntington's disease (type of inherited disease that causes nerve cells in brain to break down over time)
B. The medication has been prescribed or given in consultation with a neurologist (nerve doctor)
C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
   1. You have been genotyped for CYP2D6 (type of enzyme) and you are identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

Commercial Effective: 07/01/20

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TEZACAFTOR/IVACAFTOR

Generic	Brand			
TEZACAFTOR/IVACAFTOR	SYMDEKO			

GUIDELINES FOR USE

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

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:

A. You are 6 years of age or older
B. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
C. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
D. You have documentation that you are either homozygous (you have 2 copies of the same gene) for the F508del-CFTR (Cystic fibrosis transmembrane conductance regulator) gene mutation; **OR** you have documentation that you have at least one of the following mutations in the CFTR gene:

2789+5G→A	*D110E*	*E56K*	*P67L*	*S945L*
3272-26A→G	*D110H*	*E831X*	*R1070W*	*S977F*
3849+10kbC→T	*D1152H*	*F1052V*	*R117C*	
711+3A→G	*D1270N*	*F1074L*	*R347H*	
A1067T	*D579G*	*K1060T*	*R352Q*	
A455E	*E193K*	*L206W*	*R74W*	

RENEWAL CRITERIA

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

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THALIDOMIDE

Generic	Brand			
THALIDOMIDE	THALOMID			

GUIDELINES FOR USE

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

A. You have one of the following diagnoses:
   1. Multiple myeloma (plasma cell cancer)
   2. Erythema nodosum leprosum (ENL: type of inflammatory disease that causes skin lesions and nerve damage)
   3. Anemia due to myelodysplastic syndrome (group of disorders that disrupts red blood cell production) that has been previously treated
   4. Waldenström's Macroglobulinemia (type of cancer that affects immune system)

B. **If you have multiple myeloma, approval also requires:**
   1. Thalomid must be used in combination with dexamethasone or prednisone.

Commercial Effective: 07/01/20

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TOBRAMYCIN INHALED

Generic	Brand			
TOBRAMYCIN	BETHKIS, TOBRAMYCIN			
TOBRAMYCIN IN 0.225% NACL	TOBI			
TOBRAMYCIN	TOBI PODHALER			
TOBRAMYCIN/NEBULIZER	KITABIS PAK			

GUIDELINES FOR USE

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. You have a lung infection with a gram-negative species (type of bacteria that does not stain a purple color)

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

Commercial Effective: 10/01/20

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TOCILIZUMAB - SQ

Generic	Brand			
TOCILIZUMAB - SQ	ACTEMRA - SQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   4. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

C. **If you have giant cell arteritis (GCA), approval also requires:**
   1. You are 18 years of age or older

D. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried BOTH of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Enbrel AND Humira

(Initial criteria continued on next page)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   4. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

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TOFACITINIB

Generic	Brand			
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the following tumor necrosis factor blocker (TNF), unless there is a medical reason why you cannot (contraindication): Humira

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TOFACITINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract

B. **If you have moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 04/01/20

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TOLVAPTAN

Generic	Brand			
TOLVAPTAN	JYNARQUE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a nephrologist (kidney specialist)
D. You have confirmed polycystic kidney status via CT or MRI imaging (type of lab imaging tests) AND one of the following:
    1. You have a genotype that causes of autosomal dominant polycystic kidney disease (inherited disorder in which clusters of cysts develop in the kidneys) OR
    2. You have a family history of confirmed polycystic kidney disease in one or both parents
E. You do not have End-Stage Renal Disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis
F. You are at high risk of rapidly progressing autosomal dominant polycystic kidney disease

RENEWAL CRITERIA

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:

A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
B. You have NOT progressed to end stage renal (kidney) disease (ESRD)

Commercial Effective: 06/08/20

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TOREMIFENE

Generic	Brand			
TOREMIFENE CITRATE	FARESTON			

GUIDELINES FOR USE

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

A. You have metastatic breast cancer (cancer has spread to other parts of body)
B. You are a postmenopausal female (already gone through menopause)
C. You have an estrogen-receptor positive or unknown tumor

