Standard Commercial
Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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.

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

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

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ABALOPARATIDE

Generic	Brand			
ABALOPARATIDE	TYMLOS			

GUIDELINES FOR USE

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

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

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

(Criteria continued on next page)

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

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

Commercial Effective: 04/17/23

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ABATACEPT - SQ

Generic	Brand			
ABATACEPT	ORENCIA, ORENCIA CLICKJECT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), 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 have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR (tofacitinib immediate-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Rinvoq (upadacitinib), Simlandi (adalimumab-ryvk)

D. **If you have psoriatic arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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ABATACEPT – SQ

INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
   b. You are 6 to 17 years of age AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Rinvoq (upadacitinib)
   c. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Taltz (ixekizumab), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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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ABATACEPT – SQ

RENEWAL CRITERIA

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

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

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR (tofacitinib immediate-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Rinvoq (upadacitinib), Simlandi (adalimumab-ryvk)

(Renewal criteria continued on next page)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
      b. You are 6 to 17 years of age AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Rinvoq (upadacitinib)
      c. You are 18 years of age or older AND have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Taltz (ixekizumab), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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Commercial Effective: 10/01/24

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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 ONE of the following diagnoses:
   1. Early breast cancer (initial stage of breast cancer)
   2. Advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body)

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

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

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ABROCITINIB

Generic	Brand				
ABROCITINIB	CIBINQO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have refractory, moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
E. You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
F. You have tried or have a contraindication to (harmful for you to use) THREE preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
G. You will NOT use Cibinqo concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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ABROCITINIB

RENEWAL CRITERIA

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

A. You have refractory, moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You have shown improvement while on Cibinqo
C. You have tried or have a contraindication to (harmful for you to use) THREE preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
D. You will NOT use Cibinqo concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication(condition where your immune system attacks your own body)

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Commercial Effective: 10/01/24

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ACALABRUTINIB

Generic	Brand				
ACALABRUTINIB	CALQUENCE				
ACALABRUTINIB MALEATE	CALQUENCE				

GUIDELINES FOR USE

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

You have ONE of the following:

- Mantle cell lymphoma (MCL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Small lymphocytic lymphoma (SLL: a type of blood cancer)

If you have mantle cell lymphoma, approval also requires:

- You are 18 years of age or older
- You have received at least one prior therapy for mantle cell lymphoma (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:

- You are 18 years of age or older

Commercial Effective: 01/01/24

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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

ACNE AGE RESTRICTION OVERRIDE

Generic	Brand				
ADAPALENE	DIFFERIN				
TAZAROTENE	TAZAROTENE, TAZORAC				
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP, TRETINOIN MICROSPHERES				
TRIFAROTENE	AKLIEF				

GUIDELINES FOR USE

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

The request is for a non-cosmetic (not for appearance) diagnosis (such as melasma, photoaging, wrinkles)

You had a trial of TWO low cost generic medications (such as Adapalene lotion, cream or gel, Tretinoin cream or gel, Adapalene/Benzoyl Peroxide gel)

Commercial Effective: 01/01/24

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ADAGRASIB

Generic	Brand				
ADAGRASIB	KRAZATI				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   2. Locally advanced or metastatic colorectal cancer (CRC: a type of digestive tract cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)

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

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

Commercial Effective: 08/01/24

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ADALIMUMAB

Generic	Brand			
ADALIMUMAB	HUMIRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

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INITIAL CRITERIA (CONTINUED)

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

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Humira together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)

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ADALIMUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing, at least a 3-month trial of Humira 40mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

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

F. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Humira concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Humira together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **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:
      a. You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
      c. Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

Commercial Effective: 08/01/24

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ADALIMUMAB-ADAZ

Generic	Brand				
ADALIMUMAB-ADAZ	HYRIMOZ, ADALIMUMAB-ADAZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB-ADAZ (Hyrimoz)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

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INITIAL CRITERIA (CONTINUED)

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

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Hyrimoz together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Hyrimoz 40mg weekly dosing OR Hyrimoz 80mg every other week dosing, at least a 3-month trial of Hyrimoz 40mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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RENEWAL CRITERIA (CONTINUED)

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

F. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Hyrimoz concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement while on therapy
   2. You will NOT use Hyrimoz (adalimumab-adaz) together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

J. **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:
      a. You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
      c. Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

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Commercial Effective: 09/01/24

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ADALIMUMAB-ADBM

Generic	Brand				
ADALIMUMAB-ADBM	CYLTEZO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB-ADBM (Cyltezo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ADALIMUMAB-ADBM

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

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ADALIMUMAB-ADBM

INITIAL CRITERIA (CONTINUED)

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

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

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ADALIMUMAB-ADBM

INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Cyltezo together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)

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ADALIMUMAB-ADBM

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Cyltezo 40mg weekly dosing OR Cyltezo 80mg every other week dosing, at least a 3 month trial of Cyltezo 40mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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RENEWAL CRITERIA (CONTINUED)

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

F. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Cyltezo concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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ADALIMUMAB-ADBM

RENEWAL CRITERIA (CONTINUED)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Cyltezo together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **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:
      a. You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
      c. Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

Commercial Effective: 09/01/24

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ADALIMUMAB-ATTO

Generic	Brand				
ADALIMUMAB-ATTO	AMJEVITA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB-ATTO (Amjevita)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

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INITIAL CRITERIA (CONTINUED)

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

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Amjevita together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)

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ADALIMUMAB-ATTO

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Amjevita 40mg weekly dosing OR Amjevita 80mg every other week dosing, at least a 3-month trial of Amjevita 40mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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RENEWAL CRITERIA (CONTINUED)

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

F. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Amjevita concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Amjevita together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

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ADALIMUMAB-ATTO

RENEWAL CRITERIA (CONTINUED)

J. **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:
      d. You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      e. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
      f. Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

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Commercial Effective: 09/01/24

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ADALIMUMAB-RYVK

Generic	Brand				
ADALIMUMAB-RYVK	SIMLANDI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate, posterior, and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

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

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Simlandi together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior, and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)

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ADALIMUMAB-RYVK

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate, posterior, and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Simlandi 40 mg weekly dosing OR Simlandi 80 mg every other week dosing, at least a 3-month trial of Simlandi 40 mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   3. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   4. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

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

F. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Simlandi concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Simlandi together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **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:
      a. You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
      c. Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

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ADAPALENE-BENZOYL-CLINDAMYCIN

Generic	Brand				
ADAPALENE/BENZOYL/ CLINDAMYCIN	CABTREO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for approval:
The request is NOT for a cosmetic (for appearance) diagnosis (such as melasma [freckle-like spots on your skin], photoaging [skin damage from the sun], wrinkles)
You have acne vulgaris (a type of skin condition usually called pimples)
You are 12 years of age or older
Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)
You have tried or have a contraindication to (harmful for you to use) ONE medication in each of the following categories:
Benzoyl peroxide product
Topical retinoid (such as adapalene, tretinoin)
Topical antibiotic (such as clindamycin, erythromycin)

RENEWAL CRITERIA

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

Commercial Effective: 01/01/24

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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 ONE of the following diagnoses:
   1. Metastatic squamous non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (a different type of lung cancer that has spread to other parts of the body)

B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
   1. Your disease has worsened after using platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumors have non-resistant epidermal growth factor receptor (EGFR: type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test
   2. You will NOT be using Gilotrif concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [Osimertinib], Iressa [gefitinib])

Commercial Effective: 07/01/22

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ALECTINIB

Generic	Brand			
ALECTINIB HCL	ALECENSA			

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   2. Non-small cell lung cancer (NSCLC: a type of lung cancer)

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

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

Commercial Effective: 05/17/24

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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. You are 12 to 65 years of age
C. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. 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
E. You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, impairment of school or work)
G. You have a current claim or prescription for 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: 06/01/23

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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

Commercial Effective: 05/01/20

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

RENEWAL CRITERIA

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

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

Commercial Effective: 06/01/21

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

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

Commercial Effective: 01/01/22

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ALPELISIB-PIQRAY

Generic	Brand				
ALPELISIB	PIQRAY				

GUIDELINES FOR USE

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

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

Commercial Effective: 02/12/24

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ALPELISIB - VIJOICE

Generic	Brand				
ALPELISIB	VIJOICE				

GUIDELINES FOR USE

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

A. You have PIK3CA-related overgrowth spectrum (PROS: group of disorders that cause overgrowth of parts of the body due to mutations in a type of gene)
B. You are 2 years of age or older
C. You have severe manifestations of PROS that require systemic therapy (treatment that targets the entire body)

Commercial Effective: 10/01/22

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

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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AMBRISENTAN

Generic	Brand				
AMBRISENTAN	LETAIRIS, AMBRISENTAN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Commercial Effective: 07/01/24

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AMIFAMPRIDINE

Generic	Brand			
AMIFAMPRIDINE	FIRDAPSE			
AMIFAMPRIDINE	RUZURGI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or hematologist-oncologist (a type of blood-cancer doctor)
C. Your diagnosis is confirmed by ALL of the following:
    1. Electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing
    2. Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes
D. **If you are requesting Firdapse, approval also requires:**
    1. You are 6 years of age or older

RENEWAL CRITERIA

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

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

Commercial Effective: 07/01/24

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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: a type of bacteria) lung disease with limited or no alternative treatment options
B. You are 18 years of age or older
C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
D. Arikayce will be used as part of a combination antibacterial drug regimen
E. Arikayce is being prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or infectious disease specialist physician

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

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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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AMPHETAMINE SULFATE ODT

Generic	Brand				
AMPHETAMINE SULFATE	EVEKEO ODT				

GUIDELINES FOR USE

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

A. You have attention deficit disorder with hyperactivity (ADHD: difficulty paying attention)
B. You are 6 to 17 years of age
C. You are unable to swallow amphetamine sulfate tablets
D. You had a trial of TWO of the following immediate-release stimulant medications: methylphenidate, dexmethylphenidate, amphetamine, dextroamphetamine, dextroamphetamine-amphetamine

Commercial Effective: 04/01/23

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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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Commercial Effective: 07/01/20

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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 ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Cryopyrin-associated periodic syndromes (CAPS) including neonatal-onset multisystem inflammatory disease (NOMID) (types of immune system disorders)
   3. Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), 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 have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Initial criteria continued on next page)

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

C. **If you have cryopyrin-associated periodic syndromes including neonatal-onset multisystem inflammatory disease, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   2. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
   3. Kineret will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Ilaris [canakinumab])

D. **If you have deficiency of interleukin-1 receptor antagonist, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
   2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: nail shedding)
   3. Kineret will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Ilaris [canakinumab])

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

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

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ANAKINRA

RENEWAL CRITERIA

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

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

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
C. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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

Commercial Effective: 10/01/24

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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 (nmCRPC: prostate cancer that does not respond to hormone reduction therapy and has not spread to other parts of the body)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

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

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

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 (nmCRPC: prostate cancer that does not respond to hormone reduction therapy but has not spread)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread and responds to hormone therapy)

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

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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 (a type of movement disorder)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
C. The requested medication will be 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
D. Your doctor 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 (harmful for) to TWO Parkinson disease agents from two different classes: dopamine agonist (ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (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 (a type of movement disorder)
B. You have had improvement with motor fluctuations during OFF episodes with the use of Apokyn (such as improvement in speech, facial expression, tremor [shaking] at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

Commercial Effective: 04/01/22

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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

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:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Plaque psoriasis (PsO: a type of skin condition)
   3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for an autoimmune indication (condition where your immune system attacks your own body)

C. **If you have mild plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) one conventional (standard) systemic (treatment that targets the entire body) agent (such as methotrexate, acitretin, cyclosporine) OR one conventional topical agent (such as topical corticosteroids [such as betamethasone dipropionate, clobetasol propionate])
   3. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Otezla
      b. You have a static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) score of 2
      c. You have a Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) score of 2 to 9

(Initial criteria continued on next page)

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APREMILAST

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 to 17 years of age and weigh at least 20 kilograms (44 pounds), OR you are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor, or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Otezla
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, or genital area

E. **If you have Behcet'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. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more conservative treatments (such as colchicine, topical corticosteroid [such as triamcinolone], oral corticosteroid [such as prednisolone])

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APREMILAST

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Plaque psoriasis (PsO: a type of skin condition)
   3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for an autoimmune indication (condition where your immune system attacks your own body)

C. **If you have mild plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more OR a decrease in static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) by at least a 2-point reduction from baseline

D. **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 Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Otezla concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for an autoimmune indication (condition where your immune system attacks your own body)

E. **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)

Commercial Effective: 10/01/24

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APROCITENTAN

Generic	Brand				
APROCITENTAN	TRYVIO				

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hypertension (high blood pressure)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
D. Your blood pressure is NOT controlled on at least three anti-hypertensive medications (drugs used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine], a diuretic [such as hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
E. You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (high blood pressure that is caused by another medical condition) (except sleep apnea [a type of sleep condition with difficulty breathing])
F. You will use Tryvio concurrently (at the same time) with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
G. You have tried or have a contraindication to (harmful for you to use) a potent diuretic (chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

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APROCITENTAN

RENEWAL CRITERIA

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

A. You have hypertension (high blood pressure)
B. You continue to benefit from Tryvio
C. You will use Tryvio concurrently (at the same time) with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

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Commercial Effective: 09/23/24

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ARIMOCLOMOL

Generic	Brand				
ARIMOCLOMOL CITRATE	MIPLYFFA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)
D. Miplyffa will used in combination with miglustat (Zavesca)

RENEWAL CRITERIA

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

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You have shown improvement or a slowing of disease progression

Commercial Effective: 10/14/24

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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 ONE of the following diagnoses:
   a. Schizophrenia (a type of mental health disorder)
   b. Bipolar I disorder (a type of mood disorder)
   c. Major depressive disorder (MDD: a type of mental health disorder)

B. **If you have schizophrenia, approval also requires:**
   a. You are 18 years of age or older
   b. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   c. You have a medical necessity for medication ingestion tracking

C. **If you have major depressive disorder, approval also requires:**
   a. You are 18 years of age or older
   b. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   c. Abilify MyCite will be used as an adjunctive (add-on) treatment
   d. You have a medical necessity for medication ingestion tracking

D. **If you have bipolar I disorder, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   3. You have a medical necessity for medication ingestion tracking
   4. You meet ONE of the following:
      i. The request is for acute (short-term) treatment of manic and mixed episodes as monotherapy (used alone), OR as an adjunct (add-on) to lithium or valproate
      ii. The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

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ASCIMINIB

Generic	Brand				
ASCIMINIB HYDROCHLORIDE	SCEMBLIX				

GUIDELINES FOR USE

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

A. You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase (CP)
B. You are 18 years of age or older
C. You had a mutational analysis (a type of lab test) prior to the start of therapy AND Scemblix is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on the profile for the BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; abnormal change in a type of gene)
D. You meet ONE of the following:
    1. Your cancer has the T315I mutation (abnormal change in a type of gene)
    2. You have previously been treated with at least TWO tyrosine kinase inhibitors (TKIs) (such as Bosulif [bosutinib], Sprycel [dasatinib], Gleevec [imatinib], Tasigna [nilotinib])

Commercial Effective: 10/01/24

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ASPARAGINASE ERWINIA-RYWN

Generic	Brand				
ASPARAGINASE ERWINIA-RYWN	RYLAZE				

GUIDELINES FOR USE

Our guideline named **ASPARAGINASE ERWINIA-RYWN (Rylaze)** requires the following rule(s) be met for approval:

A. You have acute lymphoblastic leukemia (ALL: type of blood cancer) or lymphoblastic lymphoma (LBL: type of cancer affecting the immune system)
B. You are 1 month of age or older
C. You have developed hypersensitivity to E.coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)
D. Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

Commercial Effective: 01/01/22

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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: a type of genetic condition) or juvenile-onset hypophosphatasia (HPP).
B. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
C. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
D. **If you have perinatal/infantile-onset hypophosphatasia, approval also requires:**
    1. You were 6 months of age or younger at hypophosphatasia onset
    2. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing OR you meet at least TWO of the following criteria:
        a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
        b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
        c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
        d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
        e. Presence of two or more of the following:
            i. Rachitic chest deformity (chest bones are not normal)
            ii. Craniosynostosis (premature closure of skull bones)
            iii. Delay in skeletal growth resulting in delay of motor development
            iv. History of vitamin B6 dependent seizures
            v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
            vi. History or presence of fracture after birth not due to injury or delayed fracture healing

(Initial criteria continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

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

Strensiq will not be approved if you meet any of the following:
1. Your serum calcium or phosphate level is below the normal range
2. You have a treatable form of rickets (softening and weakening of bones in children, usually due to low vitamin D)

RENEWAL CRITERIA

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

A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.
B. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].

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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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ATOGEPANT

Generic	Brand				
ATOGEPANT	QULIPTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ATOGEPANT (Qulipta)** 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. Qulipta is prescribed for the preventive treatment of migraines
   3. You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   4. You have tried or have a contraindication (harmful for) to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine

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. Qulipta is prescribed for the preventive treatment of migraines
   3. You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   4. You have tried or have a contraindication (harmful for) to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine, Botox [Note: For Botox, previous trial of only **National Drug Code** (**NDC**) 00023-1145-01 or NDC 00023-3921-02 are allowable]

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ATOGEPANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

A. Qulipta is prescribed for the preventive treatment of migraines
B. You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
C. 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 Qulipta therapy
    2. You have experienced a reduction in migraine severity with Qulipta therapy
    3. You have experienced a reduction in migraine duration with Qulipta therapy

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Commercial Effective: 05/22/23

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ATORVASTATIN

Generic	Brand				
ATORVASTATIN CALCIUM	ATORVALIQ				

GUIDELINES FOR USE

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

A. The request is for ONE of the following:
   1. To reduce the risk of one of the following and you are 18 years of age or older:
      i. Myocardial infarction (MI: heart attack), stroke, revascularization procedures (restoring blood flow to heart and other areas), or angina (chest pain) and you have multiple risk factors for coronary heart disease (CHD: heart arteries get blocked with fats and plaques) but without clinically evident CHD
      ii. MI or stroke and you have type 2 diabetes mellitus (a disorder with high blood sugar) and multiple risk factors for CHD but without clinically evident CHD
      iii. Non-fatal (not deadly) MI, fatal (deadly) or non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (a type of heart failure), or angina and you have clinically evident CHD
   2. Primary hyperlipidemia (high level of fat in the blood due to genetic causes)
   3. Heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol)
   4. Homozygous familial hypercholesterolemia (HoFH: a type of inherited high cholesterol)
   5. Primary dysbetalipoproteinemia (a condition leading to increased total cholesterol and triglyceride levels in the blood)
   6. Hypertriglyceridemia (high level of fat in the blood)

B. You had a trial of or contraindication (harmful for) to generic atorvastatin tablets

C. You cannot swallow atorvastatin tablets AND had a trial of rosuvastatin (Ezallor) sprinkle capsule

D. **If you have primary hyperlipidemia, approval also requires:**
   1. You are 18 years of age or older
   2. Atorvaliq will be used in addition to diet

E. **If you have heterozygous familial hypercholesterolemia, approval also requires:**
   1. You are 10 years of age or older
   2. Atorvaliq will be used in addition to diet

F. **If you have homozygous familial hypercholesterolemia, approval also requires:**
   1. You are 10 years of age or older
   2. Atorvaliq will be used in addition to other LDL-C lowering therapies (such as ezetimibe, fenofibrate) OR will be used alone if other LDL-C lowering therapies are unavailable

(Criteria continued on next page)

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

G. **If you have dysbetalipoproteinemia or hypertriglyceridemia, approval also requires:**
   1. You are 18 years of age or older
   2. Atorvaliq will be used in addition to diet

H. 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: 12/01/23

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AVACOPAN

Generic	Brand				
AVACOPAN	TAVNEOS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA: condition that affects the blood vessels] or microscopic polyangiitis [MPA: condition that affects the blood vessels])
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
D. You are ANCA seropositive for anti-PR3 or anti-MPO (a type of lab test)
E. Tavneos will be used as adjunctive (add-on) therapy in combination with standard therapy including glucocorticoids (such as methylprednisolone, prednisone)

RENEWAL CRITERIA

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

A. You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA: condition that affects the blood vessels] or microscopic polyangiitis [MPA: condition that affects the blood vessels])
B. You continue to benefit from the medication

Commercial Effective: 10/24/22

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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 ONE of the following diagnoses:
   1. Unresectable or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that cannot be removed through surgery or has spread to other parts of the body)
   2. Advanced systemic mastocytosis (AdvSM: a type of blood disorder), including aggressive systemic mastocytosis (ASM: a type of blood disorder), systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood disorder), or mast cell leukemia (MCL: a type of blood cancer)
   3. Indolent systemic mastocytosis (ISM: a type of blood disorder)

B. **If you have unresectable or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You have a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations (a type of gene mutation)

C. **If you have advanced systemic mastocytosis, approval also requires:**
   1. You are 18 years of age or older

D. **If you have indolent systemic mastocytosis, approval also requires:**
   1. You are 18 years of age or older

Commercial Effective: 08/01/23

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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:
   1. Thrombocytopenia (a type of blood disorder) in chronic (long-term) liver disease
   2. Chronic immune thrombocytopenia (cITP: a type of blood disorder)

B. **If you have thrombocytopenia in chronic liver disease, approval also requires:**
   1. You are 18 years of age or older
   2. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   3. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L
   4. You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag])

C. **If you have chronic immune thrombocytopenia, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])
   4. You meet ONE of the following:
      a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      b. You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

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AVATROMBOPAG

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia in chronic liver disease, please refer to the Initial Criteria section.

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

A. You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Doptelet) OR a decrease in bleeding events
C. You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

Commercial Effective: 10/01/24

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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: 04/10/21

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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

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BACLOFEN

Generic	Brand				
BACLOFEN	OZOBAX, OZOBAX DS, BACLOFEN				
BACLOFEN	FLEQSUVY, BACLOFEN				
BACLOFEN	LYVISPAH				

GUIDELINES FOR USE

Our guideline named **BACLOFEN (Ozobax, Ozobax DS, Fleqsuvy, Lyvispah)** requires the following rule(s) be met for approval:

A. You have tried or have a contraindication (harmful for you to use) to generic baclofen tablets
B. You are unable to swallow generic baclofen tablets

Commercial Effective: 11/13/23

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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 ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Severe alopecia areata (a type of hair loss)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have severe alopecia areata, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have had at least 50 percent scalp hair loss as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool) for more than 6 months
   4. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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

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

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BARICITINIB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Severe alopecia areata (a type of hair loss)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have severe alopecia areata, renewal also requires:**
   1. You have experienced improvement while on therapy (such as scalp hair coverage)
   2. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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.