Commercial Effective: 07/01/20

TRAMETINIB

Generic	Brand			
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST			

GUIDELINES FOR USE

Our guideline named **TRAMETINIB DIMETHYL SULFOXIDE (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be removed by surgery or has spread)
   2. Metastatic non-small cell lung cancer (NSCLC: lung cancer that has spread in body)
   3. Melanoma (skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: thyroid cancer that has spread in body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer)

C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene) as detected by an Food and Drug Administration -approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

TREPROSTINIL

Generic	Brand			
TREPROSTINIL SODIUM	REMODULIN			
TREPROSTINIL	TYVASO			
TREPROSTINIL	ORENITRAM			

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

REMODULIN

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

A. You have pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. **For continuation of current therapy**, you must have NYHA-WHO Functional Class II, III, or IV symptoms (a way to classify how limited you are during physical activity)
E. **For new start requests**, approval also requires **ONE** of the following:
    1. You have NYHA-WHO Functional Class III or IV symptoms
    2. You have NYHA-WHO Functional Class II symptoms **AND** had a previous trial of or a medical reason why you cannot use (contraindication to) a phosphodiesterase-5 inhibitor (such as Adcirca or Revatio) or an endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)

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TREPROSTINIL

INITIAL CRITERIA (CONTINUED)

TYVASO

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

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have NYHA-WHO Functional Class III or IV symptoms (a way to classify how limited you are during physical activity)

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TREPROSTINIL

INITIAL CRITERIA (CONTINUED)

ORENITRAM

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

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have NYHA-WHO Functional Class II, III or IV symptoms (a way to classify how limited you are during physical activity)
E. You do not have severe hepatic (liver) impairment
F. You meet **ONE** of the following:
    1. Your request is for continuation of current Orenitram therapy
    2. You have tried a preferred formulary phosphodiesterase-5 inhibitor (such as sildenafil [Revatio] or tadalafil [Adcirca]) **OR** an endothelin receptor antagonist (such as Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL (Remodulin, Tyvaso, Orenitram)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. You meet **ONE** of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable from baseline in the 6-minute walk distance test **AND** your World Health Organization (WHO) functional class (a way to classify how limited you are during physical activity) has improved or remained stable

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TRIENTINE

Generic	Brand			
TRIENTINE	SYPRINE, CLOVIQUE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRIENTINE (Syprine, Clovique)** requires the following rule(s) be met for approval:

A. You have a known family history of Wilson's disease (a genetic disorder that leads to copper accumulation in the organs) or physical examination consistent with Wilson's disease
B. You meet **ONE** of the following criteria:
    1. Your plasma copper-protein ceruloplasmin (amount of copper-carrying protein in your blood) in less than 20mg/dL
    2. You had a liver biopsy (sample) positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (brownish-yellow ring around the iris of the eye)
    3. Your diagnosis has been confirmed by genetic testing for ATP7B mutations (mutation in the Wilson disease protein)
C. You have maintained a reduced copper dietary intake (less than 2mg copper per day)
D. The medication is prescribed by or given in consultation with a hepatologist (a doctor who specialize in the liver, biliary tree, gallbladder, and the pancreas)
E. You have had a previous trial of or contraindication to (medical reason why you cannot take) Depen (penicillamine)

RENEWAL CRITERIA

Our guideline named **TRIENTINE (Syprine, Clovique)** requires the following rules be met for renewal:

A. You have Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
B. You have achieved a free serum copper (amount of copper in your blood) of less than 10 mcg/dL

Commercial Effective: 07/01/20

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TRIFLURIDINE/TIPIRACIL

Generic	Brand			
TRIFLURIDINE/TIPIRACIL	LONSURF			

GUIDELINES FOR USE

Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Metastatic (has spread in the body) colorectal cancer
   2. Metastatic gastric (stomach) or gastroesophageal junction adenocarcinoma (cancer of lower portion of the throat)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)
   2. If you are negative for the RAS (type of gene) mutation (you are RAS wild-type), you had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You had previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

Commercial Effective: 07/01/20

TRIHEPTANOIN

Generic	Brand				
TRIHEPTANOIN	DOJOLVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. Your diagnosis is confirmed by documentation of at least TWO of the following:
   1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
   2. Low enzyme activity in cultured fibroblasts
   3. One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
D. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive tract doctor) or physician specialist in medical genetics/inherited metabolic disorders
E. You have previously tried commercial MCT oil (a medical food product) unless there is a medical reason you are unable to (contraindication)

RENEWAL CRITERIA

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. You had a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

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Commercial Effective: 01/01/21

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T: SLIM/MINIMED INSULIN PUMPS

Generic	Brand				
SUBCUTANEOUS INSULIN PUMP	T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, MINIMED 670G, MINIMED 770G				

GUIDELINES FOR USE

Our guideline named **T: SLIM/MINIMED INSULIN PUMPS** requires the following rule(s) be met for approval:

A. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
B. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and require frequent self-adjustments of your insulin dose for the past 6 months
D. You require glucose self-testing of at least 4 times per day on average in the previous 2 months
E. You have not received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
G. **If you are requesting the T: Slim X2 OR T: Slim X2 with Basal-IQ, approval also requires:**
    1. You are 6 years of age or older
H. **If you are requesting the T: Slim X2 with Control-IQ, approval also requires:**
    1. You are 14 years of age or older
I. **If you are requesting the MiniMed 670G, approval also requires:**
    1. You are 7 years of age or older
J. **If you are requesting the MiniMed 770G, approval also requires:**
    1. You are 2 years of age or older

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TUCATINIB

Generic	Brand				
TUCATINIB	TUKYSA				

GUIDELINES FOR USE

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

A. You have advanced unresectable (cannot be removed with surgery) or metastatic (disease that has spread to other parts of the body) human epidermal growth factor receptor 2 (HER2: type of protein)-positive breast cancer
B. You are 18 years of age or older
C. You have previously received one or more anti-HER2-based treatment for metastatic disease (specifically either trastuzumab or trastuzumab with pertuzumab)
D. The requested medication will be used in combination with trastuzumab and capecitabine

Commercial Effective: 10/01/20

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UBROGEPANT

Generic	Brand			
UBROGEPANT	UBRELVY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

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

A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
    1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
    2. You have experienced clinical improvement as defined by ONE of the following:
        a. Ability to function normally within 2 hours of dose
        b. Headache pain disappears within 2 hours of dose
        c. Treatment works consistently in majority of migraine attacks

Commercial Effective: 01/01/21

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UPADACITINIB

Generic	Brand			
UPADACITINIB	RINVOQ ER			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You are 18 years of age or older
B. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
C. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You previously tried or have a contraindication (medical reason why you cannot) to at least 3 months of treatment with at least ONE of the following DMARDs (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 05/01/20

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URIDINE TRIACETATE

Generic	Brand			
URIDINE TRIACETATE	XURIDEN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:

A. You have hereditary orotic aciduria (HOA: genetic disease where you do not have a type of protein to make a chemical)
B. Your diagnosis is confirmed by ALL of the following:
   1. Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
   2. Elevated urinary orotic acid levels according to your age-specific reference range
C. Therapy is prescribed by or given in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)

RENEWAL CRITERIA

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:

A. Your age dependent hematologic parameters (blood lab tests) have stabilized or improved from baseline while on treatment with Xuriden (uridine triacetate).

Commercial Effective: 09/07/20

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USTEKINUMAB

Generic	Brand			
USTEKINUMAB	STELARA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe active Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. Your current weight has been documented

C. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) OR dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial criteria continued on next page)

CONTINUED ON NEXT PAGE

USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. Your current weight has been documented

E. **If you have moderate to severe active Ulcerative Colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. Your current weight has been documented

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract

B. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis (PsA), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
   2. Your current weight has been documented

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VALBENAZINE

Generic	Brand			
VALBENAZINE	INGREZZA			

GUIDELINES FOR USE

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

A. You have moderate to severe tardive dyskinesia (involuntary movements, usually due to certain drugs) and it has been present for at least 3 months
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), movement disorder specialist, or psychiatrist (mental health doctor)
D. You have a history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