Commercial Effective: 10/01/24

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BEDAQUILINE FUMARATE

Generic	Brand			
BEDAQUILINE FUMARATE	SIRTURO			

GUIDELINES FOR USE

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

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

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

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

Commercial Effective: 12/01/21

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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 - SQ (Benlysta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Systemic lupus erythematosus (SLE: a type of immune condition)
   2. Lupus nephritis (LN: A type of immune condition that affects the kidneys)

B. **If you have systemic lupus erythematosus, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. **If you have lupus nephritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
   3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

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BELIMUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Systemic lupus erythematosus (SLE: a type of immune condition)
   2. Lupus nephritis (LN: a type of immune condition that affects the kidneys)

B. **If you have systemic lupus erythematosus, renewal also requires:**
   1. You have had clinical improvement while on Benlysta

C. **If you have lupus nephritis, renewal also requires:**
   1. You have had clinical improvement in renal (kidney) response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

Commercial Effective: 05/01/23

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BELUMOSUDIL

Generic	Brand				
BELUMOSUDIL MESYLATE	REZUROCK				

GUIDELINES FOR USE

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

A. You have chronic graft-versus-host-disease (cGVHD: a type of long-term immune disorder)
B. You are 12 years of age or older
C. You have failed at least TWO prior lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
D. You will NOT use Rezurock concurrently (at the same time) with Jakafi (ruxolitinib) or Imbruvica (ibrutinib)

Commercial Effective: 10/01/24

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BELZUTIFAN

Generic	Brand				
BELZUTIFAN	WELIREG				

GUIDELINES FOR USE

Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Von Hippel-Lindau (VHL) disease (genetic disorder that causes tumors to grow in the body)
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)

If you have von Hippel-Lindau disease, approval also requires:
- You are 18 years of age or older
- You require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
- You do NOT require immediate surgery

If you have advanced renal cell carcinoma, approval also requires:
- You are 18 years of age or older
- You were previously treated with a programmed death receptor-1 (PD-1) inhibitor (such as Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (such as Bavencio [avelumab])
- You were previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI: a type of treatment such as Nexavar [sorafenib])

Commercial Effective: 01/15/24

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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 ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

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 in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
   4. Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as formoterol, salmeterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline, or an oral corticosteroid [such as prednisone])
   5. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

(Initial criteria continued on next page)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
    1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
    2. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
    3. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
        i. Daytime asthma symptoms more than twice per week
        ii. Any night waking due to asthma
        iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        iv. Any activity limitation due to asthma

C. **If you have eosinophilic granulomatosis with polyangiitis, approval also requires:**
1. You are 18 years of age or older
2. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis

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BENRALIZUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)

B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      1. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Fasenra)
      2. You have decreased your use of rescue medications (such as albuterol)
      3. Your percent predicted FEV1 (a type of lung test) has increased from pre-treatment baseline (before starting Fasenra)
      4. You have experienced a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:**
   1. You have a reduction in eosinophilic granulomatosis with polyangiitis (EGPA) symptoms compared to baseline (before starting Fasenra), OR you have been able to decrease or eliminate (stop) corticosteroid (such as prednisone) use
   2. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of EGPA

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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: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Orladeyo will be used for the prevention of hereditary angioedema attacks
D. Your diagnosis is confirmed by complement testing (a type of blood test)
E. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
F. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol)

RENEWAL CRITERIA

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
C. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol)

Commercial Effective: 10/01/24

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BETAINE

Generic	Brand				
BETAINE	CYSTADANE, BETAINE ANHYDROUS				

GUIDELINES FOR USE

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

A. You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, and cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

Commercial Effective: 04/01/23

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BEXAROTENE

Generic	Brand				
BEXAROTENE SOFTGEL	TARGRETIN, BEXAROTENE				
BEXAROTENE 1% TOPICAL GEL	TARGRETIN, BEXAROTENE				

GUIDELINES FOR USE

TARGRETIN (BEXAROTENE) CAPSULE

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

A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer)
B. You are refractory (resistant) to at least one prior systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or bortezomib

TARGRETIN (BEXAROTENE) GEL

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

A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer) (stage IA or IB)
B. You meet ONE of the following:
   a. You have refractory (resistant) or persistent disease after other therapies
   b. You have not tolerated other therapies

Commercial Effective: 06/15/22

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BIMEKIZUMAB-BKZX

Generic	Brand				
BIMEKIZUMAB-BKZX	BIMZELX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You are a candidate for systemic therapy (treatment that targets the entire body) or phototherapy (light therapy)
E. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
F. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Sotyktu (deucravacitinib)
H. You meet ONE of the following:
    1. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
    2. You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
    3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
C. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Sotyktu (deucravacitinib)

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

Commercial Effective: 10/01/24

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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 ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

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

C. **If you have metastatic non-small cell lung cancer, approval also requires**:
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Mektovi will be used in combination with Braftovi (encorafenib)

Commercial Effective: 11/13/23

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BIRCH BARK EXTRACT

Generic	Brand				
BIRCH BARK EXTRACT	FILSUVEZ				

GUIDELINES FOR USE

Our guideline named **BIRCH BARK EXTRACT (Filsuvez)** requires the following rule(s) be met for approval:

A. You have epidermolysis bullosa (EB: a type of genetic skin disorder)
B. You are 6 months of age or older
C. Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa (types of genetic skin disorder)

Commercial Effective: 02/29/24

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BOSENTAN

Generic	Brand				
BOSENTAN	TRACLEER, BOSENTAN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 3 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
E. You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide
F. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide

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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:
   1. Chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML; a type of blood cancer)
   2. Accelerated phase (AP) or blast phase (BP) Philadelphia chromosome-positive chronic myelogenous leukemia

B. **If you have chronic phase Philadelphia chromosome-positive chronic myeloid leukemia, approval also requires:**
   1. You are 1 year of age or older
   2. You meet ONE of the following:
      a. You are newly diagnosed
      b. You had resistance or intolerance to prior therapy [such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)] AND you had a mutational analysis prior to initiation of therapy AND Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

C. If you have accelerated or blast phase Philadelphia chromosome-positive chronic myeloid leukemia, approval also requires:
   1. You are 18 years of age or older
   2. You had resistance or intolerance to prior therapy [such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   3. You had a mutational analysis prior to initiation of therapy
   4. Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

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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: 04/10/21

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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: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
F. You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Sotyktu (deucravacitinib)
H. You meet ONE of the following:
    1. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
    2. You have a contraindication or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
    3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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

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BRODALUMAB

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: a type of skin condition)
B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more
C. You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq
D. You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Sotyktu (deucravacitinib)

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Commercial Effective: 10/01/24

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BUDESONIDE-EOHILIA

Generic	Brand				
BUDESONIDE	EOHILIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have eosinophilic esophagitis (a type of immune system disorder)
B. You are 11 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or allergist (a type of allergy doctor)
D. You have at least 15 eosinophils/high powered field (a type of lab test) in the esophagus as confirmed by a biopsy (removal of cells or tissue from the body for examination)
E. You have tried or have a contraindication to (harmful for you to use) one inhaled corticosteroid (such as Flovent [fluticasone], Pulmicort [budesonide]) OR one proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

RENEWAL CRITERIA

Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for renewal:

A. You have eosinophilic esophagitis (EoE: a type of immune system disorder)
B. You meet ONE of the following:
    1. You have less than 15 eosinophils/high powered field (eos/hpf: a type of lab test) in the esophagus after treatment with Eohilia
    2. You have experienced an improvement in dysphagia (difficulty swallowing) compared to baseline

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Commercial Effective: 07/01/24

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BUDESONIDE - ORTIKOS

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 (a type of bowel disorder)
B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
   1. You are 8 years of age or older
   2. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product
C. **If you have mild to moderate Crohn's Disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
   3. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

Commercial Effective: 01/17/22

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BUDESONIDE - TARPEYO

Generic	Brand				
BUDESONIDE	TARPEYO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
D. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
E. You are currently on an angiotensin converting enzyme inhibitor (ACE-I: a type of drug used to protect kidneys such as benazepril, lisinopril, etc.) or an angiotensin receptor blocker (ARB: a type of drug used to protect kidneys such as losartan, valsartan, etc.) at maximum tolerated dose for at least three months OR have a contraindication (harmful for) to both
F. You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (such as greater than 1 gram protein in a 24-hour urine collection or greater than or equal to 1g/g urine protein to creatinine ratio [UPCR: test that measures the amount of protein in urine])
G. You had a trial of or contraindication to one generic systemic corticosteroid therapy (such as oral prednisone, oral prednisolone)

RENEWAL CRITERIA

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You have improved, or stable kidney function compared to baseline OR a reduction in proteinuria

Commercial Effective: 01/17/22

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C1 ESTERASE INHIBITOR - BERINERT

Generic	Brand				
C1 ESTERASE INHIBITOR	BERINERT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
C. Your diagnosis is confirmed by complement testing (a type of lab test)
D. Berinert is being used for acute (short term) attacks of hereditary angioedema
E. You will NOT be using Berinert concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Ruconest, Firazyr, Kalbitor)

RENEWAL CRITERIA

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You will NOT be using Berinert concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Ruconest, Firazyr, Kalbitor)

Commercial Effective: 11/01/22

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C1 ESTERASE INHIBITOR - CINRYZE

Generic	Brand				
C1 ESTERASE INHIBITOR	CINRYZE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 6 years of age or older
C. Cinryze will be used for the prevention of hereditary angioedema attacks
D. Your diagnosis is confirmed by complement testing (a type of blood test)
E. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
F. You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

RENEWAL CRITERIA

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
C. You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

Commercial Effective: 10/01/24

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C1 ESTERASE INHIBITOR - HAEGARDA

Generic	Brand				
C1 ESTERASE INHIBITOR	HAEGARDA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 6 years of age or older
C. Haegarda will be used for the prevention of hereditary angioedema attacks
D. Your diagnosis is confirmed by complement testing (a type of blood test)
E. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
F. You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

RENEWAL CRITERIA

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
C. You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for HAE (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

Commercial Effective: 10/01/24

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C1 ESTERASE INHIBITOR - RUCONEST

Generic	Brand				
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
C. Your diagnosis is confirmed by complement testing (a type of lab test)
D. Ruconest is being used for acute (short term) attacks of hereditary angioedema
E. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert, Firazyr, Kalbitor)

RENEWAL CRITERIA

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert, Firazyr, Kalbitor)

Commercial Effective: 11/01/22

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 progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread)

CABOMETYX

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

A. You have ONE of the following diagnoses:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Hepatocellular carcinoma (HCC: type of liver cancer)
   3. Locally advanced or metastatic differentiated thyroid cancer (DTC: type of thyroid cancer)

B. **If you have advanced renal cell carcinoma, approval also requires ONE of the following:**
   1. Cabometyx will be used as a single agent (used alone)
   2. Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (You have not received prior treatment for advanced renal cell carcinoma)

C. **If you have hepatocellular carcinoma, approval also requires:**
   1. You have previously been treated with Nexavar (sorafenib)

D. **If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have disease progression (disease has gotten worse) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (a type of cancer therapy)
   3. You are radioactive iodine-refractory (resistant to) or ineligible

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CANTHARIDIN

Generic	Brand				
CANTHARIDIN	YCANTH				

GUIDELINES FOR USE

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

A. You have molluscum contagiosum (a viral skin infection)
B. You are 2 years of age or older

Commercial Effective: 12/01/23

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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 colon cancer (colon cancer that has spread to lymph nodes)
   2. Locally advanced rectal cancer (cancer that has spread from where it started to nearby tissue or lymph nodes)
   3. Unresectable (unable to remove by surgery) or metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
   4. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   5. Unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (a type of digestive system cancer that has spread to other parts of the body)
   6. HER2 (a type of protein)-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
   7. Pancreatic adenocarcinoma (a type of cancer of the pancreas)

B. **If you have Stage III colon cancer, approval also requires:**
   1. The requested medication will be used as adjuvant (add-on) treatment

C. **If you have locally advanced rectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as perioperative (the time period before and after surgery) treatment
   3. The requested medication will be used as part of chemoradiotherapy (a type of cancer treatment)

D. **If you have advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used as a single agent (used alone), if an anthracycline (such as doxorubicin, daunorubicin)- or taxane (such as paclitaxel, docetaxel)-containing chemotherapy is not indicated
   2. The requested medication will be used in combination with docetaxel after disease progression (worsens) on prior anthracycline (such as doxorubicin, daunorubicin)-containing chemotherapy

(Criteria continued on next page)

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

E. **If you have unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as part of a combination chemotherapy (drugs used to treat cancer) regimen

F. **If you have HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received prior treatment for metastatic disease
   3. The requested medication will be used as part of a combination regimen (such as with cisplatin, trastuzumab)

G. **If you have pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as adjuvant (add-on) treatment
   3. The requested medication will be used as part of a combination chemotherapy regimen (such as with gemcitabine)

Commercial Effective: 01/23/23

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CAPIVASERTIB

Generic	Brand				
CAPIVASERTIB	TRUQAP				

GUIDELINES FOR USE

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

You have locally advanced or metastatic breast cancer (breast cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)

Truqap will be used together with Faslodex (fulvestrant)

Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, with one or more PIK3CA/AKT1/PTEN-mutations (abnormal changes in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test

You have experienced disease progression (your condition has worsened) on an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

Commercial Effective: 01/01/24

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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: 11/21/22

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CAPMATINIB

Generic	Brand				
CAPMATINIB HYDROCHLORIDE	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

Commercial Effective: 04/10/21

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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)

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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CARBOXYMETHYLCELLULOSE-CITRIC

Generic	Brand				
CARBOXYMETHYLCELLULOSE /CITRIC	PLENITY				

GUIDELINES FOR USE

Our guideline named **CARBOXYMETHYLCELLULOSE-CITRIC (Plenity)** requires the following rule(s) be met for approval:

A. The request is for weight management
B. You are 18 years of age or older
C. You have a body mass index (BMI) of 25 to 40 kg/m(2)
D. Plenity will be used in conjunction (together) with diet and exercise

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Commercial Effective: 04/13/24

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CARGLUMIC ACID

Generic	Brand				
CARGLUMIC ACID	CARBAGLU CARGLUMIC ACID				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (short-term or long-term high ammonia blood levels due to a genetic disorder)
   2. Acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (short-term high ammonia blood levels due to a genetic disorder)

B. **If you have acute or chronic hyperammonemia due to N-acetylglutamate synthase deficiency, approval also requires**:
   1. Your N-acetylglutamate synthase gene mutation is confirmed by biochemical or genetic testing (types of lab test)
   2. Requests for brand Carbaglu requires a trial of generic carglumic acid

C. **If you have acute hyperammonemia due to propionic acidemia, approval also requires**:
   1. Your diagnosis is confirmed by the presence of elevated methylcitric acid and normal methylmalonic acid (substances that indicate presence of a disease) OR genetic testing confirming mutation in the PCCA or PCCB gene (types of abnormal genes)

D. **If you have acute hyperammonemia due to methylmalonic acidemia, approval also requires**:
   1. Your diagnosis is confirmed by the presence of elevated methylmalonic acid, methylcitric acid OR genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes (types of abnormal genes)

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CARGLUMIC ACID

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of acute hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency or acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA), please refer to the Initial Criteria section.

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

A. You have chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) (long-term high ammonia blood levels due to a genetic disorder)
B. You have clinical improvement or improved plasma (blood) ammonia levels

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Commercial Effective: 07/01/22

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CELECOXIB

Generic	Brand				
CELECOXIB	ELYXYB				

GUIDELINES FOR USE

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

A. The request is for the acute (quick onset) treatment of migraines
B. You are 18 years of age or older
C. You had a trial of generic celecoxib AND over-the-counter (OTC) or generic aspirin, diclofenac, ibuprofen, or naproxen
D. You are unable to swallow pills (such as tablets or capsules)

Commercial Effective: 04/01/22

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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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CEQUR SIMPLICITY INSULIN DEVICE

Generic	Brand				
BOLUS INSULIN PUMP, 200 UNIT	CEQUR SIMPLICITY				
DIABETIC SUPPLIES,MISCELL	CEQUR SIMPLICITY INSERTER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CEQUR SIMPLICITY INSULIN DEVICE** requires the following rule(s) be met for approval:

A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You are 21 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. You follow a maintenance program of at least 3 injections of insulin per day
E. You have worked with the physician to adjust the dose of insulin for the past 6 months and have not met glucose (blood sugar) goals
F. You require bolus insulin dosing in increments of 2 units per bolus
G. You had a trial of ONE of the following preferred devices: Omnipod, Omnipod Dash, V-Go
H. If requesting more than 10 patches per month, then you must be using more than 180 units of insulin per 72 hours
I. You are on a multiple daily insulin injection regimen and meet ONE of the following criteria:
    1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations (variations) in blood glucose before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

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CEQUR SIMPLICITY INSULIN DEVICE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **CEQUR SIMPLICITY INSULIN DEVICE** requires the following rule(s) be met for renewal:

A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You have shown a positive response to therapy
C. You are adherent to your doctor follow-up visits
D. If requesting more than 10 patches per month, you are using more than 180 units of insulin per 72 hours

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Commercial Effective: 04/01/23

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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 metastatic non-small cell lung cancer (type of lung cancer that has spread)
B. You are 18 years of age or older
C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration-approved test

Commercial Effective: 10/25/21

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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:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   6. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   7. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

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

(Initial criteria continued on next page)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release)
   c. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis
4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
5. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz IR (tofacitinib immediate-release), Rinvoq (upadacitinib)

(Initial criteria continued on next page)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

F. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Cimzia
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

H. **If you have moderate to severe Crohn's disease, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
5. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   6. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   7. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

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

(Renewal criteria continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

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

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis
   3. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
   3. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab)/adalimumab-adaz/Simlandi, Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab)

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

G. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   3. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Sotyktu (deucravacitinib)

(Renewal criteria continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

H. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease
   2. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab)/adalimumab-adaz/Simlandi, Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib)

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

Commercial Effective: 11/04/24

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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)

Commercial Effective: 07/01/20

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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 (a type of seizure disorder in young children)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. Sympazan will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome
E. You are unable to take tablets or suspension
F. You had a trial of or contraindication (harmful for) to generic/branded clobazam products (Onfi)

Commercial Effective: 07/01/22

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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 ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
   2. Hystiocytic neoplasms (a type of white blood cell disorder)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor has a BRAF V600E OR V600K mutation (a type of gene mutation)
   3. Cobimetinib will be used in combination with vemurafenib (Zelboraf)

C. **If you have histiocytic neoplasms, approval also requires:**
   1. You are 18 years of age or older
   2. Cobimetinib will be used as a single agent

Commercial Effective: 11/21/22

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COLLAGENASE TOPICAL

Generic	Brand				
COLLAGENASE CLOSTRIDIUM HIST.	SANTYL				

GUIDELINES FOR USE

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

A. You have chronic dermal (skin) ulcer(s) or severe burn(s) that require(s) debridement (removal of damaged tissue from a wound)
B. **If the requested quantity is more than one tube (30 grams), approval also requires:**
   1. The higher quantity is based on the size of your wound (width/length) and the anticipated duration of therapy, using the Santyl dosing calculator (https://santyl.com/hcp/dosing)

Commercial Effective: 04/01/22

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CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE

Generic	Brand				
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER, FLASH GLUCOSE SCANNING READER	DEXCOM G6, G7 RECEIVER, FREESTYLE LIBRE 2, 3, 10, 14 READER				
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G6 TRANSMITTER				
BLOOD-GLUCOSE SENSOR	DEXCOM G6, G7 SENSOR, FREESTYLE LIBRE 2, 3 PLUS SENSOR				
FLASH GLUCOSE SENSOR, BLOOD GLUCOSE SENSOR	FREESTYLE LIBRE 2, 3, 10, 14 SENSOR				

GUIDELINES FOR USE

Our guideline named **CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
   2. 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 [a disorder with high blood sugar])
   3. You are currently stable on the requested agent

Commercial Effective: 10/21/24

CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

Generic	Brand				
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER	DEXCOM G4, DEXCOM G5				
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, EVERSENSE SMART TRANSMITTER, EVERSENSE E3 SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN 4 TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER				
BLOOD-GLUCOSE SENSOR	DEXCOM G5-G4 SENSOR, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3, GUARDIAN 4 GLUCOSE SENSOR				

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

You have type 1, type 2, or gestational (during pregnancy) diabetes (too much sugar in the blood)

You have tried or have a contraindication (harmful for) to Dexcom G6, Dexcom G7 or Freestyle Libre, OR all three products are not compatible with your current insulin pump

You meet ONE of the following:

- You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
- You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)

If you are requesting Dexcom G4 or Dexcom G5 system (meter, sensor, transmitter), approval also requires:

You are 2 years of age or older

If you are requesting Guardian Connect (sensor, transmitter), approval also requires:

You are 14 to 75 years of age

If you are requesting Guardian 4 (sensor, transmitter) or Guardian 3 (sensor, link, transmitter), approval also requires:

You are 7 years of age or older

If you are requesting Eversense Smart Transmitter or Eversense E3 Smart Transmitter, approval also requires:

You are 18 years of age or older

RENEWAL CRITERIA

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

You continue to require continuous glucose monitoring

Commercial Effective: 01/01/24

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CORTICOTROPIN

Generic	Brand				
CORTICOTROPIN	ACTHAR , ACTHAR SELFJECT, CORTROPHIN				

GUIDELINES FOR USE

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

A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
B. You are less than 2 years of age
C. Your request is for Acthar vial

Acthar vial will not be approved for any other indication other than infantile spasms. Acthar has not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Acthar pre-filled SelfJect will not be approved for infantile spasms (not Food and Drug Administration (FDA)-indicated) or any other indication. Acthar has not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Commercial Effective: 08/01/24

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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:
You have ONE of the following:
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
- Relapsed (disease that has returned) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: a type of blood cell cancer)
- Unresectable (unable to remove by surgery), recurrent, or refractory (disease does not respond to treatment) inflammatory myofibroblastic tumor (IMT: a rare type of tumor)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive or ROS1 (a type of gene)-positive as detected by a Food and Drug Administration (FDA)-approved test

If you have relapsed or refractory systemic anaplastic large cell lymphoma, approval also requires:
- You are 1 year of age or older
- Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

If you have unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires:
- You are 1 year of age or older
- Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

If the request is for Xalkori oral pellets, approval also requires:
- You are unable to swallow capsules

Commercial Effective: 01/01/24

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CYCLOSPORINE - VERKAZIA

Generic	Brand				
CYCLOSPORINE	VERKAZIA				

GUIDELINES FOR USE

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

B. You have vernal keratoconjunctivitis (allergic eye disease)
C. You have tried or have a contraindication to (harmful for you to use) TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (such as ketotifen) or mast cell stabilizers (such as cromolyn)

Commercial Effective: 01/01/24

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CYCLOSPORINE - VEVYE

Generic	Brand				
CYCLOSPORINE	VEVYE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have dry eye disease (DED: a type of eye condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
D. You have ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
E. You have tried or have a contraindication to (harmful for you to use) ONE ocular lubricant (such as carboxymethylcellulose [such as Refresh, Celluvisc, TheraTears], polyvinyl alcohol [such as LiquiTears, Refresh Classic], or a wetting agent [such as Systane, Lacri-Lube])
F. You have tried or have a contraindication to BOTH of the following preferred medications: Restasis (cyclosporine) and Xiidra (lifitegrast)

RENEWAL CRITERIA

Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for renewal:

A. You have dry eye disease (DED: a type of eye condition)
B. You have demonstrated improvement of your dry eye disease (the treatment is working)

Commercial Effective: 01/01/24

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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

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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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DABIGATRAN

Generic	Brand				
DABIGATRAN ETEXILATE MESELATE	PRADAXA				

GUIDELINES FOR USE

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

A. The request is for ONE of the following:
   1. Treatment of a venous thromboembolic event (VTE: a type of blood clot disease in your veins)
   2. Reduce the risk of venous thromboembolic event recurrence (happening again)

B. You meet ONE of the following:
   1. You are 3 months to 7 years of age
   2. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules

C. You have tried or have a contraindication (harmful for) to rivaroxaban (Xarelto) suspension

D. **If the request is for the treatment of a venous thromboembolic event, approval also requires:**
   1. You have been treated with parenteral anticoagulation agent (type of medication) for at least 5 days

E. **If the request is to reduce the risk of venous thromboembolic event recurrence, approval also requires:**
   1. You have been previously treated

Commercial Effective: 07/01/23

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 ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Melanoma (a type of skin cancer)
   3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires ONE of the following:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent (by itself)
   2. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

C. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication has not previously been used for more than one year
   3. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
   4. There is involvement of lymph node(s) following complete resection (removal by surgery)

D. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)

(Criteria continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the tablet for oral suspension, approval also requires:**
   1. You cannot swallow Tafinlar (dabrafenib) capsules

Commercial Effective: 10/01/23

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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) to other parts of the body)
B. You have epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
C. Vizimpro will be used as first-line treatment
D. You will NOT be using Vizimpro concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

Commercial Effective: 07/01/22

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DALFAMPRIDINE

Generic	Brand			
DALFAMPRIDINE	AMPYRA, DALFAMPRIDINE ER			

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 (MS: a type of nerve disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. You have symptoms of a walking disability such as mild to moderate bilateral (both sides) lower extremity weakness or unilateral (one side) weakness plus lower extremity or truncal ataxia (impaired balance or coordination)

RENEWAL CRITERIA

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

A. You have multiple sclerosis (MS: a type of nerve disorder)
B. You have experienced or maintained at least a 15% improvement in walking ability

Commercial Effective: 08/29/22

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DANICOPAN

Generic	Brand				
DANICOPAN	VOYDEYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You will use Voydeya for the treatment of extravascular hemolysis (EVH: break down of blood cells outside of your blood stream)
E. You have anemia (a hemoglobin [Hgb: a type of protein in red blood cells] level less than or equal to 9.5 g/dL) with an absolute reticulocyte (immature red blood cell) count of at least 120 x 10(9)/L
F. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
G. You have tried or have a contraindication to (harmful for you to use) Fabhalta (iptacopan)
H. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
I. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

RENEWAL CRITERIA

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

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You have experienced a clinical benefit (such as an improvement in hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before you started treatment)
C. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
D. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

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DAPRODUSTAT

Generic	Brand				
DAPRODUSTAT	JESDUVROQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
D. You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 4 months
E. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic kidney disease (CKD)
F. You will NOT use Jesduvroq concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Vafseo [vadadustat])
G. **If you are NOT currently being treated with an erythropoiesis-stimulating agent (ESA: drugs used to treat anemia such as Epogen or Procrit), approval also requires:**
    1. You have a hemoglobin level (a type of blood test) of less than 11 g/dL
H. **If you are currently being treated with an erythropoiesis-stimulating agent (ESA: drugs used to treat anemia such as Epogen or Procrit), approval also requires:**
    1. You have a hemoglobin level (a type of blood test) of less than 12 g/dL
    2. You will discontinue ESA therapy before starting Jesduvroq

RENEWAL CRITERIA

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

A. You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
B. You meet ONE of the following:
    1. You have a hemoglobin level (a type of blood test) of at least 10 g/dL
    2. Your hemoglobin level has increased by at least 2 g/dL from your baseline level

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DARBEPOETIN ALFA

Generic	Brand				
DARBEPOETIN ALFA IN POLYSORBAT	ARANESP				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effect 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 due to chronic kidney disease, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is 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 the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level is 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 the preferred medication: Retacrit (epoetin alfa-epbx)
   2. You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
   3. Your hemoglobin level is less than 10g/dL

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DARBEPOETIN ALFA

RENEWAL CRITERIA

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   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 due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. Your hemoglobin level is less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

C. **If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level is less than 10g/dL
   2. Your hemoglobin level has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

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

Commercial Effective: 06/01/24

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DARIDOREXANT

Generic	Brand				
DARIDOREXANT HCL	QUVIVIQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have insomnia (a type of sleep condition)
B. You are 18 years of age or older
C. You have premature awakening (waking up too early) and/or abnormal sleep onset delay (cannot fall asleep) lasting 30 minutes or longer, occurring 3 or more times weekly for the last month for acute (short-term) insomnia or for at least 3 months for chronic (long-term) insomnia
D. You have daytime impairment despite adequate time attempting to sleep and treatment of any treatable causes
E. You are NOT using Quviviq at the same time with Z hypnotics (such as eszopiclone, zaleplon, zolpidem) or benzodiazepines (such as estazolam, temazepam, triazolam) for sleep
F. You do NOT have narcolepsy (a type of sleep condition)
G. You had a trial of or contraindication (harmful for) to TWO generic insomnia medications (such as eszopiclone, zaleplon, zolpidem) AND Belsomra

RENEWAL CRITERIA

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

A. You have insomnia (a type of sleep condition)
B. You have demonstrated improvement of insomnia symptoms but are not currently a candidate for discontinuation
C. You are NOT using Quviviq at the same time with Z hypnotics (such as eszopiclone, zaleplon, zolpidem) or benzodiazepines (such as estazolam, temazepam, triazolam) for sleep

Commercial Effective: 05/09/22

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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 ONE of the following diagnoses:
   1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

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

C. **If you have non-metastatic castration resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)

D. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
   1. The requested medication will be used in combination with docetaxel

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DAROLUTAMIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

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

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

C. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
   1. The requested medication will be used in combination with docetaxel

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Commercial Effective: 01/01/23

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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 ONE of the following:
   1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic, accelerated, myeloid or lymphoid blast phase
   2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

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

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance (medication no longer works as well) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
   3. You had a mutational analysis (a type of lab test) prior to start of therapy AND Sprycel is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance (medication no longer works as well) or intolerance (side effect) to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are between 1 and 17 years of age, you are newly diagnosed, AND you will be using Sprycel in combination with chemotherapy (drugs used to treat cancer)

Commercial Effective: 09/23/24

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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 ONE of the following diagnoses:
   1. Transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a type of blood disorder)
   2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a type of blood disorder)

B. Therapy is prescribed by or given in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of cancer doctor)

C. You have tried or have a contraindication (harmful for) to at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

D. You meet ONE of the following:
   1. You are experiencing intolerable toxicities or clinically significant adverse effects or have a contraindication (harmful for) to current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   2. Current chelation therapy (therapy that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough

E. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
   1. You are 8 years of age or older

F. **If the request is for Ferriprox oral solution, approval also requires:**
   1. You are 3 years of age or older

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DEFERIPRONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Transfusional iron overload due to thalassemia syndrome (you have too much iron in your body due to a type of blood disorder)
   2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a type of blood disorder)

B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay above 500mcg/L (at least 2 lab values in the previous 3 months)

C. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
   1. You are 8 years of age or older

D. **If the request is for Ferriprox oral solution, approval also requires:**
   1. You are 3 years of age or older

Commercial Effective: 04/01/22

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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: 04/17/23

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DEFLAZACORT

Generic	Brand			
DEFLAZACORT	EMFLAZA, DEFLAZACORT			

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 (DMD: a type of muscle disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have tried prednisone or prednisolone for at least 6 months
F. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet **ALL** of the following:
        a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        b. There is no steroid myopathy (muscle disease due to steroid use)
        c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician], pulmonary function [forced vital capacity, lung function tests], upper limb strength [moving a wheelchair 30 feet])
    2. You have experienced a significant adverse effect (such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

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DEFLAZACORT

RENEWAL CRITERIA

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

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. **If you are currently ambulatory (can walk), approval also requires:**
   a. You have shown function or improvement since being on Emflaza as measured by a standard set of ambulatory or functional status measures (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician])
C. **If you are currently non-ambulatory (cannot walk), approval also requires:**
   1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since being on Emflaza as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength measures [moving in a wheelchair 30 feet], Physician Global Assessment [PGA: an evaluation by a physician])

Commercial Effective: 03/04/24

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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 in consultation with an infectious disease (ID) specialist
   2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI)
   3. You have 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 18 years of age or older
   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 are not using the requested medication for an 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:
      1. 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
      2. 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 (harmful for) 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:
      1. 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
      2. 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 (harmful for) TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Commercial Effective: 08/28/23

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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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DEUCRAVACITINIB

Generic	Brand				
DEUCRAVACITINIB	SOTYKTU				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, or genital area
E. You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
F. You meet ONE of the following:
    1. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
    2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
    3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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DEUCRAVACITINIB

RENEWAL CRITERIA

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

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
C. You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 10/01/24

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DEUTETRABENAZINE

Generic	Brand				
DEUTETRABENAZINE	AUSTEDO, AUSTEDO XR				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Chorea (involuntary muscle movements) associated with Huntington's disease
   2. Moderate to severe tardive dyskinesia (TD: uncontrolled body movements)

B. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or movement disorder specialist

C. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. You are 18 years of age or older
   2. Your moderate to severe tardive dyskinesia (uncontrolled body movements) has been present for at least 3 months
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), movement disorder specialist, or psychiatrist (a type of mental health doctor)
   4. You have a prior history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

Commercial Effective: 08/01/24

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DEXTROMETHORPHAN 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

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: 02/08/21

DICHLORPHENAMIDE

Generic	Brand			
DICHLORPHENAMIDE	KEVEYIS, ORMALVI, DICHLORPHENAMIDE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood) or related variants
   2. Primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood) or related variants

B. **If you have primary hyperkalemic periodic paralysis or related variants**, **approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

C. **If you have primary hypokalemic periodic paralysis or related variants, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

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DICHLORPHENAMIDE

RENEWAL CRITERIA

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

A. You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
B. You have experienced at least TWO fewer attacks per week from baseline (before you started treatment)

Commercial Effective: 05/06/24

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DICLOFENAC TOPICAL GEL

Generic	Brand				
DICLOFENAC SODIUM	SOLARAZE, DICLOFENAC SODIUM				

GUIDELINES FOR USE

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

A. You have actinic keratosis (a type of skin condition)
B. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor) or oncologist (a type of cancer doctor)
C. You had a trial of or contraindication (harmful for) to topical fluorouracil (such as Efudex, Fluoroplex, Carac)

Commercial Effective: 11/01/22

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DICLOFENAC TOPICAL SOLUTION

Generic	Brand				
DICLOFENAC SODIUM	PENNSAID, DICLOFENAC SODIUM				

GUIDELINES FOR USE

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

A. You have osteoarthritis (a type of joint condition) of the knee(s)
B. You had a trial of diclofenac 1% gel AND diclofenac 1.5% drops

Commercial Effective: 11/01/22

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DIGOXIN

Generic	Brand				
DIGOXIN	DIGOXIN				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Heart failure (a type of heart condition)
   2. Chronic atrial fibrillation (a type of heart condition)

B. **If you have chronic atrial fibrillation, approval also requires:**
   1. You are 18 years of age or older

Commercial Effective: 07/01/22

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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

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DONEPEZIL

Generic	Brand				
DONEPEZIL HCL	ADLARITY				

GUIDELINES FOR USE

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

A. You have dementia (a type of memory disorder) associated with Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
B. You had a trial of or contraindication (harmful for) to TWO generic oral acetylcholinesterase inhibitors (such as donepezil, galantamine)
C. You had a trial of or contraindication (harmful for) to one generic acetylcholine inhibitor patch (such as rivastigmine)

Commercial Effective: 07/18/22

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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, DROXIDOPA			

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

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

Commercial Effective: 03/15/21

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DULOXETINE

Generic	Brand				
DULOXETINE HCL	DRIZALMA SPRINKLE				

GUIDELINES FOR USE

Our guideline named **DULOXETINE (Drizalma Sprinkle)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Major depressive disorder (a type of mental illness)
   2. Generalized anxiety disorder (a type of mental illness)
   3. Diabetic peripheral neuropathy (a type of nerve damage caused by high blood sugar)
   4. Fibromyalgia (a type of pain disorder)
   5. Chronic musculoskeletal pain (severe pain relating to muscles and bones)

B. **If you have major depressive disorder, diabetic peripheral neuropathy, fibromyalgia, or chronic musculoskeletal pain, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of generic duloxetine
   3. You cannot swallow duloxetine capsules

C. **If you have generalized anxiety disorder, approval also requires:**
   1. You are 7 years of age or older
   2. You had a trial of generic duloxetine
   3. You cannot swallow duloxetine capsules

Commercial Effective: 04/01/23

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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:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyposis (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Rinvoq [upadacitinib]) and are switching to Dupixent
      b. You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
      c. You have atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You meet ONE of the following:
      i. You have an eosinophilic phenotype asthma (a type of inflammatory asthma) and meet all of the following:
         i. You have a pre-treatment blood eosinophil level (a type of lab test) of 150 to 1500 cells/mcL
         ii. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
      ii. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
   4. Dupixent will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)
   5. You meet ONE of the following:
      a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
      b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
      c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. Dupixent will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids)
   4. You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
   5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyposis

E. **If you have eosinophilic esophagitis, approval also requires:**
   1. You are 1 year of age or older
   2. You weigh at least 15 kilograms (33 pounds)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a type of doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) dietary therapy
   5. You have tried or have a contraindication to (harmful for you to use) a proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)
   6. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

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INITIAL CRITERIA (CONTINUED)

F. **If you have prurigo nodularis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
   3. You have multiple pruriginous lesions (wounds)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
   5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

G. **If you have chronic obstructive pulmonary disease, approval also requires:**
   1. You are 18 years of age or older
   2. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   4. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

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DUPILUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyposis (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)

B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have shown improvement while on Dupixent
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

C. **If you have moderate to severe asthma, renewal also requires:**
   1. You meet ONE of the following:
      a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma), AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
      b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
   2. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)

(Renewal criteria continued on next page)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

3. You have shown a clinical response as evidenced by ONE of the following:
   a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
   b. You have decreased your use of rescue medications (such as albuterol)
   c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Dupixent)
   d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyposis

E. **If you have eosinophilic esophagitis, renewal also requires**:
   1. You have shown improvement while on Dupixent (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less [a type of test that evaluates disease status])
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

F. **If you have prurigo nodularis, renewal also requires:**
   1. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

(Renewal criteria continued on next page)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

G. **If you have chronic obstructive pulmonary disease, renewal also requires:**
   1. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
   2. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD
   4. You have shown a clinical response as evidenced by ONE of the following:
      a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
      b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)
      c. You have had an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Dupixent)

Commercial Effective: 10/28/24

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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 ONE of the following diagnoses:
   1. Relapsed or refractory chronic lymphocytic leukemia (CLL: a type of blood cancer that has returned after treatment or does not fully respond to treatment)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)

B. You are 18 years of age or older

C. You have received at least two prior therapies for chronic lymphocytic leukemia or small lymphocytic lymphoma

Commercial Effective: 04/01/22

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EDARAVONE ORAL

Generic	Brand				
EDARAVONE	RADICAVA ORS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
C. You have had ALS (from onset of symptoms) for 3 years or less
D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of greater than 70 percent
E. You have tried riluzole OR are currently taking riluzole
F. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

RENEWAL CRITERIA

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. You do not require invasive ventilation (inserting a breathing tube into your throat)
C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R)

Commercial Effective: 06/15/22

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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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EFLAPEGRASTIM-XNST

Generic	Brand				
EFLAPEGRASTIM-XNST	ROLVEDON				

GUIDELINES FOR USE

Our guideline named **EFLAPEGRASTIM-XNST (Rolvedon)** requires the following rule(s) be met for approval:

A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
D. You are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of neutropenia (a type of blood condition) with fever
E. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 08/01/23

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EFLORNITHINE

Generic	Brand				
EFLORNITHINE HCL	IWILFIN				

GUIDELINES FOR USE

Our guideline named **EFLORNITHINE (Iwilfin)** requires the following rule(s) be met for approval:
You have high-risk neuroblastoma (HRNB: a type of rare cancer)
You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior therapy, including anti-GD2 immunotherapy (such as Unituxin [dinutuximab])

Commercial Effective: 01/15/24

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ELACESTRANT

Generic	Brand				
ELACESTRANT HYDROCHLORIDE	ORSERDU				

GUIDELINES FOR USE

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

A. You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor 1 (ESR1: a gene) mutation(s)
C. You have disease progression following endocrine therapy (disease has worsened after using a type of hormone therapy)

Commercial Effective: 07/01/23

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ELAFIBRANOR

Generic	Brand				
ELAFIBRANOR	IQIRVO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

D. You do not have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) OR a prior decompensation event (liver stops working properly)

E. You do NOT have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) with evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)

F. You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

G. You meet ONE of the following:
   1. Iqirvo will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Iqirvo will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

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ELAFIBRANOR

RENEWAL CRITERIA

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

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
B. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo
C. You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

Commercial Effective: 09/16/24

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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 (condition affecting the uterus)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
D. Your diagnosis of endometriosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
E. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
F. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
G. Requests will not be approved if you previously received ONE of the following:
    1. A 6-month course of Orilissa 200mg twice daily
    2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
    3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

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ELAGOLIX

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 (condition affecting the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
E. Requests will not be approved if you previously received ONE of the following:
    1. A 6-month course of Orilissa 200mg twice daily
    2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
    3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

Commercial Effective: 10/09/23

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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 (ADA-SCID: an inherited disorder that damages the immune system) as shown by ONE of the following:
   1. You have a confirmatory genetic test
   2. You have suggestive laboratory findings (such as elevated deoxyadenosine nucleotide levels, lymphopenia [low levels of a type of white blood cell]) AND you have hallmark signs/symptoms (such as recurrent infections, failure to thrive, persistent diarrhea)
B. Therapy is prescribed by or in consultation with an immunologist (a type of immune system doctor), hematologist-oncologist (a type of blood-cancer doctor), or physician specializing in inherited metabolic disorders
C. You meet ONE of the following:
   1. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow)
   2. Revcovi 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 (ADA-SCID: an inherited disorder that damages the immune system)
B. You have a trough plasma adenosine deaminase (ADA) activity of at least 30 mmol/hr/L AND trough deoxyadenosine nucleotide (dAXP) levels less than 0.02 mmol/L
C. You have shown improvement in or maintenance of immune function from baseline (such as a decrease in the number and severity of infections)
D. You have NOT received successful hematopoietic cell transplantation (HCT: blood cell transplant from bone marrow) 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 chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 12 years of age or older OR weigh at least 30 kilograms (66 pounds)
C. You have genotype 1 or 4 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Zepatier concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as phenytoin, carbamazepine, rifampin, efavirenz [such as Atripla, Sustiva], atazanavir [such as Evotaz, Reyataz], darunavir [such as Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [such as Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John's wort)
H. You will NOT use Zepatier concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
I. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Harvoni

(Criteria continued on next page)

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

J. **If you are treatment-naive (no prior treatment), approval also requires ONE of the following:**
   1. You have genotype 1a infection AND you do not have baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein)
   2. You have genotype 1b infection
   3. You have genotype 4 infection
   4. You received a kidney transplant (replaced your kidney) AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)
   5. You have genotype 1a infection, with baseline NS5A polymorphisms, AND Zepatier will be used with ribavirin

K. **If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:**
   1. You have genotype 1a infection, without baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein), AND were previously treated with peginterferon/ribavirin
   2. You have genotype 1b infection AND were previously treated with peginterferon/ribavirin
   3. You have genotype 1 infection, were previously treated with a peginterferon/ribavirin/protease inhibitor triple regimen, AND Zepatier will be used with ribavirin
   4. You have genotype 1a infection with baseline NS5A polymorphisms, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   5. You have genotype 4 infection, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   6. You received a kidney transplant (replaced your kidney), were previously treated with a non-direct acting antiviral (such as interferon), AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)

L. Zepatier will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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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 (CF: a type of lung disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You meet ONE of the following:
   1. You have at least ONE *F508del* mutation (an abnormal change) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   2. You have at least ONE of the following mutations (abnormal change) in the CFTR gene:

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C; S1251N*	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del*	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y; G576A; R668C	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*

D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W; D1270N*	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W; V201M*	*S364P*	*Y161S*
E116K	*G576A; R668C*	*L165S*	*R74W; V201M; D1270N*	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

RENEWAL CRITERIA

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

A. You have cystic fibrosis (CF: a type of lung disorder)
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 a less than expected decline in forced expiratory volume (FEV1: amount of air exhaled in one second)
    2. You have improved, maintained, or demonstrated a less than expected decline in body mass index (BMI: a tool for evaluating body fat)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 07/01/24

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ELTROMBOPAG - ALVAIZ

Generic	Brand				
ELTROMBOPAG CHOLINE	ALVAIZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   3. Severe aplastic anemia (a type of blood disorder)

B. **If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 6 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])
   4. You have tried or have a contraindication to (harmful for you to use) Promacta (eltrombopag)
   5. You meet ONE of the following:
      c. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      d. You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

(Initial criteria continued on next page)

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ELTROMBOPAG - ALVAIZ

INITIAL CRITERIA (CONTINUED)

C. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. You are 18 years of age or older
   2. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of drug for hepatitis) or limits your ability to maintain interferon-based therapy
   3. You have tried or have a contraindication to (harmful for you to use) Promacta (eltrombopag)

D. **If you have severe aplastic anemia, approval also requires:**
   1. You are 18 years of age or older
   2. You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)
   3. You have tried or have a contraindication to (harmful for you to use) Promacta (eltrombopag)

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 - ALVAIZ** requires the following rules be met for renewal:

A. You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Alvaiz) OR a decrease in bleeding events
C. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) or a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

Commercial Effective: 10/01/24

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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 type of bleeding disorder)
B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
C. Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
D. You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])
E. **If you have hemophilia A with factor VIII inhibitors (a type of protein), approval also requires:**
    1. You have a history of a high titer (concentration) of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter
F. **If you have hemophilia A without factor VIII inhibitors (a type of protein), approval also requires ONE of the following:**
    1. You have moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal
    2. You have mild hemophilia A, defined as 5 percent - 40 percent factor VIII activity compared to normal, and meet ONE of the following:
        a. You have experienced severe, traumatic, or spontaneous (sudden) bleeding episode(s) (may occur in joint or muscle)
        b. You have experienced a life-threatening bleed (such as intracranial hemorrhage [ICH: a type of bleeding in the head])
        c. It is difficult to access your veins which prevents or delays you in receiving regular clotting factor infusions

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 type of bleeding disorder)
B. You have shown a clinical benefit compared to baseline (before starting Hemlibra)
C. You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])

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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 cannot be completely removed with surgery or has spread to other parts of the body)
   2. Metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
   3. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

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

C. **If you have metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Braftovi will be used in combination with Erbitux (cetuximab)
   4. You have previously received treatment (such as irinotecan)

D. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Braftovi will be used in combination with Mektovi (binimetinib)

Commercial Effective: 11/13/23

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ENSIFENTRINE

Generic	Brand				
ENSIFENTRINE	OHTUVAYRE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You are 18 years of age or older
C. Ohtuvayre will be used as maintenance treatment (taken on a regular basis)
D. Therapy is prescribed by or in consultation with a pulmonologist (a type of lung/breathing doctor)
E. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater

RENEWAL CRITERIA

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

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater
C. You have shown a clinical response as evidenced by ONE of the following:
    1. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Ohtuvayre)
    2. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum (mucus) production, etc.)
    3. You have an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Ohtuvayre)

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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 ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   2. Solid tumors (an abnormal mass)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have ROS1-positive (abnormal change in a type of gene) tumors, as detected by a Food and Drug Administration (FDA)-approved test

C. **If you have solid tumors, approval also requires:**
   1. You are 1 month of age or older
   2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (you have an abnormal change in a type of gene that does not have any known resistance), as detected by a Food and Drug Administration (FDA)-approved test
   3. Your tumor is metastatic (has spread to other parts of the body) or surgical resection (removal) is likely to result in severe morbidity (disease)
   4. You have progressed (gotten worse) after treatment or there are no satisfactory alternative treatments

D. **If the request is for Rozlytrek 50mg pellets, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) Rozlytrek capsules that are used to make an oral suspension
   2. You have difficulty or are not able to swallow capsules

Commercial Effective: 12/01/23

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EPLONTERSEN

Generic	Brand				
EPLONTERSEN SODIUM	WAINUA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (*transthyretin*) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

RENEWAL CRITERIA

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

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You have not progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
C. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

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EPOETIN ALFA

Generic	Brand				
EPOETIN ALFA	EPOGEN, PROCRIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine (Retrovir) therapy (a 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, nonvascular surgery (surgery not relating to the heart or blood vessels)

B. **If you have anemia due to chronic kidney disease, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is 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 the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level is 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 the preferred medication: Retacrit (epoetin alfa-epbx)
   2. You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
   3. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level is less than 13g/dL

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EPOETIN ALFA

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine (Retrovir) therapy (a 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 are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. Your hemoglobin level is less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

C. **If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level is less than 10g/dL
   2. Your hemoglobin level has approached or exceeds 12g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

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

E. **If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

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

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EPOETIN ALFA-EPBX

Generic	Brand				
EPOETIN ALFA-EPBX	RETACRIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine (Retrovir) therapy (a 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
   2. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

B. **If you have anemia due to chronic kidney disease, approval also requires:**
   1. Your hemoglobin level (a type of blood test) is 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. Your hemoglobin level is 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 (Retrovir) therapy, approval also requires:**
   1. Your hemoglobin level is 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 or have a contraindication to (harmful for you to use) a lower ribavirin dose
   2. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:**
   1. Your hemoglobin level is less than 13g/dL

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine (Retrovir) therapy (a 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 are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. Your hemoglobin level is less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

C. **If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level is less than 10g/dL
   2. Your hemoglobin level has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions

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

E. **If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

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

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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 (a type of bladder cancer that has spread to nearby tissue or other parts of the body)
B. You are 18 years of age or older
C. You have a susceptible (can be treated with the drug) fibroblast growth factor receptor 3 (FGFR3: a type of protein) genetic alteration (mutation) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
D. You have disease progression (condition has worsened) on or after at least one line of prior systemic therapy (treatment that targets the entire body, such as cisplatin, Keytruda [pembrolizumab])

Commercial Effective: 02/12/24

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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 will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

C. **If you have chronic migraines (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 will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

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ERENUMAB-AOOE

GUIDELINES FOR USE (CONTINUED)

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 will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
C. 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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Commercial Effective: 08/01/23

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ERGOTAMINE-CAFFEINE

Generic	Brand				
ERGOTAMINE TARTRATE/CAFFEINE	MIGERGOT				

GUIDELINES FOR USE

Our guideline named **ERGOTAMINE-CAFFEINE (Migergot)** requires the following rule(s) be met for approval:

A. Migergot is being used to abort (stop) or prevent vascular headaches (such as migraines, migraine variants, so-called 'histaminic cephalalgia' [types of headaches])
B. You cannot swallow ergotamine/caffeine tablets
C. You had a trial of or contraindication (harmful for) to generic ergotamine/caffeine tablets AND two triptans (such as sumatriptan, rizatriptan)

Commercial Effective:04/01/23

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ERLOTINIB

Generic	Brand			
ERLOTINIB HCL	TARCEVA, ERLOTINIB HCL			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test
   2. You will NOT be using Tarceva (erlotinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Commercial Effective: 07/01/22

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:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of ONE DMARD (disease-modifying anti-rheumatic drug), 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, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial criteria continued on next page)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as naproxen, ibuprofen, meloxicam)

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INITIAL CRITERIA (CONTINUED)

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

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ETANERCEPT

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

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

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires**:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

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

F. **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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 07/01/24

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ETHACRYNIC ACID

Generic	Brand				
ETHACRYNIC ACID	EDECRIN, ETHACRYNIC ACID				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), cirrhosis (liver damage), or renal disease (including nephrotic syndrome [a type of kidney disorder])
   2. Ascites (accumulation of fluid in the abdominal cavity) due to malignancy (cancer), idiopathic (unknown cause) edema, or lymphedema (swelling in an arm or leg due to build-up of lymph fluid)

B. You had a trial of or contraindication (harmful for) to TWO generic loop diuretics (such as furosemide, bumetanide, torsemide)

Commercial Effective: 07/01/22

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ETRASIMOD

Generic	Brand				
ETRASIMOD ARGININE	VELSIPITY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
D. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
E. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
F. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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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ETRASIMOD

RENEWAL CRITERIA

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

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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.