Commercial Effective: 07/01/20

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VANDETANIB

Generic	Brand			
VANDETANIB	CAPRELSA			

GUIDELINES FOR USE

Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:

A. You are currently stable on the requested medication
B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery or has spread in body)

Commercial Effective: 07/01/20

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VEMURAFENIB

Generic	Brand			
VEMURAFENIB	ZELBORAF			

GUIDELINES FOR USE

Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:

A. You have unresectable or metastatic melanoma with a BRAF V600E mutation (you have skin cancer with a certain type of gene mutation and it cannot be removed with surgery or it has spread in the body) as detected by an Food and Drug Administration-approved test
B. You have Erdheim-Chester Disease with a BRAF V600 mutation (rare type of slow growing blood cancer that has a type of gene mutation)

Commercial Effective: 07/01/20

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VENETOCLAX

Generic	Brand			
VENETOCLAX	VENCLEXTA			

GUIDELINES FOR USE

Our guideline named **VENETOCLAX (Venclexta)** requires that the following rules are met for approval:

A. You have **ONE** of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer), small lymphocytic lymphoma (SLL: type of immune system cancer)
   2. Newly-diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many undeveloped white blood cells)

B. **If you have chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
   1. You are 18 years of age or older

C. **If you have newly-diagnosed acute myeloid leukemia (AML), approval also requires:**
   1. You are 75 years of age or older, **OR** you are 18 years of age or older with comorbidities (additional diseases) that preclude (prevent) the use of intensive induction chemotherapy
   2. The requested medication will be used in combination with azacitidine or decitabine or low-dose cytarabine

Commercial Effective: 07/01/20

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V-GO INSULIN DEVICES

Generic	Brand				
SUB-Q INSULIN DEVICE, 20 UNIT	V-GO 20				
SUB-Q INSULIN DEVICE, 30 UNIT	V-GO 30				
SUB-Q INSULIN DEVICE, 40 UNIT	V-GO 40				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
C. You follow a maintenance program of at least 3 injections of insulin per day
D. You have worked with your doctor to adjust your insulin dose for the past 6 months and still have not met your glucose (blood sugar) goals
E. You do not require regular adjustments to your basal rate during a 24-hour time period
F. You require bolus insulin dosing in increments of 2 units per bolus
G. You do not require a total daily insulin dose of more than 76 units
H. You meet ONE of the following criteria while on a multiple daily insulin injection regimen:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
I. You previously had a trial of the Omnipod or Omnipod Dash (type of insulin device)

RENEWAL CRITERIA

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for renewal:

A. You have shown a positive response to therapy AND are adherent to your doctor follow-up visits

VISMODEGIB

Generic	Brand			
VISMODEGIB	ERIVEDGE			

GUIDELINES FOR USE

Our guideline for **VISMODEGIB (Erivedge)** requires **ONE** of the following rule(s) be met for approval:

A. You have metastatic basal cell carcinoma.
B. You have locally advanced basal cell carcinoma (type of skin cancers that have spread in the body or is advanced but has not spread) that has returned after surgery or you are not a candidate for surgery or radiation.

Commercial Effective: 07/01/20

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VOXELOTOR

Generic	Brand				
VOXELOTOR	OXBRYTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
B. You are 12 years of age or older
C. Your hemoglobin (a protein that carries oxygen in the blood) is less than 10.5 g/dL
D. The medication is prescribed by or given in consultation with a hematologist (a doctor who specializes in the study of blood, blood-forming organs and blood diseases)
E. You are having symptoms of anemia which are interfering with activities of daily living
F. You had a previous trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for renewal:

A. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
B. You have maintained an improvement in symptoms associated with anemia (condition where the blood doesn't have enough healthy red blood cells)

Commercial Effective: 04/01/20

ZANUBRUTINIB

Generic	Brand				
ZANUBRUTINIB	BRUKINSA				

GUIDELINES FOR USE

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

A. You have a diagnosis of mantle cell lymphoma (type of white blood cell cancer)
B. You are 18 years of age or older
C. You have previously received at least ONE prior therapy for mantle cell lymphoma

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Commercial Effective: 04/01/20

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