Commercial Effective: 10/01/24

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EVEROLIMUS-AFINITOR DISPERZ

Generic	Brand				
EVEROLIMUS	AFINITOR DISPERZ, EVEROLIMUS				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
   2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures

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

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

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Commercial Effective: 04/10/23

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EVEROLIMUS-AFINITOR

Generic	Brand				
EVEROLIMUS	AFINITOR, TORPENZ, EVEROLIMUS				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Advanced hormone receptor-positive (HR: a type of protein), human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer
   2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   4. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
   5. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)

B. **If you have advanced hormone receptor-positive, HER2-negative breast cancer, approval also requires:**
   1. You are a postmenopausal woman
   2. The requested medication will be used in combination with Aromasin (exemestane)
   3. You have failed or have a contraindication to (harmful for you to use) treatment with Femara (letrozole) or Arimidex (anastrozole)

C. **If you have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
      b. You have well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI: relating to the digestive system) or lung origin

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, approval also requires:**
   1. You are 18 years of age or older
   2. You do NOT require immediate surgery

(Criteria continued on next page)

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

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

Commercial Effective: 08/01/24

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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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FECAL MICROBIOTA CAPSULE

Generic	Brand				
FECAL MICROBIO SPORE, LIVE-BRPK	VOWST				

GUIDELINES FOR USE

Our guideline named **FECAL MICROBIOTA CAPSULE (Vowst)** requires the following rule(s) be met for approval:

A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
B. You are 18 years of age or older
C. **If you have NOT previously received Vowst, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin], fidaxomicin [Dificid]) treatment for recurrent CDI (defined as at least 3 CDI episodes)
D. **If you have been previously treated with Vowst, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

Commercial Effective: 06/01/23

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FECAL MICROBIOTA SUSPENSION

Generic	Brand				
FECAL MICROBIOTA, LIVE-JSLM	REBYOTA				

GUIDELINES FOR USE

Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:

A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
B. You are 18 years of age or older
C. **If you have NOT previously received Rebyota, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin]) treatment for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior
D. **If you have been previously treated with Rebyota, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Rebyota AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

Commercial Effective:05/22/23

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FEDRATINIB

Generic	Brand				
FEDRATINIB DIHYDROCHLORIDE	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 have shown symptom improvement by meeting ONE of the following:
   1. You have a spleen volume reduction of 35% or greater from baseline
   2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

Commercial Effective: 01/01/22

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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 ONE of the following:
   1. Dravet syndrome (a rare type of seizure)
   2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)

B. **If you have Dravet syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivative, clobazam, topiramate

C. **If you have Lennox-Gastaut syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to valproic acid or derivatives
   4. You had a trial of or contraindication (harmful for) to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

RENEWAL CRITERIA

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

A. You have seizures associated with Dravet syndrome (a rare type of seizure)
B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

Commercial Effective: 07/01/22

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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, FENTANYL			

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 every 48 hours dosing requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

Commercial Effective: 10/14/24

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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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FERRIC MALTOL

Generic	Brand				
FERRIC MALTOL	ACCRUFER				

GUIDELINES FOR USE

Our guideline named **FERRIC MALTOL (Accrufer)** requires the following rule(s) be met for approval:

A. You have iron deficiency (low iron levels)
B. You are 18 years of age or older
C. You had a trial of an over-the-counter (OTC) oral iron preparation (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 10/01/21

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FILGRASTIM

Generic	Brand				
FILGRASTIM	NEUPOGEN				

GUIDELINES FOR USE

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

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Neupogen for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Neupogen to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Commercial Effective: 07/01/23

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FILGRASTIM-AAFI

Generic	Brand				
FILGRASTIM-AAFI	NIVESTYM				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-AAFI (Nivestym)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Nivestym for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles or due to unknown cause)
   6. You will be using Nivestym to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Commercial Effective: 07/01/23

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FILGRASTIM-AYOW

Generic	Brand				
FILGRASTIM-AYOW	RELEUKO				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a nonmyeloid malignancy (a type of cancer) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a nonmyeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Releuko for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Releuko to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Commercial Effective: 07/01/23

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FILGRASTIM-SNDZ

Generic	Brand				
FILGRASTIM-SNDZ	ZARXIO				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-SNDZ (Zarxio)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Zarxio for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Zarxio to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Commercial Effective: 07/01/23

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FINASTERIDE-TADALAFIL

Generic	Brand				
FINASTERIDE/TADALAFIL	ENTADFI				

GUIDELINES FOR USE

Our guideline named **FINASTERIDE-TADALAFIL (Entadfi)** requires the following rule(s) be met for approval:

A. You are male and have benign prostatic hyperplasia (BPH: a type of prostate condition)
B. You are 18 years of age or older
C. You had a trial of or contraindication (harmful for) to TWO alpha blockers (such as terazosin, doxazosin, tamsulosin)
D. You had a trial of or contraindication (harmful for) to ONE 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
E. You had a trial of or contraindication (harmful for) to tadalafil 2.5 mg or tadalafil 5 mg

Requests will not be approved if you have received a 26-week course of Entadfi.

Commercial Effective: 08/29/22

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FINERENONE

Generic	Brand				
FINERENONE	KERENDIA				

GUIDELINES FOR USE

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

A. You have chronic kidney disease (CKD: long-term kidney disease) associated with type 2 diabetes (T2D: a disorder with high blood sugar)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) a sodium-glucose co-transporter-2 (SGLT2) inhibitor (such as Farxiga [dapagliflozin], Invokana [canagliflozin], Jardiance [empagliflozin], Steglatro [ertugliflozin])

Commercial Effective: 06/10/24

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FINGOLIMOD

Generic	Brand			
FINGOLIMOD	GILENYA, FINGOLIMOD			

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 (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 10 years of age or older
C. You do NOT have ANY of the following contraindications to (harmful for you to use) Gilenya:
    1. A recent (within the past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke (a type of brain damage), transient ischemic attack (a type of stroke), decompensated heart failure (a type of heart condition) requiring hospitalization, or Class III/IV heart failure (a type of heart condition)
    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 (a small device that is placed [implanted] in your chest to help control your heartbeat)
    3. A baseline QTc interval of 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: 06/01/24

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FINGOLIMOD LAURYL SULFATE

Generic	Brand				
FINGOLIMOD LAURYL SULFATE	TASCENSO ODT				

GUIDELINES FOR USE

Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (a type of nerve disorder), to include clinically isolated syndrome (a type of nerve disorder that occurs once), relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive disease (advanced disease)
B. You are 10 years of age or older
C. You had a trial of fingolimod capsules
D. You are unable to swallow fingolimod capsules
E. You had a trial of or contraindication (harmful for) to one other agent indicated for the treatment of multiple sclerosis
F. You do not have any of the following contraindications (harmful for) to Tascenso ODT:
    1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
    2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker
    3. A baseline QTc interval of 500 msec or greater (a measure of the speed of electrical conduction in the heart)
    4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Commercial Effective: 01/16/23

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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

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FLUOROURACIL CREAM

Generic	Brand				
FLUOROURACIL 0.5%	CARAC, FLUOROURACIL				
FLUOROURACIL 1%	FLUOROPLEX				

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

GUIDELINE FOR USE

CARAC

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

A. You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the face and anterior (front) scalp
B. You have tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil 5%, imiquimod, diclofenac 3%)

FLUOROPLEX

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

A. You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure)
B. You have tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

Commercial Effective: 05/17/24

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FOSCARBIDOPA-FOSLEVODOPA

Generic	Brand				
FOSCARBIDOPA/ FOSLEVODOPA	VYALEV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for approval:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. You are 18 years of age or older
C. Vyalev is being used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
E. Your disease is responsive to treatment with levodopa
F. You are currently being treated with at least 400mg of levodopa per day
G. Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 2.5 hours per day over 3 consecutive days, with a minimum of 2 hours each day)

RENEWAL CRITERIA

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for renewal:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. You have experienced improvement in motor symptoms with the use of Vyalev

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Commercial Effective: 11/04/24

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FOSDENOPTERIN

Generic	Brand				
FOSDENOPTERIN HYDROBROMIDE	NULIBRY				

GUIDELINES FOR USE

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

A. You have molybdenum cofactor deficiency (MoCD) Type A (rare condition characterized by brain dysfunction)

Commercial Effective: 07/01/21

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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: a type of blood disorder)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
D. You will NOT use Tavalisse concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])
E. You meet ONE of the following:
    1. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
    2. You have a platelet count of less than 50 x 10^9/L AND a prior bleeding event

RENEWAL CRITERIA

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

A. You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Tavalisse) OR a decrease in bleeding events
C. You will NOT use Tavalisse concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

Commercial Effective: 10/01/24

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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 (a type of headache)
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (at least 15 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

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FREMANEZUMAB-VFRM

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 (a type of headache)
B. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
C. You meet ONE of the following:
    1. You have experienced a decrease in migraine or headache frequency of at least 2 days per month with Ajovy therapy
    2. You have experienced a decrease in migraine severity with Ajovy therapy
    3. You have experienced a decrease in migraine duration (length of time) with Ajovy therapy

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Commercial Effective: 07/01/24

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FUTIBATINIB

Generic	Brand				
FUTIBATINIB	LYTGOBI				

GUIDELINES FOR USE

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

A. You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
B. You are 18 years of age or older
C. You have been previously treated for unresectable, locally advanced or metastatic iCCA
D. You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements
E. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting Lytgobi and at the recommended scheduled times

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Commercial Effective: 11/14/22

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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 will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
    4. You have tried ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, 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 will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
    4. You have tried ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
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

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:**
    1. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
    2. You meet ONE of the following:
        a. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
        b. You have experienced a reduction in migraine severity with Emgality therapy
        c. 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: 04/15/24

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GANAXOLONE

Generic	Brand				
GANAXOLONE	ZTALMY				

GUIDELINES FOR USE

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

A. You have seizures
B. You are 2 years of age or older
C. Your seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD: a type of genetic disorder)

Commercial Effective: 10/01/22

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GEFITINIB

Generic	Brand			
GEFITINIB	IRESSA, GEFITINIB			

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 to other parts of the body)
B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a gene) as detected by an FDA (Food and Drug Administration)-approved test
C. You will NOT be using Iressa (gefitinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

Commercial Effective: 05/22/23

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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: 04/10/21

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GIVINOSTAT

Generic	Brand				
GIVINOSTAT HYDROCHLORIDE	DUVYZAT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

RENEWAL CRITERIA

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

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat
C. **If you are currently ambulatory (can walk), approval also requires:**
    1. You have shown improvement since starting Duvyzat, as measured by a standard set of ambulatory or functional status measures (such as 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
D. **If you are currently non-ambulatory (cannot walk), approval also requires:**
    1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since starting Duvyzat, as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

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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

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

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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:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in your blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Mavyret concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)
H. You will NOT use Mavyret concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

I. **If you are treatment naive (no prior treatment), approval also requires ALL of the following:**
   1. You meet ONE of the following:
      a. You do not have cirrhosis (liver damage or scarring)
      b. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
      c. You received a liver transplant (replaced your liver)
      d. You received a kidney transplant (replaced your kidney)
   2. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa or Harvoni, if you have genotype 1, 4, 5, or 6 infection, OR you had an intolerance or contraindication to the preferred medication: Epclusa, if you have genotype 2 or 3 infection

J. **If you are treatment-experienced (failed prior treatment) and prior therapy did not contain an NS5A inhibitor, approval also requires ONE of the following:**
   1. You have genotype 1, 2, 4, 5, or 6 infection, and you have compensated cirrhosis (a condition where there is liver damage and scarring without major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) or you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
   2. You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]), and you do not have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
   3. You have genotype 3 infection, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

K. **If you are treatment-experienced (failed prior treatment), approval also requires ALL of the following:**
   1. You meet ONE of the following:
      a. You are less than 18 years of age AND had prior treatment with an interferon
      b. You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir]), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
      c. You have failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
      d. You have failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
      e. You have failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
      f. You are less than 18 years of age, have genotype 3, AND you had prior treatment with an interferon
   2. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa or Harvoni, if you have genotype 1, 4, 5, or 6 infection, OR you had an intolerance or contraindication to the preferred medication Epclusa, if you have genotype 2 or 3 infection

L. Mavyret will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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GLP-1 AGONIST

Generic	Brand				
EXENATIDE MICROSPHERES	BYDUREON BCISE				
EXENATIDE	BYETTA				
TIRZEPATIDE	MOUNJARO				
SEMAGLUTIDE	OZEMPIC, RYBELSUS				
DULAGLUTIDE	TRULICITY				
LIRAGLUTIDE	VICTOZA, LIRAGLUTIDE				

GUIDELINES FOR USE

Our guideline named **GLP-1 AGONIST (Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza [liraglutide])** requires the following rule(s) be met for approval:

A. You have type 2 diabetes (a disorder with high blood sugar)
B. Your diagnosis of type 2 diabetes is confirmed by medical records OR chart notes

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Commercial Effective: 09/01/24

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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 (UCD: a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
C. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
D. Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
E. You do NOT have a deficiency (low level) of N-acetylglutamate synthetase (NAGS: a type of enzyme) or acute hyperammonemia (sudden and short-term increase in ammonia levels to a critical level)
F. You have tried or have a contraindication to (harmful for you to use) Buphenyl (sodium phenylbutyrate)

RENEWAL CRITERIA

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

A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
B. You had a clinical benefit compared to baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

Commercial Effective: 07/01/24

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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 have tried a prescription strength aluminum chloride product (such as Drysol)
D. You will NOT use Qbrexza concurrently (at the same time) with other topical anticholinergics indicated for primary axillary hyperhidrosis (such as Sofdra [sofpironium bromide])

Commercial Effective: 08/01/24

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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:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), 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 or have a contraindication to methotrexate
   5. You meet ONE of the following:
      a. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

D. **If you have moderate to severe ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   5. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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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GOLIMUMAB - SQ

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index a type of disease evaluation tool) score while on therapy
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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.

Commercial Effective: 10/01/24

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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:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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GUSELKUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 10/14/24

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

Generic	Brand				
MORPHINE SULFATE	MORPHINE SULFATE				
OXYCODONE HCL	OXYCODONE HCL				

GUIDELINES FOR USE

Our guideline named **HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (morphine sulfate, oxycodone hydrochloride)** requires the following rule(s) be met for approval:

A. You have pain severe enough to require opioid analgesic and for which alternative treatments are inadequate
B. You meet ONE of the following:
    1. You are enrolled in hospice OR you are receiving palliative care or end-of-life care
    2. You meet ALL of the following:
        a. You have previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
        b. You have trouble swallowing opioid tablets, capsules, or large volumes of liquid

Commercial Effective: 10/01/21

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HYDROCORTISONE

Generic	Brand				
HYDROCORTISONE	ALKINDI SPRINKLE				

GUIDELINES FOR USE

Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:

A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
B. You are less than 18 years of age
C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

Commercial Effective: 04/01/21

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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

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Commercial Effective: 03/04/22

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IBREXAFUNGERP

Generic	Brand				
IBREXAFUNGERP CITRATE	BREXAFEMME				

GUIDELINES FOR USE

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

A. The request is for ONE of the following:
   1. Treatment of vulvovaginal candidiasis (VVC: vaginal yeast infection)
   2. Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC: repeated vaginal yeast infection)

B. **If you are using Brexafemme for the treatment of vulvovaginal candidiasis, approval also requires:**
   1. You are a post-menarchal (you have started having your period) female
   2. You have tried or have a contraindication to (harmful for) oral fluconazole AND an intravaginal azole (type of drug that is inserted into the vagina and used to treat yeast infections such as terconazole cream)

C. **If you are using Brexafemme for the reduction in the incidence of recurrent vulvovaginal candidiasis, approval also requires:**
   1. You are a post-menarchal (you have started having your period) female
   2. You have tried or have a contraindication to (harmful for) oral fluconazole (you had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
   3. You are NOT currently on oteseconazole for RVVC
   4. You meet ONE of the following:
      a. You have not previously received Brexafemme AND you had 3 or more episodes of RVVC in the past 12 months
      b. You have been previously treated with Brexafemme and meet ALL of the following:
         i. You have successfully completed a course of Brexafemme for prevention of RVVC
         ii. You are either being treated or have just completed treatment for a new recurrence of VVC

Commercial Effective: 04/01/23

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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 ONE of the following:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   3. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   4. Chronic graft versus host disease (cGVHD: a type of immune disorder)

B. **If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older

C. **If you have chronic graft versus host disease, approval also requires:**
   1. You are 1 year of age or older
   2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   3. You will NOT use Imbruvica concurrently (at the same time) with Jakafi (ruxolitinib) or Rezurock (belumosudil)

Note: Requests for Imbruvica (ibrutinib) 560 mg tablet will not be approved. This strength does not have a Food and Drug Administration (FDA)-approved indication.

Commercial Effective: 10/01/24

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ICATIBANT

Generic	Brand			
ICATIBANT ACETATE	FIRAZYR, SAJAZIR, ICATIBANT ACETATE			

GUIDELINES FOR USE

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy doctor or immune system doctor) or hematologist (blood doctor)
D. Your diagnosis is confirmed by complement testing (a type of lab test)
E. The requested medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
F. The requested medication will NOT be used concurrently (at the same time) with other acute treatments for HAE attacks (such as Berinert, Ruconest, Kalbitor)

Commercial Effective: 08/01/22

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IDELALISIB

Generic	Brand			
IDELALISIB	ZYDELIG			

GUIDELINES FOR USE

Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
A. You have relapsed chronic lymphocytic leukemia (CLL: a type of blood cancer)
B. Zydelig will be used in combination with rituximab

Commercial Effective: 04/01/22

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ILOPROST

Generic	Brand				
ILOPROST TROMETHAMINE	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: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
    1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
    2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
    3. Oral cGMP stimulator (such as Adempas [riociguat])
    4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Commercial Effective: 11/25/24

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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)

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IMIQUIMOD

Generic	Brand				
IMIQUIMOD 2.5% or 3.75%	ZYCLARA				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Actinic keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the full face or balding scalp
   2. External genital or perianal (around the anus) warts

B. **If you have actinic keratosis of the full face or balding scalp, approval also requires:**
   1. You are 18 years of age or older
   2. You are immunocompetent (healthy immune system)
   3. You had a trial of TWO generic topical agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

C. **If you have external genital or perianal warts, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication (harmful for) to generic imiquimod 5% topical cream

Commercial Effective: 06/12/23

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IMMUNE GLOBULIN - CUTAQUIG

Generic	Brand				
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG				

GUIDELINES FOR USE

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

A. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

Commercial Effective: 07/01/24

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IMMUNE GLOBULIN - CUVITRU

Generic	Brand				
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU				

GUIDELINES FOR USE

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

A. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

Commercial Effective: 07/01/24

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IMMUNE GLOBULIN - HIZENTRA

Generic	Brand				
IMMUN GLOB G(IGG)/PRO/IGA 0-50	HIZENTRA				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Primary immunodeficiency disease (genetic disease where the immune system is weak)
   2. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

Commercial Effective: 07/01/24

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IMMUNE GLOBULIN - HYQVIA

Generic	Brand				
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA				

GUIDELINES FOR USE

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

1. You have ONE of the following:
   A. Primary immunodeficiency disease (genetic disease where the immune system is weak)
   B. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

Commercial Effective: 07/01/24

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IMMUNE GLOBULIN - IV/SQ

Generic	Brand				
IMMUN GLOB G(IGG)/GLY/IGA OV50	GAMMAGARD LIQUID				
IMMUNE GLOBUL G/GLY/IGA AVG 46	GAMMAKED, GAMUNEX-C				

GUIDELINES FOR USE

Our guideline named **IMMUNE GLOBULIN - IV/SQ (Gammagard Liquid, Gammaked, Gammunex-C**) requires the following rule(s) be met for approval:

A. **For subcutaneous (SQ) injection, approval requires:**
   1. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

B. **For intravenous (IV) injection, approval requires:**
   1. You have ONE of the following:
      a. Primary immunodeficiency disease (genetic disease where the immune system is weak)
      b. Immune (idiopathic) thrombocytopenic purpura (a type of blood disorder)
      c. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
      d. Multifocal motor neuropathy (a nerve disorder with increasing muscle weakness)
      e. Kawasaki syndrome (inflammation in the walls of blood vessels in the body)
      f. B-cell chronic lymphocytic leukemia (blood and bone marrow cancer of immune cells) with hypogammaglobulinemia (low levels of immunoglobulins)
      g. Autoimmune hemolytic anemia (body destroys red blood cells more rapidly than it produces them)
      h. Pure red cell aplasia (bone marrow stops making red blood cells)
      i. Guillain-Barre syndrome (immune system attacks the nerves)
      j. Myasthenia gravis (a type of chronic autoimmune disorder)
      k. Autoimmune Graves' ophthalmopathy (a type of eye disease)
      l. Cytomegalovirus-induced pneumonitis (lung tissue inflammation caused by a virus) related to a solid organ transplant
      m. Prevention of bacterial infection in an HIV (human immunodeficiency virus: an immune system disease caused by a virus)- infected child
      n. Reduction of secondary infections in pediatric HIV infections
      o. Dermatomyositis (a type of muscle and skin disorder) or polymyositis (a type of inflammatory muscle disease)

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

p. Autoimmune uveitis (birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
q. Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
r. IgM (immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (a type of nerve damage)
s. Stiff-man syndrome (a nerve disorder with increasing muscle stiffness [rigidity] and repeated episodes of painful muscle spasms)
t. Neonatal sepsis (blood infection in infants)
u. Rotaviral enterocolitis (severe diarrhea among infants and young children)
v. Toxic shock syndrome (a life-threatening complication of certain bacterial infections)
w. Enteroviral meningoencephalitis (inflammation of the brain and surrounding tissues caused by a virus)
x. Toxic epidermal necrolysis or Stevens-Johnson syndrome (types of serious bacterial skin infections)
y. 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

2. If the request is for Gammaked or Gammunex-C, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gammaplex, Gammagard S-D, Gammagard Liquid, Octagam, Panzyga, Privigen

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Commercial Effective: 07/01/24

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IMMUNE GLOBULIN - XEMBIFY

Generic	Brand				
IMMUNE GLOBULIN, GAMMA(IGG)KLHW	XEMBIFY				

GUIDELINES FOR USE

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

A. You have primary immunodeficiency disease (genetic disease where the immune system is weak)

Commercial Effective: 07/01/24

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INAVOLISIB

Generic	Brand				
INAVOLISIB	ITOVEBI				

GUIDELINES FOR USE

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

A. You have locally advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
C. Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
D. Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
E. You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

Commercial Effective: 11/11/24

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INFLIXIMAB-DYYB - SQ

Generic	Brand				
INFLIXIMAB-DYYB	ZYMFENTRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Zymfentra will be used following treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   4. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   5. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   6. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

(Initial criteria continued on the next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Zymfentra will be used following treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   4. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   5. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   6. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

C. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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.

Commercial Effective: 10/01/24

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INGENOL

Generic	Brand				
INGENOL MEBUTATE	PICATO				

GUIDELINES FOR USE

Do not approve requests for Picato gel.

(NOTE: Picato discontinued due to safety concerns and increased risk of cancer.)

Commercial Effective: 10/01/21

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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 ONE of the following:
   1. Type 1 diabetes mellitus (a disorder with high blood sugar)
   2. Type 2 diabetes mellitus (a disorder with high blood sugar)

B. **If you have type 1 diabetes mellitus, approval also requires:**
   1. You are 18 years of age or older
   2. You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
   3. Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)
   4. You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev

C. **If you have type 2 diabetes mellitus, approval also requires:**
   1. You are 18 years of age or older
   2. You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
   3. You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
   4. Your prescriber has indicated that you are physically unable to or unwilling to use injectable insulin

NOTE: Afrezza will NOT be approved if you have any of the following conditions: chronic lung disease (type of long-term lung disease), active lung cancer, currently in diabetic ketoacidosis (condition where body breaks down fat too fast), you are currently smoking or you quit smoking within the past 6 months.

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INHALED INSULIN

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Type 1 diabetes mellitus (a disorder with high blood sugar)
   2. Type 2 diabetes mellitus (a disorder with high blood sugar)

B. **If you have type 1 diabetes, renewal also requires:**
   1. You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
   2. Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)
   3. Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)

C. **If you have type 2 diabetes, renewal also requires:**
   1. You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
   2. Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)

Commercial Effective: 09/01/24

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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 with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Amvuttra
G. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (*transthyretin*) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

RENEWAL CRITERIA

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

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
C. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

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INSULIN PUMPS

Generic	Brand				
SUBCUTANEOUS INSULIN PUMP	T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, TANDEM MOBI SYSTEM, MINIMED 670G, MINIMED 770G, MINIMED 780G, MINIMED 630G				

GUIDELINES FOR USE

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

A. The requested insulin pump is prescribed by or 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)

(Criteria continued on next page)

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

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 6 years of age or older
I. **If you are requesting the Tandem Mobi System, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 6 years of age or older
J. **If you are requesting the MiniMed 670G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 7 years of age or older
K. **If you are requesting the MiniMed 770G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 2 years of age or older
L. **If you are requesting the MiniMed 780G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 7 years of age or older
M. **If you are requesting the MiniMed 630G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 14 years of age or older

Commercial Effective: 10/01/24

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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 the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic hepatitis C (type of liver inflammation)
   2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
   3. Condylomata acuminate (genital warts)
   4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
   5. Chronic hepatitis B (type of liver inflammation)
   6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
   7. Malignant melanoma (serious type of skin cancer)
   8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
   9. Follicular lymphoma (type of lymphatic system cancer)
   10. Angioblastoma (certain blood-vessel tumors of the brain)
   11. Carcinoid (cancer) tumor
   12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
   13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)
   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)

(Initial criteria continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of 50 IU/mL or higher
   3. The requested medication will be used with ribavirin or you have a contraindication (harmful for)
   4. You had a trial of or contraindication (harmful for) to peginterferon alfa-2a or peginterferon alfa-2b

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 have chronic hepatitis C (type of liver inflammation), renewal also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. If you already received 24 weeks or more of interferon treatment, your HCV (hepatitis C virus) RNA level (amount of virus in your blood) is undetectable (less than 50 IU/mL) at 24 weeks

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Commercial Effective: 06/15/22

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INTERFERON FOR MS - AVONEX

Generic	Brand				
INTERFERON BETA-1A	AVONEX, AVONEX PEN				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - AVONEX** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 11/01/22

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INTERFERON FOR MS - BETASERON

Generic	Brand				
INTERFERON BETA-1B	BETASERON				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - BETASERON** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 11/01/22

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INTERFERON FOR MS - EXTAVIA

Generic	Brand				
INTERFERON BETA-1B	EXTAVIA				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - EXTAVIA** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Avonex (interferon beta-1a), Copaxone/Glatiramer/Glatopa (glatiramer), fingolimod, Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a/albumin), Betaseron (interferon beta-1b), dimethyl fumarate, Mavenclad (cladribine), Mayzent (siponimod), Vumerity (diroximel fumarate), Aubagio (teriflunomide), Kesimpta (ofatumumab), Zeposia (ozanimod)
(PLEASE NOTE: these medications may also require prior authorization)

Commercial Effective: 07/01/24

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INTERFERON FOR MS - PLEGRIDY

Generic	Brand				
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - PLEGRIDY** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 11/01/22

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INTERFERON FOR MS - REBIF

Generic	Brand				
INTERFERON BETA-1A/ALBUMIN	REBIF, REBIF REBIDOSE				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - REBIF** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 11/01/22

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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IPTACOPAN

Generic	Brand				
IPTACOPAN HCL	FABHALTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)

B. **If you have paroxysmal nocturnal hemoglobinuria, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
   4. You will NOT use Fabhalta concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

C. **If you have primary immunoglobulin A nephropathy, approval also requires:**
   1. You are 18 years of age or older
   2. You are at risk of rapid disease progression (such as urine protein-to-creatinine ratio [UPCR: test that measures the amount of protein in urine] of at least 1.5 g/g)

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IPTACOPAN

RENEWAL CRITERIA

NOTE: For the diagnosis of primary immunoglobulin A nephropathy (IgAN), please refer to the Initial Criteria section.

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

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [type of protein in red blood cells] levels) compared to baseline
C. You will NOT use Fabhalta concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

Commercial Effective: 10/01/24

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ISAVUCONAZONIUM

Generic	Brand				
ISAVUCONAZONIUM	CRESEMBA				

GUIDELINES FOR USE

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

A. You meet ONE of the following:
   1. This is a request for continuation of therapy after you were started on Cresemba in the hospital
   2. You have invasive aspergillosis (a type of fungal infection)
   3. You have invasive mucormycosis (a type of fungal infection)

B. **If you have invasive aspergillosis, approval also requires:**
   1. You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
   2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You have tried or have a contraindication to (harmful for you to use) voriconazole

C. **If you have invasive mucormycosis, approval also requires:**
   1. You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
   2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

Commercial Effective: 10/12/24

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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 have **ONE** of the following fungal infections:
   1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary (affecting the lungs) disease and disseminated, nonmeningeal (not affecting spinal cord and brain membranes) histoplasmosis
   3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with an infectious disease specialist

D. You had a previous trial of a generic itraconazole formulation

E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

Commercial Effective: 07/01/21

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 have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (an abnormal change) in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
E. You have ONE of the following mutations (abnormal change) in the CFTR (cystic fibrosis transmembrane conductance regulator) gene:

711+3A→G	*F311del*	*I148T*	*R75Q*	*S589N*
2789+5G→A	*F311L*	*I175V*	*R117C*	*S737F*
3272-26A→G	*F508C*	*I807M*	*R117G*	*S945L*
3849+10kbC→T	*F508C; S1251N*	*I1027T*	*R117H*	*S977F*
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W*	*R170H*	*S1251N*
A455E	*G178R*	*L320V*	*R347H*	*S1255P*
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q*	*T1053I*
D110H	*G551D*	*L1480P*	*R553Q*	*V232D*
D192G	*G551S*	*M152V*	*R668C*	*V562I*
D579G	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
D1152H	*G1069R*	*P67L*	*R1070Q*	*W1282R*
D1270N	*G1244E*	*Q237E*	*R1070W*	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D*	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N*	
E831X	*H1375P*	*R74W*	*S549R*	

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IVACAFTOR

RENEWAL CRITERIA

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

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated a less than expected decline in forced expiratory volume (FEV1: amount of air exhaled in one second)
    2. You have improved, maintained, or demonstrated a less than expected decline in body mass index (BMI: a tool for evaluating body fat)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 07/01/24

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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 ONE of the following diagnoses:
   1. Newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
   2. Relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or has not responded to treatment)
   3. Relapsed or refractory myelodysplastic syndromes (MDS: a type of blood cancer that has returned or has not respond to treatment)
   4. Locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)

B. **If you have a new diagnosis of acute myeloid leukemia, approval also requires:**
   1. Tibsovo will be used in combination with azacitidine or as monotherapy (one drug treatment)
   2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
      a. You are 75 years of age or older
      b. You are 18 years of age or older AND have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)

C. **If you have relapsed or refractory acute myeloid leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have relapsed or refractory myelodysplastic syndromes, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

E. **If you have locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has an isocitrate dehydrogenase-1 (IDH1) mutation (type of enzyme mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Your cancer has been previously treated

Commercial Effective: 11/13/23

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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 SYRINGE, TALTZ AUTOINJECTOR			

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:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Taltz
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

(Initial criteria continued on next page)

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

(Initial criteria continued on next page)

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Taltz
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the ody) levels above the upper limit of normal
      c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

E. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 08/12/24

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LACOSAMIDE

Generic	Brand				
LACOSAMIDE	MOTPOLY XR				

GUIDELINES FOR USE

Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)

B. **If you have primary-onset seizures, approval also requires:**
   1. You weigh at least 50 kilograms (110 pounds)
   2. You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
   3. You are not able to tolerate lacosamide immediate-release

C. **If you have primary generalized tonic-clonic seizures, approval also requires:**
   1. You weigh at least 50 kilograms (110 pounds)
   2. Motpoly XR will be used as adjunctive (add-on) treatment
   3. You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
   4. You are not able to tolerate lacosamide immediate-release

Commercial Effective: 07/22/24

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LACTIC ACID/CITRIC/POTASSIUM

Generic	Brand				
LACTIC ACID/CITRIC/POTASSIUM	PHEXXI				

Please refer to CONTRACEPTIVE ZERO COST SHARE OVERRIDE section below if the request is also for zero copay override.

GUIDELINES FOR USE

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

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

CONTRACEPTIVE ZERO COST SHARE OVERRIDE CRITERIA

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

A. The request is for ONE of the following:
   1. A generic contraceptive agent
   2. A single-source brand (SSB) contraceptive agent that has no preferred generic agents or therapeutically equivalent products available
   3. A multi-source brand (MSB) contraceptive agent
B. **If the request is for a single-source brand or multi-source brand contraceptive medication, approval also requires ONE of the following:**
   1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   2. You have tried or have a documented medical contraindication (harmful for) to two preferred medications (or one if only one agent is available)
   3. Your doctor has provided documentation confirming that the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

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LANADELUMAB-FLYO

Generic	Brand			
LANADELUMAB-FLYO	TAKHZYRO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 2 years of age or older
C. Takhzyro will be used for the prevention of hereditary angioedema attacks
D. Your diagnosis is confirmed by complement testing (a type of blood test)
E. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
F. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for HAE (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

RENEWAL CRITERIA

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

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema attacks (reductions in attack frequency or attack severity) compared to baseline
C. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for HAE (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat])

Commercial Effective: 10/01/24

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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: 04/10/21

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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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LAZERTINIB

Generic	Brand				
LAZERTINIB MESYLATE	LAZCLUZE				

GUIDELINES FOR USE

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

A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
B. You are 18 years of age or older
C. Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw)
D. Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

Commercial Effective: 09/09/24

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LEBRIKIZUMAB-LBKZ

Generic	Brand				
LEBRIKIZUMAB-LBKZ	EBGLYSS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
E. You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
F. You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
H. You will NOT use Ebglyss concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), Cibinqo (abrocitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
I. You have tried or have a contraindication to (harmful for you to use) TWO of the following:
    1. High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    2. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
    3. Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole])
    4. Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
    5. Phototherapy (a type of light therapy)

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LEBRIKIZUMAB-LBKZ

RENEWAL CRITERIA

Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for renewal:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You have shown improvement while on Ebglyss
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm)
D. You will NOT use Ebglyss concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), Cibinqo (abrocitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 10/14/24

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L-GLUTAMINE

Generic	Brand			
GLUTAMINE (L-GLUTAMINE)	ENDARI, GLUTAMINE (L-GLUTAMINE)			

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 (a type of blood disorder)
B. You are 5 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. The patient had a trial of or contraindication to (harmful for you to use) hydroxyurea
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year (a sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered [injected into the vein] narcotic [a class of drugs used to treat pain] or parenterally administered ketorolac, the occurrence of chest syndrome, priapism [prolonged erection of penis], or splenic sequestration [sickle-shaped blood cells trapped in spleen])
    2. You are having sickle-cell associated symptoms (such as pain or anemia [a type of blood condition]) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

RENEWAL CRITERIA

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

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

Commercial Effective: 08/05/24

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LEDIPASVIR/SOFOSBUVIR

Generic	Brand			
LEDIPASVIR/ SOFOSBUVIR	HARVONI, LEDIPASVIR/ SOFOSBUVIR			

GUIDELINES FOR USE

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

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have genotype 1, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You will NOT use Harvoni concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. John's wort)
G. You will NOT use Harvoni concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
H. If the request is for Harvoni 45mg/200mg pellets, approval also requires:
    1. You are unable to swallow tablets
I. **If you are treatment-naïve (no prior treatment), approval also requires ONE of the following:**
    1. You do not have cirrhosis (liver damage and scarring)
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
    3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
    4. You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, AND Harvoni will be used with ribavirin
    5. You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

(Criteria continued on next page)

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

J. **If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:**
   1. You do not have cirrhosis (liver damage and scarring) AND were previously treated with a peginterferon alfa-based regimen
   2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) AND were previously treated with a peginterferon alfa-based regimen
   3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
   4. You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
   5. You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
   6. You have decompensated cirrhosis, failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
   7. You have received a liver transplant, have decompensated cirrhosis, AND Harvoni will be used with ribavirin

K. Harvoni will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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Commercial Effective: 07/22/24

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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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LENACAPAVIR

Generic	Brand				
LENACAPAVIR SODIUM	SUNLENCA				

GUIDELINES FOR USE

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

A. You have human immunodeficiency virus type 1 (HIV-1: a type of immune disorder)
B. You are 18 years of age or older
C. You are treatment-experienced
D. You have a multidrug resistant (not responding to treatment) HIV-1 infection and have failed your current antiretroviral regimen (HIV treatment) due to resistance, intolerance (side effects), or safety considerations

Commercial Effective: 06/01/23

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LENALIDOMIDE

Generic	Brand				
LENALIDOMIDE	REVLIMID, LENALIDOMIDE				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Multiple myeloma (MM: a type of blood cancer)
   2. Anemia (a type of blood condition) due to a myelodysplastic syndrome (MDS: a type of blood cancer)
   3. Mantle cell lymphoma (MCL: a type of blood cell)
   4. Follicular lymphoma (FL: a type of blood cancer)
   5. Marginal zone lymphoma (MZL: a type of blood cancer)

B. **If you have multiple myeloma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as induction, consolidation, or maintenance treatment for multiple myeloma

C. **If you have anemia due to a myelodysplastic syndrome, approval also requires:**
   1. You are 18 years of age or older
   2. Your myelodysplastic syndrome is associated with a deletion 5q abnormality (a type of gene mutation)

D. **If you have mantle cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have relapsed or progressed (disease has returned or worsened) after two prior therapies, one of which included Velcade (bortezomib)

E. **If you have follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously been treated for follicular lymphoma
   3. The requested medication will be used in combination with a rituximab product (a type of cancer drug)

F. **If you have marginal zone lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously been treated for marginal zone lymphoma
   3. The requested medication will be used in combination with a rituximab product (a type of cancer drug)

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LENIOLISIB

Generic	Brand				
LENIOLISIB PHOSPHATE	JOENJA				

GUIDELINES FOR USE

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

A. You have activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS: a type of mutation that impacts the immune system)
B. You are 12 years of age or older

Commercial Effective: 07/01/23

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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 (DTC: cancer cells look/act like normal thyroid cells)
   2. Advanced renal cell cancer (RCC: kidney cancer)
   3. Unresectable hepatocellular carcinoma (HCC: liver cancer that cannot be removed by surgery)
   4. Advanced endometrial carcinoma (EC: 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 (re-appears in the same spot) or metastatic (has spread to other parts of the body)
   2. Your thyroid cancer is progressive (getting worse)
   3. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

C. **If you have advanced renal cell cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used as first-line treatment in combination with pembrolizumab (Keytruda)
      b. Lenvima is used in combination with everolimus AND 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 unresectable hepatocellular carcinoma, approval also requires:**
   1. Lenvima is being used as a first-line treatment

E. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. Your cancer is mismatch repair proficient (pMMR), as determined by a Food and Drug Administration (FDA)-approved test, or is not microsatellite instability-high (MSI-H) (markers of the cancer to help determine what treatment options are appropriate)
   3. You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
   4. You are not a candidate for curative surgery or radiation

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LETERMOVIR

Generic	Brand				
LETERMOVIR	PREVYMIS				

GUIDELINES FOR USE

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

A. The request is for ONE of the following:
   1. Prophylaxis (prevention) of cytomegalovirus (CMV: a type of virus) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT: cells transplanted from a matching donor) recipient
   2. Prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient

B. **If the request is for prophylaxis of cytomegalovirus infection and disease in an allogeneic hematopoietic stem cell transplant recipient, approval also requires:**
   1. You are 6 months of age or older AND weigh at least 6 kilograms (13.2 pounds)
   2. You are a CMV-seropositive recipient [R+] of an allogeneic HSCT
   3. Prevymis will be started between Day 0 and Day 28 post-transplant (before or after engraftment [a type of transplant])
   4. You meet ONE of the following:
      a. You are NOT at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 100 days post (after)-transplant
      b. You are at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 200 days post (after)-transplant

C. **If the request is for prophylaxis of cytomegalovirus disease in a kidney transplant recipient, approval also requires:**
   1. You are 12 years of age or older AND weigh at least 40 kilgrams (88 pounds)
   2. You are a kidney transplant recipient at high risk (donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
   3. Prevymis will be started between Day 0 and Day 7 post (after)-transplant
   4. You will not receive Prevymis beyond 200 days post-transplant

Commercial Effective: 09/23/24

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LEUPROLIDE

Generic	Brand				
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   3. Central precocious puberty (CPP: early sexual development in girls and boys)

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

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

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LEUPROLIDE

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or advanced prostate cancer, please refer to the Initial Criteria section.

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

A. You have central precocious puberty (CPP: early sexual development in girls and boys)
B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
C. You have NOT reached the actual age which corresponds to your current pubertal age

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Commercial Effective: 07/01/24

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LEUPROLIDE-ELIGARD

Generic	Brand				
LEUPROLIDE ACETATE	ELIGARD				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

Commercial Effective: 01/23/23

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LEVACETYLLEUCINE

Generic	Brand				
LEVACETYLLEUCINE	AQNEURSA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)

RENEWAL CRITERIA

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

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You have shown disease improvement or a reduction in disease progression

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Commercial Effective: 10/14/24

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LEVAMLODIPINE

Generic	Brand				
LEVAMLODIPINE MALEATE	CONJUPRI, LEVAMLODIPINE MALEATE				

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 or have a contraindication (harmful for) to TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine)
D. You have tried or have a contraindication (harmful for) to TWO other antihypertensive agents in another class (such as hydrochlorothiazide, lisinopril, losartan)

Commercial Effective: 06/01/22

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LEVETIRACETAM

Generic	Brand				
LEVETIRACETAM	SPRITAM				

GUIDELINES FOR USE

Our guideline named **LEVETIRACETAM (Spritam)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Partial-onset seizures (type of seizure)
   2. Myoclonic seizures in juvenile myoclonic epilepsy (type of seizure in childhood)
   3. Primary generalized tonic-clonic seizures (type of seizure)

B. **If you have partial-onset seizures, approval also requires:**
   1. You are 4 years of age or older
   2. You are unable to swallow levetiracetam tablets
   3. You had a trial of levetiracetam oral solution

C. **If you have myoclonic seizures in juvenile myoclonic epilepsy, approval also requires:**
   1. You are 12 years of age or older
   2. Spritam will be used as adjunctive (add-on) therapy
   3. You are unable to swallow levetiracetam tablets
   4. You had a trial of levetiracetam oral solution

D. **If you have primary generalized tonic-clonic seizures, approval also requires:**
   1. You are 6 years of age or older
   2. Spritam will be used as adjunctive (add-on) therapy
   3. You are unable to swallow levetiracetam tablets
   4. You had a trial of levetiracetam oral solution

Commercial Effective: 04/01/23

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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:

H. You have Parkinson's disease (a nerve system disorder that affects movement)
I. 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
J. You are currently being treated with carbidopa/levodopa
K. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
L. You are **NOT** currently taking more than 1600mg of levodopa per day
M. 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:

C. You have Parkinson's disease (a nerve system disorder that affects movement)
D. 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.

Commercial Effective: 07/01/20

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LEVOKETOCONAZOLE

Generic	Brand				
LEVOKETOCONAZOLE	RECORLEV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have Cushing's syndrome (a type of hormone disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. You are not a candidate for surgery or surgery has not been curative
E. You have tried or have a contraindication (harmful for) to oral ketoconazole

RENEWAL CRITERIA

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

A. You have Cushing's syndrome (a type of hormone disorder)
B. You continue to have improvement of Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
C. You continue to tolerate treatment with Recorlev

Commercial Effective: 02/01/22

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LEVOTHYROXINE-ERMEZA

Generic	Brand				
LEVOTHYROXINE SODIUM	ERMEZA				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer
B. You had a trial and failure (drug did not work) of Thyquidity
C. You had a trial and failure (drug did not work) of generic levothyroxine tablets
D. You are unable to swallow levothyroxine tablets or capsules
E. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)

Commercial Effective: 04/01/23

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LEVOTHYROXINE-TIROSINT

Generic	Brand				
LEVOTHYROXINE SODIUM	TIROSINT, LEVOTHYROXINE				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. **If you have congenital or acquired hypothyroidism, approval also requires:**
   1. You are 6 years of age or older
   2. You have tried and failed (drug did not work) generic levothyroxine tablets
   3. There is a rationale (reason) for NOT using generic levothyroxine tablets

C. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. You are 6 years of age or older
   2. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   3. You have tried and failed (drug did not work) generic levothyroxine tablets
   4. There is a rationale (reason) for NOT using generic levothyroxine tablets

Commercial Effective: 07/01/24

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LEVOTHYROXINE-TIROSINT-SOL

Generic	Brand				
LEVOTHYROXINE SODIUM	TIROSINT-SOL				

GUIDELINES FOR USE

Our guideline named **LEVOTHYROXINE-TIROSINT-SOL** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. **If you have congenital or acquired hypothyroidism, approval also requires:**
   1. You have tried and failed (drug did not work) Thyquidity
   2. You have tried and failed (drug did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets
   3. There is a rationale (reason) for not using Thyquidity and generic levothyroxine tablets

C. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. Tirosint-Sol will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   2. You have tried and failed (drug did not work) Thyquidity
   3. You have tried and failed (drug did not work) or have a contraindication to (harmful for you to use) generic levothyroxine tablets
   4. There is a rationale (reason) for not using Thyquidity and generic levothyroxine tablets

Commercial Effective: 07/01/24

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LIRAGLUTIDE - SAXENDA

Generic	Brand				
LIRAGLUTIDE	SAXENDA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The request is for weight loss OR weight loss management
B. You are 12 years of age or older
C. You have evidence of active enrollment in an exercise and caloric reduction program, which may include other optional weight loss/behavioral modification programs
D. You will NOT use Saxenda concurrently (at the same time) with a GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Ozempic [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
F. **If you are 12 to 17 years of age, approval also requires:**
    1. You have a body weight greater than 60 kg
    2. You have an initial BMI corresponding to 30 kg/m(2) for adults

CONTINUED ON NEXT PAGE

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LIRAGLUTIDE - SAXENDA

RENEWAL CRITERIA

Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for renewal:

A. The request is for weight loss OR weight loss management
B. You are 12 years of age or older
C. **If you are 18 years of age or older, approval also requires:**
    1. You have achieved or maintained at least a 5 percent weight loss of baseline body weight after 16 weeks of treatment
D. **If you are 12 to 17 years of age, approval also requires:**
    1. You have achieved or maintained at least a 1 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after at least 12 weeks of treatment on your maximally tolerated dose

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Commercial Effective: 10/01/24

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LIXISENATIDE

Generic	Brand				
LIXISENATIDE	ADLYXIN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
You have type 2 diabetes (a disorder with high blood sugar)
You are 18 years of age or older
Adlyxin is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
You have tried metformin (immediate-release/ extended-release), a sulfonylurea (such as glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above medications (such as glipizide-metformin, pioglitazone-metformin)
You have tried a preferred GLP-1 agonist (such as Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
Adlyxin will NOT be used together with a DPP-4 inhibitor (such as Januvia [sitagliptin], alogliptin, saxagliptin)

RENEWAL CRITERIA

Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
You have type 2 diabetes (a disorder with high blood sugar)
Adlyxin is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
Adlyxin will NOT be used together with a DPP-4 inhibitor (such as Januvia [sitagliptin], alogliptin, saxagliptin)

Commercial Effective: 01/01/24

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LOFEXIDINE

Generic	Brand			
LOFEXIDINE HCL	LUCEMYRA, LOFEXIDINE HCL			

GUIDELINES FOR USE

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

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

Commercial Effective: 09/09/24

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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)

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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 have ONE of the following diagnoses:
   1. Hodgkin's lymphoma (type of immune system cancer)
   2. Primary and metastatic brain tumors (tumor that has spread to other parts of body)

B. **If you have primary and metastatic brain tumors, approval also requires:**
   1. You have previously received appropriate surgical and/or radiotherapeutic procedures
   2. The requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine)

Commercial Effective: 01/01/23

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LONAFARNIB

Generic	Brand				
LONAFARNIB	ZOKINVY				

GUIDELINES FOR USE

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

A. You have Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies (rare genetic disorders that cause premature aging in children)
B. You are 1 year of age or older
C. You have a body surface area (BSA) of 0.39 meters squared or more
D. **If you have processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:**
    1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
    2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

Commercial Effective: 04/01/21

LONAPEGSOMATROPIN-TCGD

Generic	Brand				
LONAPEGSOMATROPIN-TCGD	SKYTROFA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 1 to 17 years of age and weigh at least 11.5 kilograms (25.3 pounds)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
E. You meet ONE of the following:
    1. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
    2. Your height velocity is less than the 25th percentile for your age
    3. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
F. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 1 to 17 years of age and weigh at least 11.5 kilograms (25.3 pounds)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
E. You meet ONE of the following:
    1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
    2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
F. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 02/26/24

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LORCASERIN

Generic	Brand				
LORCASERIN HCL	BELVIQ, BELVIQ XR				

GUIDELINES FOR USE

Do not approve requests for Belviq or Belviq XR.

(**NOTE:** Safety concerns [increased risk of cancer] have prompted market withdrawal of Belviq and Belviq XR.)

Commercial Effective: 10/01/21

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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 metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme) - positive which is shown by an FDA (Federal and Drug Administration) approved test

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Commercial Effective: 04/10/21

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LOTEPREDNOL

Generic	Brand				
LOTEPREDNOL ETABONATE	EYSUVIS				

GUIDELINES FOR USE

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

A. You have dry eye disease
B. You previously tried one generic loteprednol ophthalmic product **AND** one non-loteprednol ophthalmic (eye) corticosteroid (such as fluorometholone, dexamethasone, prednisolone) unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 04/01/21

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LOTILANER

Generic	Brand				
LOTILANER	XDEMVY				

GUIDELINES FOR USE

Our guideline named **LOTILANER (Xdemvy)** requires the following rule(s) be met for approval:
A. You have Demodex blepharitis (a type of inflammatory eye condition)
B. You are 18 years of age or older

Commercial Effective: 12/01/23

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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 have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 year of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You are homozygous (have two copies of the same gene) for the F508del-CFTR (cystic fibrosis transmembrane conductance regulator: a type of gene) mutation (abnormal change)

RENEWAL CRITERIA

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

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated a less than expected decline in FEV1 (forced expiratory volume: amount of air exhaled in one second)
    2. You have improved, maintained, or demonstrated a less than expected decline in BMI (body mass index: a tool for evaluating body fat)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 07/01/24

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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 (a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (a doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (a type of hormone doctor), or surgeon
D. You have chronic liver disease
E. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
F. You have a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
G. You are not receiving other thrombopoietin receptor agonist therapy, such as avatrombopag, romiplostim, eltrombopag

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Commercial Effective: 04/01/22

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MACITENTAN

Generic	Brand				
MACITENTAN	OPSUMIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Commercial Effective: 07/01/24

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MACITENTAN-TADALAFIL

Generic	Brand				
MACITENTAN/ TADALAFIL	OPSYNVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age or older
C. You have WHO Functional Class II-III symptoms (a way to classify how limited physical activity)
D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
E. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
F. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
G. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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MACITENTAN-TADALAFIL

RENEWAL CRITERIA

Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
B. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
C. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Commercial Effective: 07/01/24

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MARALIXIBAT

Generic	Brand				
MARALIXIBAT CHLORIDE	LIVMARLI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
   2. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])
   3. You meet ONE of the following:
      a. You are 3 months to 11 months of age
      b. You are 12 months of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Bylvay (odevixibat)

C. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. You are 12 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Bylvay (odevixibat)

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MARALIXIBAT

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. **If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
   2. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

C. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

Commercial Effective: 08/12/24

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MARIBAVIR

Generic	Brand				
MARIBAVIR	LIVTENCITY				

GUIDELINES FOR USE

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

A. You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
B. You are 12 years of age or older
C. You are refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

Commercial Effective:01/01/22

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MARSTACIMAB-HNCQ

Generic	Brand				
MARSTACIMAB-HNCQ	HYMPAVZI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

B. **If you have hemophilia A (congenital factor VIII deficiency), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Your hemophilia is without factor VIII inhibitors (a type of protein)
   4. Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   5. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

C. **If you have hemophilia B (congenital factor IX deficiency), approval also requires**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Your hemophilia is without factor IX inhibitors (a type of protein)
   4. Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   5. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

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MARSTACIMAB-HNCQ

RENEWAL CRITERIA

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

B. **If you have hemophilia A (congenital factor VIII deficiency), renewal also requires:**
   1. Your hemophilia is without factor VIII inhibitors (a type of protein)
   2. You have shown a clinical benefit compared to baseline (before starting Hympavzi)
   3. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

C. **If you have hemophilia B (congenital factor IX deficiency), renewal also requires:**
   1. Your hemophilia is without factor IX inhibitors (a type of protein)
   2. You have shown a clinical benefit compared to baseline (before starting Hympavzi)
   3. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

Commercial Effective: 11/25/24

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MAVACAMTEN

Generic	Brand				
MAVACAMTEN	CAMZYOS				

GUIDELINES FOR USE

NITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You are 18 years of age or older
C. You have New York Heart Association (NYHA) class II-III (classification system for heart failure) symptoms
D. You have a left ventricular outflow track gradient (a predictor of heart failure and cardiovascular death) of 50 mmHg or higher
E. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
F. You had a trial of or contraindication (harmful for) to beta-blockers (such as metoprolol, carvedilol) AND non-dihydropyridine calcium channel blockers (such as verapamil, diltiazem)

RENEWAL CRITERIA

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

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You have experienced continued clinical benefit (such as reduction of symptoms, NYHA classification improvement)

Commercial Effective:06/01/22

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MAVORIXAFOR

Generic	Brand				
MAVORIXAFOR	XOLREMDI				

GUIDELINES FOR USE

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

A. You have WHIM (warts, hypogammaglobulinemia [low levels of antibodies in the blood], infections, and myelokathexis [low white blood cell count]) syndrome (a rare genetic disorder of the immune system)
B. You are 12 years of age or older

Commercial Effective: 05/27/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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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. You have ONE of the following:
   1. *Enterobius vermicularis* (pinworm) infection
   2. *Trichuris trichiura* (whipworm) infection
   3. *Ascaris lumbricoides* (roundworm) infection
   4. *Ancylostoma duodenale* (hookworm) infection
   5. *Necator americanus* (hookworm) infection

B. **If you have *Enterobius vermicularis* (pinworm) infection, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) over-the-counter (OTC) pyrantel pamoate

C. **If you have Trichuris trichiura (whipworm) or Ascaris lumbricoides (roundworm) infection, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza)

D. **If you have Ancylostoma duodenale (hookworm) or Necator americanus (hookworm) infection, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza) OR over-the-counter (OTC) pyrantel pamoate

Commercial Effective: 07/01/24

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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

Generic	Brand			
MECHLORETHAMINE HCL	VALCHLOR			

GUIDELINES FOR USE

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

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

Commercial Effective: 04/10/23

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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:

B. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
   3. 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)
   4. Hypereosinophilic syndrome (HES: a type of blood disorder)

C. **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 in consultation with a physician specializing in pulmonary (relating to lungs/breathing) or allergy medicine
   3. You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
   4. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   5. You will NOT use Nucala concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 (interleukin-5) biologic (such as Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

(Initial criteria continued on next page)

CONTINUED ON NEXT PAGE

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

D. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. Nucala will be used as add-on maintenance treatment
   4. You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
   5. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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

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

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MEPOLIZUMAB

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 ONE of the following:
   3. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   4. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)

B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Nucala concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 (interleukin-5) biologic (such as Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Nucala)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Nucala)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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METHOTREXATE - JYLAMVO

Generic	Brand				
METHOTREXATE	JYLAMVO				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Acute lymphoblastic leukemia (ALL: a type of blood cancer)
   2. Mycosis fungoides (cutaneous T-cell lymphoma) (a type of blood cancer affecting the skin)
   3. Relapsed or refractory non-Hodgkin lymphoma (a type of blood cancer that has returned or did not respond to treatment)
   4. Rheumatoid arthritis (a type of joint condition)
   5. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   6. Severe psoriasis (a type of skin condition)

B. **If you have acute lymphoblastic leukemia, approval also requires:**
   1. Jylamvo will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
   2. You cannot swallow generic methotrexate tablets

C. **If you have mycosis fungoides (cutaneous T-cell lymphoma), approval also requires:**
   1. You are 18 years of age or older
   2. You cannot swallow generic methotrexate tablets

D. **If you have relapsed or refractory non-Hodgkin lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Jylamvo will be used as part of a metronomic combination chemotherapy regimen (a type of therapy to treat cancer where lower doses are given over a long period to reduce side effects)
   3. You cannot swallow generic methotrexate tablets

E. **If you have rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. You cannot swallow generic methotrexate tablets

F. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You cannot swallow generic methotrexate tablets

G. **If you have severe psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. You cannot swallow generic methotrexate tablets

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METHOXY PEG-EPOETIN BETA

Generic	Brand				
METHOXY PEG-EPOETIN BETA	MIRCERA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METHOXY PEG-EPOETIN BETA (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 the preferred medication: Retacrit (epoetin alfa-epbx)
    2. Your hemoglobin level (type of blood test) is less than 10g/dL
C. **If you are between 3 months and 17 years of age, approval also requires:**
    1. You are changing from another erythropoiesis-stimulating agent (ESA, such as Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after your hemoglobin level (type of blood test) has been stabilized with the ESA

RENEWAL CRITERIA

Our guideline named **METHOXY PEG-EPOETIN BETA (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, renewal also requires ONE of the following:**
    1. Your hemoglobin level (type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
    2. Your hemoglobin level is less than 11g/dL if you are on dialysis
    3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions
    4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions
C. **If you are between 3 months and 17 years of age, renewal also requires ONE of the following:**
    1. Your hemoglobin level (type of blood test) is less than 12g/dL
    2. Your hemoglobin level has reached 12g/dL and your dose is being or has been reduced/interrupted to decrease the need for blood transfusions

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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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METHYLTESTOSTERONE

Generic	Brand				
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST, METHYLTESTOS-TERONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (not due to disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, approval also requires:
   1. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate
   3. If you are 40 years of age or older, approval also requires that your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate

(Initial criteria continues on next page)

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

D. **If you are a female with metastatic breast cancer, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate
   2. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

E. **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 the treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

RENEWAL CRITERIA

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (not due to disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:**
   1. You have NOT received more than two 6-month courses of testosterone replacement therapy

(Renewal criteria continues on next page)

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

D. **If you are a female with metastatic breast cancer, renewal also requires:**
   1. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

E. **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 the treatment of gender dysphoria may be approved

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Commercial Effective: 04/01/24

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METOCLOPRAMIDE

Generic	Brand				
METOCLOPRAMIDE HCL	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 (a disorder from high blood sugar that causes delayed emptying of food from the stomach)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) metoclopramide ODT (orally disintegrating tablet)

Commercial Effective: 08/01/24

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METRONIDAZOLE

Generic	Brand				
METRONIDAZOLE	LIKMEZ				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Trichomoniasis (a type of infection caused by a parasite)
   2. Acute intestinal amebiasis (amoebic dysentery: a type of infection of the intestines) OR amebic liver abscess (a collection of pus in the liver caused by a parasite)
   3. Serious infections caused by susceptible anaerobic bacteria, such as *Bacteroides* species, *Clostridium* species, *Peptococcus* species (infections caused by types of bacteria that can be treated with Likmez)

B. You have tried or have a contraindication to (harmful for you to use) generic metronidazole tablets

C. You are unable to swallow metronidazole tablets

D. **For the treatment of trichomoniasis or serious infections caused by susceptible anaerobic bacteria, approval also requires:**
   1. You are 18 years of age or older

Commercial Effective: 02/01/24

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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: a type of blood cancer)
   2. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
   3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
   4. Mast cell leukemia (MCL: type of blood cell cancer)

B. **If you have newly diagnosed acute myeloid leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration (FDA)-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

C. **If you have aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia, approval also requires:**
   1. You are 18 years of age or older

Commercial Effective: 04/01/22

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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: a type of hormone disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your diagnosis is confirmed by ONE of the following:
    1. 24-hour urine free cortisol (a type of test that measures the amount of cortisol in the urine) (at least 2 or more tests to confirm)
    2. Overnight 1mg dexamethasone test (a type of diagnostic test)
    3. Late-night salivary cortisol (a type of test that measures the amount of cortisol in the saliva at night) (at least 2 or more tests to confirm)
E. Your hypercortisolism (high levels of cortisol) is NOT due to chronic glucocorticoids (long-term use of a class of drugs that consists of steroids, such as prednisone)
F. You also have type 2 diabetes mellitus (a disorder with high blood sugar) OR glucose intolerance (a condition that results in high blood sugar)
G. You have failed surgical treatment (surgery did not work) for Cushing's syndrome OR you are NOT a candidate for surgery

RENEWAL CRITERIA

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

A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
B. You continue to have improvement of glucose tolerance or stable glucose tolerance (such as reduced hemoglobin A1C level [a type of lab test], improved fasting glucose)
C. You continue to tolerate Korlym
D. You are NOT a candidate for surgery OR have failed surgery (surgery did not work) for Cushing's syndrome

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Commercial Effective: 02/12/24

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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 Fabry disease (a rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
D. You have an amenable (responsive) galactosidase alpha (GLA: a type of gene) gene 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 or likely pathogenic)
E. You will NOT use Galafold concurrently (taking at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
F. You are symptomatic OR have evidence of injury from globotriaosylceramide (GL-3: a type of fat) 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: a type of imaging lab), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. **If you are a female, approval also requires:**
    1. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing
H. **If you are a male patient, approval also requires ONE of the following:**
    1. You do not have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing

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MIGALASTAT

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 will NOT use Galafold concurrently (taking at the same time) with another Fabry disease therapy (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
    1. Symptoms such as pain, hypohidrosis/anhidrosis (little to no sweat), exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas (dark red/purple raised spots), abnormal cornea, tinnitus (ringing in the ears), or hearing loss
    2. Imaging such as brain/cardiac MRI (magnetic resonance imaging: a type of imaging lab), DEXA (test to measure bone density), or renal (kidney) ultrasound
    3. Laboratory or histological (viewed by microscope) testing such as globotriaosylceramide (GL-3: a type of fat) in plasma/urine, renal biopsy

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Commercial Effective: 10/01/23

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MIGLUSTAT-OPFOLDA

Generic	Brand				
MIGLUSTAT	OPFOLDA				

GUIDELINES FOR USE

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

A. You have late-onset Pompe disease (a type of genetic disorder) due to lysosomal acid alpha-glucosidase (GAA: a type of enzyme) deficiency
B. You are 18 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. You are not improving on your current enzyme replacement therapy (ERT) such as Lumizyme (alglucosidase alfa)
E. Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

Commercial Effective: 12/01/23

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MIGLUSTAT-ZAVESCA

Generic	Brand				
MIGLUSTAT	ZAVESCA, YARGESA, MIGLUSTAT				

GUIDELINES FOR USE

Our guideline named **MIGLUSTAT-ZAVESCA (Yargesa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mild to moderate type 1 Gaucher disease (a type of genetic condition)
   2. Niemann-Pick disease type C (NPC: a type of genetic condition)

B. **If you have mild to moderate type 1 Gaucher disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as monotherapy (one drug treatment)
   3. Enzyme replacement therapy (a type of treatment) is not a therapeutic option for you (due to reasons such as allergy, hypersensitivity [allergic reaction], poor access to veins)

C. **If you have Niemann-Pick disease type C, approval also requires:**
   1. The requested medication will be used in combination with Miplyffa (arimoclomol)

Commercial Effective: 10/14/24

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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 have Leishmaniasis (type of parasite disease) with ONE of the following types of infection:
   1. Visceral leishmaniasis (affects your organs) caused by *Leishmania donovani (type of parasite)*
   2. Cutaneous leishmaniasis (affects your skin layers) caused by any of the following types of parasites:
      a. *Leishmania braziliensis*
      b. *Leishmania guyanensis*
      c. *Leishmania panamensis*
   3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by *Leishmania braziliensis*

B. Species identification must be confirmed via ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
   1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
   2. Culture medium
   3. Polymerase chain reaction (lab method to make copies of genes)
   4. Serologic testing (testing your blood and body fluids such as rK39 Rapid Test)

Commercial Effective: 11/01/21

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MINOCYCLINE MICROSPHERES (NSA)

Generic	Brand			
MINOCYCLINE HCL MICROSPHERES	ARESTIN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an oral health care professional
D. You do NOT have a history of minocycline or tetracycline sensitivity or allergy
E. You do NOT have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. Arestin will be administered by an oral health professional
G. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. Arestin will NOT be used for an acutely abscessed periodontal pocket (infection with pus-filled pocket)
I. Arestin will NOT be used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus (a disorder with high blood sugar)
    2. Chemotherapy (a type of drug used to treat cancer)
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. Arestin will NOT be used in the regeneration (reconstruction) of alveolar bone (part of the bone that has tooth sockets), either in preparation for or in conjunction (together) with the placement of endosseous (dental) implants or in the treatment of failing implants

RENEWAL CRITERIA

Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:

A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
B. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

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

B. The medication is prescribed by or recommended by a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management specialist)

C. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment

D. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

E. 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

F. 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

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Commercial Effective: 07/01/20

MIRIKIZUMAB-MRKZ

Generic	Brand				
MIRIKIZUMAB-MRKZ	OMVOH				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for approval:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
D. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
E. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
F. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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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MIRIKIZUMAB-MRKZ

RENEWAL CRITERIA

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for renewal:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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.

Commercial Effective: 10/01/24

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MITAPIVAT

Generic	Brand				
MITAPIVAT SULFATE	PYRUKYND				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for approval:
A. You have hemolytic anemia (a type of blood condition)
B. You are 18 years of age or older
C. You have pyruvate kinase (PK: a type of enzyme) deficiency

RENEWAL CRITERIA

Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for renewal:
A. You have hemolytic anemia (a type of blood condition)
B. You have pyruvate kinase (PK: a type of enzyme) deficiency
C. You have had clinical benefit while on Pyrukynd

Commercial Effective: 07/01/22

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MOBOCERTINIB

Generic	Brand				
MOBOCERTINIB SUCCINATE	EXKIVITY				

GUIDELINES FOR USE

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

A. You have locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or has spread to other parts of the body) non-small cell lung cancer (NSCLC: type of lung cancer)
B. You are 18 years of age or older
C. You have epidermal growth factor receptor (EGFR) exon 20 insertion mutations (type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
D. Your disease progressed (disease has gotten worse) on or after platinum-based chemotherapy such as cisplatin, carboplatin, oxaliplatin

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Commercial Effective: 01/01/22

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MOMELOTINIB

Generic	Brand				
MOMELOTINIB DIHYDROCHLORIDE	OJJAARA				

GUIDELINES FOR USE

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

A. You have intermediate or high-risk myelofibrosis (MF: a type of blood cancer), including primary MF (MF that developed on its own) or secondary MF (MF that developed from another blood disorder, such as post-polycythemia vera [PV: a type of blood cancer] or post-essential thrombocythemia [ET: a type of blood disease])
B. You are 18 years of age or older
C. You have anemia (a type of blood condition)

Commercial Effective: 12/01/23

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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

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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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MYCOPHENOLATE

Generic	Brand				
MYCOPHENOLATE MOFETIL	MYHIBBIN				

GUIDELINES FOR USE

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

A. The request is for the prophylaxis (prevention) of an organ rejection
B. You have a history of an allogeneic (from a donor) kidney, heart or liver transplant
C. Myhibbin will be used in combination with other immunosuppressants (such as cyclosporine)
D. You have tried or have a contraindication to (harmful for you to use) generic mycophenolate mofetil tablets
E. You are unable to swallow mycophenolate mofetil tablets

Commercial Effective: 07/01/24

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NAFARELIN

Generic	Brand				
NAFARELIN ACETATE	SYNAREL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Moderate to severe pain from endometriosis (condition affecting the uterus)
   3. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have moderate to severe pain from endometriosis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   3. Your diagnosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   4. You have tried or have a contraindication to (harmful for you to use) a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   5. You are NOT using Synarel concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide])
   6. You have NOT received more than 6 months of treatment with Synarel per lifetime

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

(Initial criteria continued on next page)

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

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

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or pain from endometriosis, please refer to the Initial Criteria section.

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

A. You have central precocious puberty (CPP: early sexual development in girls and boys)
B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
C. You have NOT reached the actual age which corresponds to your current pubertal age

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Commercial Effective: 07/01/24

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NALTREXONE - BUPROPION

Generic	Brand				
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for approval:

A. The request is for weight loss OR weight loss management
B. You are 18 years of age or older
C. You have evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program
D. You meet ONE of the following:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

RENEWAL CRITERIA

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for renewal:

A. The request is for weight loss OR weight loss management
B. You have achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets two times a day)

Commercial Effective: 07/01/24

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NEDOSIRAN

Generic	Brand				
NEDOSIRAN SODIUM	RIVFLOZA				

GUIDELINES FOR USE

Our guideline named **NEDOSIRAN (Rivfloza)** requires the following rule(s) be met for approval:
You have primary hyperoxaluria type 1 (PH1: a type of rare genetic disorder)
You are 9 years of age and older
You have relatively preserved kidney function (such as an estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] of at least 30mL/min/1.73m(2))

Commercial Effective: 02/12/24

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NEMOLIZUMAB-ILTO

Generic	Brand				
NEMOLIZUMAB-ILTO	NEMLUVIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for approval:

A. You have prurigo nodularis (PN: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
D. You have multiple pruriginous lesions (wounds)
E. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
F. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Dupixent (dupilumab)
G. You will NOT use Nemluvio concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), Cibinqo (abrocitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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NEMOLIZUMAB-ILTO

RENEWAL CRITERIA

Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for renewal:

A. You have prurigo nodularis (PN: a type of skin condition)
B. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
C. You will NOT use Nemluvio concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), Cibinqo (abrocitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 09/01/24

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NERATINIB

Generic	Brand			
NERATINIB MALEATE	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 requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
   4. The medication is being requested within 2 years of completing the last trastuzumab dose

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: 04/10/21

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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 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 in chronic phase or accelerated phase, approval also requires:**
   1. If you are 18 years of age or older, you are resistant or intolerant to prior therapy including Gleevec (imatinib)
   2. If you are 1 to 17 years of age, you are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You had a mutational analysis prior to initiation of therapy AND Tasigna is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile

Commercial Effective: 04/01/22

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NIMODIPINE SOLUTION

Generic	Brand			
NIMODIPINE	NYMALIZE, NIMODIPINE			

GUIDELINES FOR USE

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:

A. You have a history of a subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain)
B. You are 18 years of age or older
C. Your SAH is from a ruptured intracranial berry aneurysm (part of blood vessel in your brain has expanded and burst) within the past 21 days
D. You are unable to swallow nimodipine oral capsules

Commercial Effective: 10/14/24

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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, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
   4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
   5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50 percent at baseline

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You have systemic sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40 percent of predicted value
   6. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   3. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities such as infection, heart failure)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45 percent of predicted value

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NINTEDANIB

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: 08/28/23

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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. Advanced epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)
   2. Recurrent (returning) epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum based-chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to platinum-based chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*
   4. Your cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
   5. The requested medication will be used as monotherapy (used by itself for treatment)
   6. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)
   7. You have completed at least two lines of platinum-based chemotherapy (such as cisplatin, carboplatin)

Commercial Effective: 10/01/23

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NIRAPARIB-ABIRATERONE

Generic	Brand				
NIRAPARIB-ABIRATERONE	AKEEGA				

GUIDELINES FOR USE

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

A. 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)
B. Your cancer has a deleterious (harmful) or suspected deleterious BRCA mutation (BRCAm: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
C. Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
D. You meet ONE of the following:
    1. You had a bilateral orchiectomy (both testicles have been surgically removed)
    2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
    3. Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Commercial Effective: 12/01/23

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NIROGACESTAT

Generic	Brand				
NIROGACESTAT HYDROBROMIDE	OGSIVEO				

GUIDELINES FOR USE

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

A. You have progressing desmoid tumors (noncancerous growths in the connective tissue)
B. You are 18 years of age or older
C. You require systemic treatment (therapy that targets the entire body)

Commercial Effective: 05/06/24

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NITISINONE

Generic	Brand			
NITISINONE	ORFADIN, NITYR, NITISINONE			

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 in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg, 20 mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have tried or have a contraindication (harmful for) to generic nitisinone capsules

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

Commercial Effective: 04/17/23

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NITROFURANTOIN SUSPENSION

Generic	Brand				
NITROFURANTOIN	FURADANTIN, NITROFURANTOIN				

GUIDELINES FOR USE

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

A. You have a urinary tract infection (UTI: a type of infection)
B. Your infection is caused by susceptible (can be treated with the drug) strains of *Escherichia coli, enterococci, Staphylococcus aureus, Klebsiella* or *Enterobacter* species (types of bacteria)
C. You have tried or have a contraindication to (harmful for you to use) nitrofurantoin capsules
D. You are not able to swallow nitrofurantoin capsules

Commercial Effective: 08/01/24

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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 (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210 if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. You do not have cirrhosis (liver damage and scarring) OR you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)

D. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

E. You do NOT have complete biliary obstruction (blockage of bile ducts)

F. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])

G. You meet ONE of the following:
   1. Ocaliva will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Ocaliva will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

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OBETICHOLIC ACID

RENEWAL CRITERIA

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

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
B. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Ocaliva
C. You have NOT developed complete biliary obstruction (blockage of bile ducts)
D. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])

Commercial Effective: 09/16/24

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OCTREOTIDE - IM

Generic	Brand				
OCTREOTIDE ACETATE, MI-SPHERES	SANDOSTATIN LAR DEPOT, OCTREOTIDE ACETATE, MI-SPHERES				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   2. You had an inadequate response (drug did not work) to surgery or radiotherapy (another type of cancer treatment), OR surgery or radiotherapy is not an option for you
   3. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:**
   1. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, approval also requires:**
   1. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

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OCTREOTIDE - IM

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, renewal also requires:**
   1. You have had a reduction, normalization, or maintenance of insulin-like growth factor (IGF-1: a type of hormone) levels based on your age and gender
   2. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, renewal also requires:**
   1. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, renewal also requires:**
   1. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms

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Commercial Effective: 10/14/24

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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 - ORAL (Mycapssa)** requires the following rule(s) be met for approval:

A. You have acromegaly (a type of hormone disorder)
B. Therapy is prescribed by or in consultation with an endocrinologist (doctor who specializes in hormones)
C. You have responded to and tolerated treatment with octreotide or lanreotide

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for renewal:

A. You have acromegaly (a type of hormone disorder)
B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
C. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

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Commercial Effective: 10/01/22

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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 type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)
   4. You had an inadequate response to or cannot be treated with **ALL** of the following:
      i. Surgical resection (removal by surgery)
      ii. Pituitary irradiation (radiation therapy directed at the pituitary)
      iii. Bromocriptine mesylate at maximally tolerated doses

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma), approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

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OCTREOTIDE - SQ

GUIDELINES FOR USE (CONTINUED)

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 type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, renewal also requires:**
   1. You have a reduction, normalization or maintenance of insulin-like growth factor (IGF-1: a growth hormone) levels based on age and gender
   2. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor OR profuse watery diarrhea associated with vasoactive intestinal peptide tumor, renewal also requires:**
   1. You have an improvement or sustained remission (symptoms have gone away) of clinical symptoms

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Commercial Effective: 10/01/22

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ODEVIXIBAT

Generic	Brand				
ODEVIXIBAT	BYLVAY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

B. **If you have pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. You are 3 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
   3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

C. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
   1. You are 12 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
   3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

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ODEVIXIBAT

RENEWAL CRITERIA (CONTINUED)

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

A. You have ONE of the following:
   1. Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

B. **If you have pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

C. **If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
   2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

Commercial Effective: 07/01/24

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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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OLANZAPINE/SAMIDORPHAN

Generic	Brand				
OLANZAPINE/ SAMIDORPHAN MALATE	LYBALVI				

GUIDELINES FOR USE

Our guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Schizophrenia (type of mental health disorder)
   2. Bipolar I disorder (type of mood disorder)

B. **If you have schizophrenia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   3. You are at high risk for weight gain
   4. You have tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred brand medications: Vraylar, Rexulti

C. **If you have bipolar I disorder, approval also requires:**
   1. You are 18 years of age or older
   2. Lybalvi will be used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate, OR used as maintenance monotherapy treatment
   3. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   4. You are at high risk for weight gain
   5. You have tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred brand medications: Vraylar, Rexulti

Commercial Effective: 08/12/24

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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. Recurrent (returning) or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
   2. HER2 ((human epidermal growth factor receptor 2: a type of protein)-negative high risk early breast cancer (a type of breast cancer)
   3. HER2-negative metastatic breast cancer (a type of breast cancer that has spread to other parts of the body)
   4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
   5. Homologous recombination repair (HRR) gene-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
   6. BRCA-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   5. You meet ONE of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
      b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation) positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You are in complete or partial response to your most recent platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. You have completed at least two or more lines of platinum-based chemotherapy such as paclitaxel, docetaxel, cisplatin, carboplatin
   5. Lynparza will be used as monotherapy (used alone) for maintenance treatment

D. **If you have HER2-negative high risk early breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used as adjuvant (add-on) treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before main treatment or as add-on therapy such as doxorubicin, paclitaxel)

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   4. You meet ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and you have been treated with a prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered inappropriate for you

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GUIDELINES FOR USE (CONTINUED)

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (such as paclitaxel, docetaxel, cisplatin, carboplatin)

G. **If you have homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa or Zytiga)
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

H. **If you have BRCA-mutated metastatic castration-resistant prostate cancer, approval also requires, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used in in combination with abiraterone (Yonsa or Zytiga) AND prednisone or prednisolone
   3. Your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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OLUTASIDENIB

Generic	Brand				
OLUTASIDENIB	REZLIDHIA				

GUIDELINES FOR USE

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

A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation as detected by a Food and Drug Administration (FDA)-approved test

Commercial Effective: 04/01/23

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OMACETAXINE

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 or accelerated phase chronic myeloid leukemia (CML: type of blood cell cancer)
B. You are 18 years of age or older
C. You had a resistance or intolerance to TWO or more tyrosine kinase inhibitors (such as Gleevec, Sprycel, Tasigna, Bosulif, Iclusig)

Commercial Effective: 04/11/22

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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)

Commercial Effective: 07/01/20

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OMALIZUMAB

Generic	Brand				
OMALIZUMAB	XOLAIR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody that is produced by your immune system if you have an allergy) serum (blood) level of 30 IU/mL or higher
   5. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   6. You will NOT use Xolair concurrently (at the same time) with Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

(Initial criteria continued on next page)

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. Xolair will be used as add-on maintenance treatment
   4. You had a 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)
   5. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have an IgE-mediated food allergy, approval also requires:**
   1. You are 1 year of age or older
   2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Xolair
   3. You have an IgE (type of antibody that is produced by your immune system if you have an allergy) serum (blood) level of at least 30 IU/mL
   4. You have an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
   5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
   6. You have an active prescription for epinephrine auto-injector/injection while on Xolair
   7. You will NOT use Xolair concurrently (at the same time) with a peanut-specific immunotherapy (such as Palforzia)

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
   4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine] or Allegra [fexofenadine])

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OMALIZUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Xolair concurrently (at the same time) with Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Xolair)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline (before starting Xolair)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

D. **If you have an IgE-mediated food allergy, renewal also requires:**
   a. You have persistent IgE-mediated food allergy
   b. You have an active prescription for epinephrine auto-injector/injection while on Xolair
   c. You will NOT use Xolair concurrently (at the same time) with a peanut-specific immunotherapy (such as Palforzia)

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine] or Allegra [fexofenadine])

Commercial Effective: 07/01/24

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OMAVELOXOLONE

Generic	Brand				
OMAVELOXOLONE	SKYCLARYS				

GUIDELINES FOR USE

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

A. You have Friedreich's ataxia (a type of nervous system and movement disorder)
B. You are 16 years of age or older

Commercial Effective: 07/01/23

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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			

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 are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the use of an opioid and an antipsychotic medication together is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Commercial Effective: 01/01/25

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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 are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor agrees to proceed with the concurrent use (at the same time) of an opioid and a benzodiazepine for a clinically appropriate indication (reason)
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Commercial Effective: 01/01/25

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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 are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Commercial Effective: 01/01/25

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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 medications for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   2. You are enrolled in a hospice (end of life care)
   3. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   4. You have sickle cell disease (a type of blood disorder)
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your prescriber is aware that there is more than one provider prescribing opiates for you, AND you meet **TWO** of the following:
   1. Your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do NOT have a history of substance abuse or addiction
   5. Your prescriber has committed to monitoring the state's Prescription Monitoring Program to make sure your controlled substance history is consistent with prescribing record

Commercial Effective: 01/01/25

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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 are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that they are aware that you are concurrently receiving more than one long-acting opioid medication
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Commercial Effective: 01/01/25

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OPIOID-NAIVE CUMULATIVE DOSING (ONCD)

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID-NAIVE CUMULATIVE DOSING** allows approval of a higher quantity of an opioid medication if at least ONE of the following conditions is met:

- You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
- You are enrolled in hospice (end of life care)
- You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
- You have sickle cell disease (a type of blood disorder)
- You are not opioid naive (you have been consistently using opioid pain medications)
- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

If none of these conditions apply, BOTH of the following criteria must be met:

- The provider has indicated that your current level of opioid utilization (use) is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

Commercial Effective: 01/01/25

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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 meet at least **ONE** of the following conditions:

A. You are enrolled in hospice (end of life care)
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. You are NOT opioid naïve (you have been consistently using opioid pain medications)
F. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary
G. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

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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 are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the additional fill of the requested opioid medication is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Commercial Effective: 01/01/25

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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 of **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) at the pharmacy or by a prior authorization. The hard-stop threshold of **[enter hard stop threshold]**-mg morphine milligram equivalent (MME) is not overridable and requires a prior authorization.
An override will be provided if ONE (A or B) of the following rule(s) are met:

A. You meet ONE of the following conditions:
    1. You are receiving treatment for palliative care (treatment for comfort from symptoms)
    2. You have sickle cell disease (a type of blood disorder)
    3. You are enrolled in a hospice (end of life care)
    4. Your doctor is a pain management specialist
    5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only
B. Your physician confirms that the requested high dose is considered medically necessary.
    1. If the requested dose is lower than 300 MME, your prescriber must provide a maximum opioid threshold. If your prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding **[enter hard-stop threshold]**-mg morphine milligram equivalent (MME), the claim will be approved up to 25 percent greater than the previously approved MME.
    2. If the requested dose is equal to or greater than 300 MME, approval will be granted if you are stable on the dose.

Commercial Effective: 01/01/25

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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 are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you
E. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Commercial Effective: 01/01/25

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ORLISTAT

Generic	Brand				
ORLISTAT	XENICAL, ORLISTAT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ORLISTAT (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. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

RENEWAL CRITERIA

Our guideline named **ORLISTAT (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 18 years of age or older, approval also requires:**
    1. You have achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment
C. **If you are younger than 18 years of age, approval also requires:**
    1. You have achieved or maintained at least a 5 percent decrease from baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

Commercial Effective: 10/01/24

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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 (a type of hormone disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
E. You had a trial of or contraindication (harmful for) to oral ketoconazole

RENEWAL CRITERIA

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

A. You have Cushing's disease (a type hormone disorder)
B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
C. You continue to tolerate treatment with Isturisa

Commercial Effective: 08/01/23

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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 non-small cell lung cancer (NSCLC: a type of lung cancer)
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. Tagrisso will be used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor), and your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
    2. Your cancer is locally advanced and unresectable (stage III) (cancer that has spread to nearby tissue or lymph nodes and cannot be surgically removed), and you meet ALL of the following:
        a. Your disease has NOT worsened during or following concurrent (at the same time) or sequential (one after the other) platinum-based (such as cisplatin, carboplatin) chemoradiation therapy (a type of treatment that combines chemotherapy and radiation)
        b. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
    3. Your cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
        a. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
        b. Your tumor has an epidermal growth factor receptor (EGFR) T790M mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND your disease has worsened while on or after EGFR tyrosine kinase-inhibitor therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

(Criteria continued on next page)

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

4. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body), and you meet ALL of the following:
   a. Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (such as cisplatin, carboplatin)
   b. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

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Commercial Effective: 10/21/24

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OTESECONAZOLE

Generic	Brand					
OTESECONAZOLE	VIVJOA					

GUIDELINES FOR USE

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

A. You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
B. You are female
C. You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or you have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
D. You are NOT currently on ibrexafungerp for RVVC
E. **If you have not previously received Vivjoa, approval also requires:**
    1. You had 3 or more episodes of RVVC in the past 12 months
F. **If you have previously received Vivjoa, approval also requires:**
    1. You have successfully completed a course of Vivjoa for prevention of RVVC
    2. You are either being treated or have just completed treatment for a new recurrence of VVC

Commercial Effective: 04/01/23

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OXYMETAZOLINE

Generic	Brand				
OXYMETAZOLINE HCL/PF	UPNEEQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have blepharoptosis (drooping of the upper eyelid)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
D. You have been evaluated for surgical intervention
E. You had a trial of TWO ophthalmic alpha-adrenergic agonists (such as apraclonidine, tetrahydrozoline, naphazoline)

RENEWAL CRITERIA

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

D. You have blepharoptosis (drooping of the upper eyelid)
E. You continue to have benefit from Upneeq

Commercial Effective: 04/01/221

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OZANIMOD

Generic	Brand				
OZANIMOD	ZEPOSIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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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OZANIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

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

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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.

Commercial Effective: 10/01/24

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PACRITINIB

Generic	Brand				
PACRITINIB CITRATE	VONJO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
B. You are 18 years of age or older
C. You have a platelet count below 50,000/uL

RENEWAL CRITERIA

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

A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
B. You have shown symptom improvement by meeting ONE of the following:
   1. You have a spleen volume reduction of 35% or greater from baseline
   2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

Commercial Effective: 04/01/22

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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 breast cancer
B. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
C. **If you are using Ibrance in combination with an aromatase inhibitor (such as anastrozole, letrozole, exemestane), approval also requires:**
    1. Your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body)
    2. Ibrance will be used as initial endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen)
    3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
D. **If you are using Ibrance in combination with fulvestrant (Faslodex), approval also requires:**
    1. Your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body)
    2. Your disease has worsened after endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)
    3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
E. **If you are using Ibrance in combination with Itovebi (inavolisib) and fulvestrant (Faslodex), approval also requires:**
    1. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
    2. Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
    3. You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

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PALOPEGTERIPARATIDE

Generic	Brand				
PALOPEGTERIPARATIDE	YORVIPATH				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hypoparathyroidism (low levels of parathyroid hormone)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis (balance)
E. You have tried activated vitamin D (such as calcitriol) and calcium

RENEWAL CRITERIA

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

A. You have hypoparathyroidism (low levels of parathyroid hormone)
B. You are independent of or managed on a lowered dose of vitamin D and calcium supplements

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Commercial Effective: 09/23/24

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PALOVAROTENE

Generic	Brand				
PALOVAROTENE	SOHONOS				

GUIDELINES FOR USE

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

A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
B. You meet ONE of the following:
   1 You are female and 8 years of age or older
   2. You are male and 10 years of age or older

Commercial Effective: 12/01/23

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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)

Commercial Effective: 07/01/20

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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 level of potassium in the blood)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor) or cardiologist (a type of heart doctor)
D. Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia (high level of potassium in the blood)
E. You are NOT currently receiving dialysis (process of removing excess water, toxins from the blood)
F. You have tried ONE of the following to lower the risks for hyperkalemia (high level of potassium in the blood):
    1. You are not taking both an angiotensin converting enzyme inhibitor (ACE-I, such as lisinopril, benazepril) and an angiotensin receptor blocker (ARB, such as valsartan, losartan) at the same time
    2. You have lowered the dose of a renin-angiotensin-aldosterone system (RAAS) inhibitor (such as lisinopril, valsartan, spironolactone)
G. You meet ONE of the following:
    1. Your estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) is less than 30mL/min/1.73m^2, AND you have tried a loop diuretic (such as bumetanide, ethacrynic acid, furosemide, torsemide)
    2. Your estimated glomerular filtration rate (eGFR) is at least 30 mL/min/1.73m^2, AND you have tried a loop diuretic (such as bumetanide, ethacrynic acid, furosemide, torsemide) OR a thiazide diuretic (such as chlorthalidone, hydrochlorothiazide, metolazone)
H. If you are 18 years of age or older, you have tried Lokelma (sodium zirconium cyclosilicate)

Commercial Effective: 10/01/24

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PAZOPANIB

Generic	Brand			
PAZOPANIB HCL	VOTRIENT, PAZOPANIB HCL			

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: a type of kidney cancer)
   2. Advanced soft tissue sarcoma (STS: cancer that starts in soft tissues [muscle, tendons, fat, lymph vessels, blood vessels, nerves])

B. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older

C. **If you have advanced soft tissue sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received prior chemotherapy (a type of cancer therapy such as anthracycline treatment)
   3. You do NOT have adipocytic soft tissue sarcoma (STS: a type of fat cell cancer) or gastrointestinal stromal tumors (GIST: a type of digestive tumor)

Commercial Effective: 11/06/23

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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 an allergy to peanuts
B. You are 4 to 17 years of age
C. Therapy is prescribed by or in consultation with an allergist (allergy doctor) or immunologist (immune system doctor)
D. You have a clinical history of an allergic reaction to peanuts
E. Palforzia will be used together with a peanut-avoidance diet
F. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
G. You meet ONE of the following:
    1. If you have completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
    2. If you have NOT completed a purposeful food challenge: you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

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PEANUT ALLERGEN POWDER-DNFP

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 in consultation with an allergist (allergy doctor) or immunologist (immune system doctor)
C. Palforzia will be used together with a peanut-avoidance diet
D. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
E. You meet ONE of the following:
    1. If you have completed a purposeful food challenge (a type of test): you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
    2. If you have NOT completed a purposeful food challenge: you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

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Commercial Effective: 07/01/24

PEGCETACOPLAN - SQ

Generic	Brand				
PEGCETACOPLAN	EMPAVELI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
E. You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Ultomiris (ravulizumab-cwvz) or Soliris (eculizumab)
F. You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

RENEWAL CRITERIA

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

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (baseline is defined as your condition after treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
C. You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

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PEGFILGRASTIM

Generic	Brand				
PEGFILGRASTIM	NEULASTA, NEULASTA ONPRO				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM (Neulasta, Neulasta Onpro)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects the blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)
      b. You are requesting Neulasta Onpro AND you have a barrier to access (such as travel barriers, you are unable to return to the clinic for Neulasta injections)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 07/01/24

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PEGFILGRASTIM - APGF

Generic	Brand				
PEGFILGRASTIM-APGF	NYVEPRIA				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM - APGF (NYVEPRIA)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You will be using Nyvepria to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Commercial Effective: 07/01/23

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PEGFILGRASTIM - BMEZ

Generic	Brand				
PEGFILGRASTIM-BMEZ	ZIEXTENZO				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM - BMEZ (Ziextenzo)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You will be using Ziextenzo to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 07/01/23

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PEGFILGRASTIM - CBQV

Generic	Brand				
PEGFILGRASTIM-CBQV	UDENYCA, UDENYCA ONBODY				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM - CBQV (Udenyca, Udenyca Onbody)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects the blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)
      b. You are requesting Udenyca Onbody AND you have a barrier to access (such as travel barriers, you are unable to return to the clinic for Udenyca injections)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 07/01/24

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PEGFILGRASTIM-FPGK

Generic	Brand				
PEGFILGRASTIM-FPGK	STIMUFEND				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-FPGK (Stimufend)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You will be using Stimufend to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 07/01/23

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PEGFILGRASTIM-JMDB

Generic	Brand				
PEGFILGRASTIM-JMDB	FULPHILA				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM - JMDB (Fulphila)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You will be using Fulphila to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 07/01/23

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PEGFILGRASTIM-PBBK

Generic	Brand				
PEGFILGRASTIM-PBBK	FYLNETRA				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You will be using Fylnetra to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You had a trial of or contraindication (harmful for) to the preferred agent: Nyvepria (pegfilgrastim-apgf)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred agent: Nyvepria (pegfilgrastim-apgf)

Commercial Effective: 07/01/23

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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, PegIntron)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis B (a type of liver infection)
B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
C. **If you are between 3 to 17 years of age, approval also requires:**
   1. You do NOT have cirrhosis (liver damage)
   2. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive chronic hepatitis B
   3. You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)
D. **If you are 18 years of age or older, approval also requires:**
   1. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive or HBeAg-negative chronic hepatitis B
   2. You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

Note: Pegasys and PegIntron will not be approved for the treatment of hepatitis C.

Commercial Effective: 05/01/23

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PEGVALIASE-PQPZ

Generic	Brand			
PEGVALIASE-PQPZ	PALYNZIQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for approval:

A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
B. You are 18 years of age or older
C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
D. You have tried Kuvan (sapropterin)
E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

RENEWAL CRITERIA

Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for renewal:

A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
B. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

Commercial Effective: 04/10/23

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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 ONE of the following diagnoses:
   1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
   2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

B. **If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
   3. You have a fibroblast growth factor receptor 2 (FGFR2: a type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
   4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

C. **If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:**
   1. You are 18 years of age or older
   2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
   3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

Commercial Effective: 01/01/23

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PENICILLAMINE

Generic	Brand			
PENICILLAMINE	CUPRIMINE, PENICILLAMINE			
PENICILLAMINE	DEPEN, PENICILLAMINE			
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 ONE of the following diagnoses:
   1. Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
   2. Cystinuria (a type of genetic metabolic disorder)
   3. Active rheumatoid arthritis (a type of joint condition)

B. I**f you have Wilson's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   2. You have a Leipzig score of 4 or greater (a type of diagnostic score)
   3. You are willing to follow a diet avoiding high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   4. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine)

(Initial criteria continued on next page)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you have cystinuria, approval also requires:**
   1. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
   2. You have a daily cystine output greater than 300mg per 24 hours after urine cystine excretion testing
   3. You have failed to respond to an adequate trial of or has a contraindication (harmful for) to conventional therapy which includes ALL of the following:
      a. Increased fluid intake
      b. Modest reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   4. You have nephrolithiasis (kidney stones) and ONE of the following:
      a. Your kidney stone analysis shows that there is a presence of cystine (an amino acid)
      b. Your urine analysis shows that there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria and positive test results in the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body)
   5. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine) AND Thiola (tiopronin)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You do not have a history or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine)

E. **If you have an active prior authorization approval for Depen, D-Penamine** will be approved without meeting additional criteria during the period of Depen shortage.

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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 ONE of the following diagnoses:
   1. Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
   2. Cystinuria (a type of genetic metabolic disorder)
   3. Active rheumatoid arthritis (a type of joint condition)

B. **If you have Wilson's disease, approval also requires:**
   1. You have achieved a free serum copper of less than 10 mcg/dLl

C. **If you have cystinuria, approval also requires:**
   1. You have achieved a cystine excretion of less than 200 mg/day

D. **If you have active rheumatoid arthritis, approval also requires:**
   1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

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Commercial Effective: 05/08/23

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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: 04/10/21

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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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PHENTERMINE - TOPIRAMATE

Generic	Brand				
PHENTERMINE/ TOPIRAMATE	QSYMIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for approval:

A. The request is for weight loss OR weight loss management
B. You are 12 years of age or older
C. You have evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program
D. **If you are 18 years of age or older, approval also requires:**
    1. You meet ONE of the following:
        a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
        b. You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
E. **If you are 12 to 17 years of age, approval also requires:**
    1. Your initial body mass index (BMI: a tool for evaluating body fat) is in the 95th percentile or greater for age and sex

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PHENTERMINE - TOPIRAMATE

RENEWAL CRITERIA

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** 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 Qsymia 7.5/46mg, renewal also requires ONE of the following:**
   1. You are 18 years of age or older AND have achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment
   2. You are 12 to 17 years of age AND have achieved or maintained at least a 3 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after at least 3 months of treatment
C. **If you are requesting Qsymia 15/92mg, renewal also requires ONE of the following:**
   1. You are 18 years of age or older AND have achieved or maintained at least a 5 percent weight loss of baseline body weight after 3 months of treatment
   2. You are 12 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

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Commercial Effective: 10/01/24

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PILOCARPINE

Generic	Brand				
PILOCARPINE HCL	VUITY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PILOCARPINE (Vuity)** requires the following rule(s) be met for approval:
You have presbyopia (not able to focus on nearby objects)
You are 18 years of age or older
Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
You have tried or have a contraindication (harmful for) to generic pilocarpine ophthalmic (eye) solution
You will NOT use Vuity concurrently (at the same time) with another pilocarpine eyedrop

RENEWAL CRITERIA

Our guideline named **PILOCARPINE (Vuity)** requires the following rule(s) be met for renewal:
You have presbyopia (not able to focus on nearby objects)
You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
You will NOT use Vuity concurrently (at the same time) with another pilocarpine eyedrop
You continue to have benefit from Vuity

Commercial Effective: 01/01/24

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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, PIRFENIDONE			

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: a type of lung condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (a type of joint condition), radiation, sarcoidosis (a type of inflammatory disorder), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (HIV: a type of immune disorder), viral hepatitis (a type of liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air exhaled from lungs) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

RENEWAL CRITERIA

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

A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

Commercial Effective: 01/01/23

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PIRTOBRUTINIB

Generic	Brand				
PIRTOBRUTINIB	JAYPIRCA				

GUIDELINES FOR USE

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

You have ONE of the following:

- Relapsed or refractory mantle cell lymphoma (MCL: type of white blood cell cancer)
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (types of blood cancers)

If you have relapsed or refractory mantle cell lymphoma, approval also requires:

- You are 18 years of age or older
- You have previously received at least TWO lines of systemic therapy (treatment that targets the entire body) for mantle cell lymphoma, including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:

- You are 18 years of age or older
- You have previously received at least TWO prior lines of therapy (treatment that targets the entire body), including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib]) AND a BCL-2 inhibitor (B-cell lymphoma-2 inhibitor such as Venclexta [venetoclax])

Commercial Effective: 01/01/24

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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 with narcolepsy, approval also requires:**
   1. You have narcolepsy that is confirmed by **ONE** of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
   3. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have cataplexy with narcolepsy, approval also requires:**
   1. Wakix is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

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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
   3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep) from baseline

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Commercial Effective: 01/01/23

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PLASMINOGEN

Generic	Brand				
PLASMINOGEN HUMAN-TVMH	RYPLAZIM				

GUIDELINES FOR USE

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

A. You have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia: a type of genetic condition)

Commercial Effective: 04/01/22

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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 named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic myeloid leukemia (CML: type of blood cancer)
   2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of white blood cell cancer)

B. **If you have chronic myeloid leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You had a mutational analysis (a type of test) before starting therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
   3. You meet ONE of the following:
      a. You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
      b. You have chronic phase CML AND have a resistance to or are not able to safely use at least TWO prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)
      c. You have accelerated phase or blast phase CML AND there are no other kinase inhibitors, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), that can be used for your disease

C. **If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is positive for the T315I mutation (a type of abnormal gene)
      b. There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
      c. You are newly diagnosed AND Iclusig will be used in combination with chemotherapy

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PONESIMOD

Generic	Brand				
PONESIMOD	PONVORY				

GUIDELINES FOR USE

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

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have tried ONE sphingosine-1-phosphate receptor modulator (such as fingolimod, Mayzent [siponimod]) AND ONE other medication indicated for the treatment of multiple sclerosis (PLEASE NOTE: these medications may also require prior authorization)

Commercial Effective: 07/01/24

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POSACONAZOLE

Generic	Brand				
POSACONAZOLE	NOXAFIL, POSACONAZOLE				

GUIDELINES FOR USE

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

A. The request is for ONE of the following:
   1. Continuation of therapy after hospital discharge
   2. Treatment of invasive aspergillosis (type of fungal infection)
   3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
   4. Oropharyngeal candidiasis (fungal infection of the throat)
   5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach)

B. **If the request is for treatment of invasive aspergillosis, approval also requires:**
   1. You are 13 years of age or older
   2. You are requesting Noxafil (posaconazole) tablets

C. **If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:**
   1. You are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or you have hematologic malignancies (cancer affecting the blood) with prolonged neutropenia (low levels of a type of white blood cell) from chemotherapy (cancer treatment)
   2. If the request is for posaconazole (Noxafil) tablets, you meet ONE of the following:
      You are 18 years of age or older
      You are 2 years of age or older AND weigh greater than 40 kg
   3. If the request is for posaconazole (Noxafil) suspension, you meet ALL of the following:
      You are 13 years of age or older
      You are unable to swallow tablets
   4. If the request is for posaconazole (Noxafil) PowderMix, you meet the following:
      You are 2 to 18 years of age AND weigh less than 40 kg
      You are unable to swallow tablets

D. **If the request is for oropharyngeal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial of or contraindication (harmful for) to fluconazole OR itraconazole
   3. You are requesting Noxafil (posaconazole) oral suspension

(Criteria continued on next page)

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

E. **If the request is for esophageal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial and failure of or contraindication (harmful for) to TWO of the following: fluconazole, itraconazole solution, or voriconazole

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Commercial Effective: 01/01/23

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PRALSETINIB

Generic	Brand				
PRALSETINIB	GAVRETO				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor that has been detected by a Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor
   3. You need systemic therapy (treatment that targets the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is an appropriate treatment option)

Commercial Effective: 09/11/23

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

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)

Commercial Effective: 04/01/20

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QUIZARTINIB

Generic	Brand				
QUIZARTINIB DIHYDROCHLORIDE	VANFLYTA				

GUIDELINES FOR USE

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

A. You have newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
B. You are 18 years of age or older
C. Your cancer is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD: a type of mutation) positive as detected by a Food and Drug Administration (FDA)-approved test
D. You meet ONE of the following:
   1. Vanflyta will be used in combination with standard cytarabine and anthracycline (such as daunorubicin, idarubicin) as induction therapy (a type of therapy to treat cancer), followed by use with cytarabine as consolidation therapy (type of therapy to treat cancer)
   2. Vanflyta will be used as maintenance monotherapy (one drug treatment) following consolidation chemotherapy

Commercial Effective: 12/01/23

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RANOLAZINE

Generic	Brand				
RANOLAZINE	ASPRUZYO SPRINKLE				

GUIDELINES FOR USE

Our guideline named **RANOLAZINE (Aspruzyo Sprinkle)** requires the following rule(s) be met for approval:

A. You have chronic angina (a type of heart condition)
B. You had a trial of or contraindication (harmful for) to ranolazine ER (extended release) tablets
C. You are unable to swallow ranolazine ER tablets
D. You had a trial of or contraindication (harmful for) to a nitrate (such as nitroglycerin, isosorbide mononitrate, isosorbide dinitrate)

Commercial Effective: 10/01/22

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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 ONE of the following diagnoses:
   1. Metastatic colorectal cancer (CRC: a type of digestive cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, unable to remove by surgery, or has spread to other parts of the body)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
   2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
   3. If you have RAS wild-type (a type of unmutated gene) metastatic colorectal cancer, approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. **If you have hepatocellular carcinoma, approval also requires:**
   1. You had previous treatment with Nexavar (sorafenib)

Commercial Effective: 04/01/22

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RELUGOLIX

Generic	Brand				
RELUGOLIX	ORGOVYX				

GUIDELINES FOR USE

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

A. You have advanced prostate cancer
B. You are 18 years of age or older

Commercial Effective: 04/01/21

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

Generic	Brand				
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. Your diagnosis of endometriosis is confirmed via surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   5. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   6. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:**
   1. You had improvement of heavy menstrual bleeding on therapy
   2. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:**
   1. You have had improvement in pain related to endometriosis while on therapy
   2. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

Commercial Effective: 09/12/22

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REPOTRECTINIB

Generic	Brand				
REPOTRECTINIB	AUGTYRO				

GUIDELINES FOR USE

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

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   2. Solid tumors

B. **If you have non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have *ROS1*-positive (abnormal change in a type of gene) tumors

C. **If you have solid tumors, approval also requires:**
   1. You are 12 years of age and older
   2. Your tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (abnormal change in a type of gene)
   3. Yours tumors are locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body), OR surgical resection (removal by surgery) is likely to result in severe morbidity (illness)
   4. You have progressed following treatment OR have no satisfactory alternative (other) therapy

Commercial Effective: 08/01/24

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RESMETIROM

Generic	Brand				
RESMETIROM	REZDIFFRA				

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
B. You are 18 years of age or older
C. You do not have cirrhosis (liver damage and scarring)
D. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (doctor who treats digestive conditions)
E. You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
F. Your diagnosis has been confirmed by biopsy (removal of cells or tissue from the body for examination) or noninvasive testing (such as elastography [type of imaging test]) within the past 12 months which demonstrates ONE of the following:
    1. You have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)
    2. You have a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS: a scoring system used to measure disease activity and severity) of at least 4

RENEWAL CRITERIA

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

A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
B. You do NOT meet any of the following:
    1. You are a non-responder (defined as NAFLD [non-alcoholic fatty liver disease] Activity Score [NAS: a scoring system used to measure disease activity and severity] not decreasing by at least 2 points from baseline [before start of treatment] AND no reduction [no improvement] in liver fibrosis stage [scoring system to measure liver damage])
    2. You have experienced NASH resolution (defined as NAFLD Activity Score [NAS] of less than or equal to 3 AND liver fibrosis stage 0 to 1)

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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. The request is for ONE of the following:
   1. Reduction of risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence
   2. Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

B. **For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor)
   3. You have tried lactulose or you are currently taking lactulose monotherapy (one drug treatment)

C. **If you have irritable bowel syndrome with diarrhea, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication (harmful for you to use) to tricyclic anti-depressants (such as amitriptyline, nortriptyline) or dicyclomine

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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. The request is for ONE of the following:
   1. Travelers' diarrhea
   2. *Clostridium difficile* infection (a type of bacterial infection)
   3. Treatment of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage)

B. **If you have traveler's diarrhea, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication (harmful for you to use) to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

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. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   2. You had at least one previous occurrence of *Clostridium difficile* infection
   3. You have been treated with vancomycin for the current *Clostridium difficile* infection

RENEWAL CRITERIA (CONTINUED)

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Reduction of risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence
   2. Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

B. **If you have irritable bowel syndrome with diarrhea, renewal also requires:**
   1. Your last treatment course of Xifaxan has been at least 6 weeks ago
   2. You have experienced at least 30 percent decrease in abdominal pain (on a 0-10 point pain scale)
   3. You have experienced at least 50 percent reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

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RILONACEPT

Generic	Brand				
RILONACEPT	ARCALYST				

GUIDELINES FOR USE

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

A. You meet ONE of the following:
   1. You have Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS: an inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: a disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   2. You have Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)
   3. Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

B **If you have Cryopyrin-Associated Periodic Syndromes including Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:**
   1. You are 12 years of age or older
   2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
   4. Arcalyst will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

(Criteria continued on next page)

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RILONACEPT

GUIDELINE FOR USE (CONTINUED)

C. **If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
   2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
   3. Arcalyst will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

D. **If the request is for the treatment or reduction in risk of recurrent pericarditis, approval also requires:**
   1. You are 12 years of age or older
   2. You had an episode of acute pericarditis (a type of short-term heart condition)
   3. You have been symptom-free for 4 to 6 weeks
   4. You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), and new or worsening pericardial effusion (a type of heart condition)
   5. You had a trial of or contraindication to (harmful for) two NSAIDS (non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin) AND colchicine
   6. Arcalyst will NOT be used concurrently with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

Commercial Effective: 10/01/23

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RILUZOLE

Generic	Brand			
RILUZOLE	EXSERVAN, TIGLUTIK			

GUIDELINES FOR USE

Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
B. You are 18 years of age or older
C. You have tried riluzole tablets
D. You are unable to take riluzole tablet formulation

Commercial Effective: 06/01/21

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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. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines
   2. Preventive treatment of episodic migraines

B. **If the request is for the acute treatment of migraines, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   3. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

C. **If the request is for the preventive treatment of episodic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

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RIMEGEPANT

RENEWAL CRITERIA

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines
   2. Preventive treatment of episodic migraines

B. **If the request is for the acute treatment of migraines, renewal also requires:**
   1. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   2. You meet ONE of the following:
      a. 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])
      b. You have experienced clinical improvement as defined by ONE of the following:
         i. Ability to function normally within 2 hours of dose
         ii. Headache pain disappears within 2 hours of dose
         iii. Treatment works consistently in a majority of migraine attacks

C. **If the request is for the preventive treatment of episodic migraines, renewal also requires:**
   1. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
   2. You meet ONE of the following:
      a. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
      b. You have experienced a reduction in migraine severity
      c. You have experienced a reduction in migraine duration

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Commercial Effective: 04/01/24

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RIOCIGUAT

Generic	Brand				
RIOCIGUAT	ADEMPAS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)

B. **If you have pulmonary arterial hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   4. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

C. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. You have persistent or recurrent disease after surgical treatment (condition continues to exist or returns after surgery) OR you are not a candidate for surgery OR you have inoperable (not able to operate on) chronic thromboembolic pulmonary hypertension
   4. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   5. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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RIOCIGUAT

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)
   2. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

Commercial Effective: 07/01/24

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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: 04/10/21

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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 rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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

(Initial criteria continued on next page)

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

E. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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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: a type of nerve and muscle movement disorder)
B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by a gene mutation analysis indicating mutations (abnormal changes) 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. Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. **If you are pre-symptomatic (symptoms have not yet appeared), approval also requires:**
    1. You have up to (no more than) three copies of the survival motor neuron 2 (SMN2: type of protein in spinal cord) gene based on screening that was 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. 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 experienced a less than expected clinical benefit with gene therapy

RENEWAL CRITERIA

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

A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated a less than expected decline in other muscle function (such as pulmonary [lung/breathing] function)

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RITLECITINIB

Generic	Brand				
RITLECITINIB TOSYLATE	LITFULO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have severe alopecia areata (a type of hair loss)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have had at least 50 percent scalp hair loss as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool) for more than 6 months
E. You will NOT use Litfulo concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

RENEWAL CRITERIA

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

A. You have severe alopecia areata (a type of hair loss)
B. You have shown improvement while on therapy (such as scalp hair coverage)
C. You will NOT use Litfulo concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 07/01/24

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ROFLUMILAST 0.15% CREAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You are 6 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
D. You have tried or have a contraindication to (harmful for you to use) ONE of the following topical non-steroidal immunomodulating medications (a type of medication): Eucrisa (crisaborole), Opzelura (ruxolitinib), or a calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
E. You are NOT using Zoryve together with ANY of the following for atopic dermatitis:
    1. Other non-steroid topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

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ROFLUMILAST 0.15% CREAM

RENEWAL CRITERIA

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
C. You are NOT using Zoryve together with ANY of the following for atopic dermatitis:
    1. Other non-steroid topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Commercial Effective: 08/01/24

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ROFLUMILAST 0.3% CREAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have plaque psoriasis (a type of skin condition)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
E. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
    1. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

RENEWAL CRITERIA

Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have plaque psoriasis (a type of skin condition)
B. You have achieved or maintained clear or minimal disease
C. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

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ROFLUMILAST - FOAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have seborrheic dermatitis (a type of skin condition)
B. You are 9 years of age or older
C. Your seborrheic dermatitis covers less than or equal to 20 percent of your body surface area (BSA) (may involve scalp, face, trunk [the central part of your body], or intertriginous areas [between skin folds])
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
        a. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
        b. Topical antifungal (such as ketoconazole, ciclopirox)
        c. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    2. You previously had a successful treatment with roflumilast foam

Commercial Effective: 10/14/24

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ROPEGINTERFERON ALFA-2B-NJFT

Generic	Brand				
ROPEGINTERFERON ALFA-2B-NJFT	BESREMI				

GUIDELINES FOR USE

Our guideline named **ROPEGINTERFERON ALFA-2B-NJFT (Besremi)** requires the following rule(s) be met for approval:

A. You have polycythemia vera (a type of blood cancer)
B. You are 18 years of age or older

Commercial Effective: 04/01/22

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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:
   1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
   2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
   3. You are in complete or partial response to platinum-based chemotherapy (a type of therapy to treat cancer)
   4. The requested medication will be used for maintenance treatment

C. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
   3. You have been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy (types of therapy to treat cancer)
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (removal of testicles)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

Commercial Effective: 01/23/23

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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:
   1. Intermediate or high-risk myelofibrosis (a type of blood cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera (a type of blood cancer)
   3. Steroid-refractory acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
   4. Chronic graft-versus-host disease (a type of long-term immune disorder)

B. **If you have intermediate or high-risk myelofibrosis, 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 or contraindication to (harmful for you to use) hydroxyurea

D. **If you have steroid-refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

E. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   3. You will NOT use Jakafi concurrently (at the same time) with Rezurock (belumosudil) or Imbruvica (ibrutinib)

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RUXOLITINIB

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera or acute graft-versus-host disease, please refer to the Initial Criteria section.

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

A. You have ONE of the following:
   1. Intermediate or high-risk myelofibrosis (a type of blood cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Chronic graft-versus-host disease (a type of long-term immune disorder)

B. **If you have intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, renewal also requires that you have shown symptom improvement by meeting ONE of the following:**
   1. You have had at least a 50 percent reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   2. You have had at least a 50 percent reduction in palpable (can be felt by external examination) spleen length
   3. You have had a spleen volume reduction of at least 35 percent from baseline

C. **If you have chronic graft-versus-host disease, renewal also requires:**
   1. You will NOT use Jakafi concurrently (at the same time) with Rezurock (belumosudil) or Imbruvica (ibrutinib)

Commercial Effective: 10/01/24

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RUXOLITINIB TOPICAL

Generic	Brand				
RUXOLITINIB PHOSPHATE	OPZELURA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. **If you have mild to moderate atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. You are NOT immunocompromised (low immune system)
   3. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) AND a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   4. You will NOT use Opzelura concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

(Initial criteria continued on next page)

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

C. **If you have nonsegmental vitiligo, approval also requires:**
   1. You are 12 years of age or older
   2. You have depigmented (lightening of the skin) areas covering 10 percent or less of your total body surface area (BSA)
   3. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   4. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. **If you have mild to moderate atopic dermatitis, renewal also requires:**
   1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (symptoms or disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
   2. You will NOT use Opzelura concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

C. **If you have nonsegmental vitiligo, renewal also requires:**
   1. You have experienced or maintained clinically meaningful repigmentation (recoloration of the skin after loss in color)
   2. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Commercial Effective: 10/01/24

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SACROSIDASE

Generic	Brand			
SACROSIDASE	SUCRAID			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:

A. You have a genetically determined sucrase deficiency , which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or medical geneticist (doctor who treats gene disorders)
C. Your diagnosis is confirmed by ONE of the following:
    1. Small bowel biopsy (removal of cells or tissue from the body for examination)
    2. Sucrose breath test
    3. Genetic test

RENEWAL CRITERIA

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

A. You have a genetically determined sucrase deficiency which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
B. You have experienced or maintained improvement on treatment

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Commercial Effective: 07/01/22

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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 have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)
   3. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease modifying antirheumatic drug), 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 have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib] due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have polymyalgia rheumatica, approval also requires:**
   1. You are 18 years of age or older
   2. You had an inadequate response (drug did not work) to corticosteroids (such as prednisone) or cannot tolerate a corticosteroid taper

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You weigh at least 63 kg (138 pounds)
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitors [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR (tofacitinib immediate-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Rinvoq (upadacitinib)

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SARILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica, please refer to the Initial Criteria section.

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitors [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR (tofacitinib immediate-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Rinvoq (upadacitinib)

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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 type of brain disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. You have a positive serologic (blood) test for the anti-aquaporin-4 (AQP4: a type of protein) antibody
E. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
F. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (a type of brain disorder)
    2. Acute myelitis (a type of brain disorder)
    3. Area postrema syndrome (a type of brain disorder)
    4. Acute brainstem syndrome (a type of brain disorder)
    5. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic MRI lesions (affected areas)
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

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 type of brain disorder)
B. You have experienced a reduction in relapse frequency from baseline
C. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

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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:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   5. You meet ONE of the following:
      a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to FOUR of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab), Otezla (apremilast)
   b. You are 18 years of age or older AND have tried or have a contraindication to FOUR of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Sotyktu (deucravacitinib)

C. **If you have psoriatic arthritis, approval also requires:**
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
4. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
5. Requests for the 300mg maintenance dosage in psoriatic arthritis without coexisting plaque psoriasis requires that you have tried the 150mg maintenance dosing schedule AND continue to have active psoriatic arthritis
6. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
   b. You are 6 to 17 years of age AND have tried or have a contraindication to THREE of the preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Rinvoq (upadacitinib)
   c. You are 18 years of age or older AND have tried or have a contraindication to THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz IR/XR (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   5. Requests for the 300mg maintenance dosage requires that you have tried the 150mg maintenance dosage schedule AND continue to have active ankylosing spondylitis
   6. You have tried or have a contraindication to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR/XR (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   5. You have tried or have a contraindication to TWO of the following preferred medications: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)
   6. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      b. Sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

F. **If you have enthesitis-related arthritis, approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

G. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Cosentyx together with other systemic biologics (such as Humira [adalimumab]) for the treatment of hidradenitis suppurativa or other interleukin-17 (IL-17) inhibitors (such as Taltz [ixekizumab]) for any indication
   4. You have tried or have a contraindication to (harmful for you to use) TWO topical therapies (such as clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or oral antibiotics (such as, tetracycline, dapsone)
   5. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), Hyrimoz (adalimumab-adaz), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Simlandi (adalimumab-ryvk)

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SECUKINUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

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: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab), Otezla (apremilast)
      b. You are 18 years of age or older AND have tried or have a contraindication to FOUR of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk), Sotyktu (deucravacitinib)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Rinvoq (upadacitinib)
      b. You are 6 to 17 years of age AND have tried or have a contraindication to THREE of the preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Rinvoq (upadacitinib)
      c. You are 18 years of age or older AND have tried or have a contraindication to THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

(Renewal criteria continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Cimzia (certolizumab), Rinvoq (upadacitinib), Taltz (ixekizumab)

F. **If you have enthesitis-related arthritis, renewal also requires:**
   1. You have experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion

G. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement on therapy
   2. You will NOT use Cosentyx together with other systemic biologics (such as Humira [adalimumab]) for the treatment of hidradenitis suppurativa or other interleukin-17 (IL-17) inhibitors (such as Taltz [ixekizumab]) for any indication
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Hyrimoz (adalimumab-adaz), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Simlandi (adalimumab-ryvk)

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.

Commercial Effective: 10/01/24

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SELADELPAR

Generic	Brand				
SELADELPAR LYSINE	LIVDELZI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

D. You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)

E. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Iqirvo [elafibranor])

F. You meet ONE of the following:
   1. Livdelzi will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Livdelzi will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

G. You meet ONE of the following:
   1. Alleviation of (decreasing) your pruritus (itching) is a goal of treatment with Livdelzi
   2. You had a trial of or contraindication to (harmful for you to use) ONE of the following preferred medications: Ocaliva (obeticholic acid), Iqirvo (elafibranor)

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SELADELPAR

RENEWAL CRITERIA

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

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
B. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Livdelzi
C. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Iqirvo [elafibranor])

Commercial Effective: 11/11/24

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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: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
    1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
    2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
    3. Oral cGMP stimulator (such as Adempas [riociguat])
    4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Commercial Effective: 07/01/24

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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. Multiple myeloma (MM: a type of blood cancer)
   2. Relapsed or refractory multiple myeloma (RRMM: a type of blood cancer that returned or did not respond to treatment)
   3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), including DLBCL arising from follicular lymphoma

B. You are 18 years of age or older

C. **If you have multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with bortezomib (Velcade) and dexamethasone
   2. You have received at least one therapy before Xpovio

D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with dexamethasone
   2. You have received at least four prior therapies for the treatment of RRMM)
   3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
      a. Two proteasome inhibitors (such as bortezomib [Velcade], carfilzomib [Kyprolis])
      b. Two immunomodulatory agents (such as lenalidomide [Revlimid], pomalidomide [Pomalyst])
      c. One anti-CD38 monoclonal antibody (such as daratumumab [Darzalex])

E. **If you have relapsed or refractory diffuse large B-cell lymphoma, approval also requires:**
   1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

Commercial Effective: 08/01/23

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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:
   1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
   4. Locally advanced or metastatic solid tumor (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)

B. **If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a rearranged during transfection (*RET:* type of gene) gene fusion, as detected by a Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 2 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*: type of gene) mutation, as detected by a Food and Drug Administration (FDA)-approved test
   3. You require systemic therapy (treatment that travels through the entire body)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 2 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*: type of gene) gene fusion, as detected by a Food and Drug Administration (FDA)-approved test
   3. You require systemic therapy (treatment that travels through the entire body)
   4. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate

E. **If you have a locally advanced or metastatic solid tumor, approval also requires:**
   1. You are 2 years of age or older
   2. Your tumor has a rearranged during transfection (*RET*: type of gene) gene fusion, as detected by a Food and Drug Administration (FDA)-approved test
   3. Your tumor has progressed on or following prior systemic treatment OR you have no satisfactory alternative treatment options

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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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SEMAGLUTIDE - WEGOVY

Generic	Brand				
SEMAGLUTIDE	WEGOVY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The request is for ONE of the following:
   1. To reduce the risk of major adverse cardiovascular events (MACE: cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke [a type of brain damage])
   2. Weight loss or weight management

B. **If you will use Wegovy to reduce the risk of major adverse cardiovascular events, approval also requires:**
   1. You are 18 years of age or older
   2. You are overweight (your BMI [body mass index: a tool for evaluating body fat] is at least 27 kg/m[2])
   3. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   4. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of drug such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   5. You have established cardiovascular disease as evidenced by ONE of the following:
      a. Prior myocardial infarction (heart attack)
      b. Prior stroke (ischemic [stroke caused by blood clot] or hemorrhagic [stroke caused by broken blood vessels in the brain])
      c. Carotid artery stenosis of at least 50 percent (the blood vessel that transports blood to the brain is blocked)
      d. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication (pain caused by too little blood flow) with ankle-brachial index (ABI: a type of test to check blood flow) less than 0.85 (at rest), peripheral arterial revascularization procedure (surgery to restore blood flow in blocked arteries/veins), or amputation due to atherosclerotic disease (buildup of fat)

(Initial criteria continued on the next page)

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INITIAL CRITERIA (CONTINUED)

6. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event:
   a. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (a type of brain damage caused by broken blood vessels in the brain)
   b. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   c. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

C. **If you will use Wegovy for weight loss or weight management, approval also requires:**
   1. There is evidence of your active enrollment in an exercise and caloric reduction program, which may include other optional weight loss/behavioral modification programs
   2. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of drug such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   3. You meet ONE of the following:
      a. You are 18 years of age or older and meet ONE of the following:
         i. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
         ii. You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
      b. You are 12 to 17 years of age and meet the following:
         a. You have an initial body mass index (BMI: a tool for evaluating body fat) in the 95th percentile or greater standardized for your age and sex

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

USE THIS CRITERIA FOR BENEFIT EXCLUSION OF WEIGHT LOSS

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

A. The request is to reduce the risk of major adverse cardiovascular events (MACE: cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke [a type of brain damage])
B. You are 18 years of age or older
C. You are overweight (your BMI [body mass index: a tool for evaluating body fat] is at least 27 kg/m[2])
D. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
E. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of drug such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
F. You have established cardiovascular disease as evidenced by ONE of the following:
    1. Prior myocardial infarction (heart attack)
    2. Prior stroke (ischemic [stroke caused by blood clot] or hemorrhagic [stroke caused by broken blood vessels in the brain])
    3. Carotid artery stenosis of at least 50 percent (the blood vessel that transports blood to the brain is blocked)
    4. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication (pain caused by too little blood flow) with ankle-brachial index (ABI: a type of test to check blood flow) less than 0.85 (at rest), peripheral arterial revascularization procedure (surgery to restore blood flow in blocked arteries/veins), or amputation due to atherosclerotic disease (buildup of fat)

(Initial criteria continued on the next page)

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

G. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event:
   1. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (a type of brain damage caused by broken blood vessels in the brain)
   2. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   3. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

NOTE: Your plan does NOT cover Wegovy when it is only used for weight loss or weight management.

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. To reduce the risk of cardiovascular death, heart attack, and stroke (a type of brain damage)
   2. Weight loss or weight management

B. **If you will use Wegovy to reduce the risk of cardiovascular death, heart attack, and stroke, renewal also requires:**
   1. You have cardiovascular disease (such as prior heart attack, prior stroke, carotid artery stenosis of at least 50 percent [the blood vessel that transports blood to the brain is blocked], symptomatic peripheral arterial disease [PAD])
   2. Wegovy will be used in addition to a reduced calorie diet and increased physical activity
   3. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of drug such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   4. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event (such as a non-fatal myocardial infarction [heart attack], non-fatal stroke [a type of brain damage]):
      a. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (a type of brain damage caused by broken blood vessels in the brain)
      b. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
      c. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

(Renewal criteria continued on next page)

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA (CONTINUED)

C. **If you will use Wegovy for weight loss or weight management, renewal also requires:**
   1. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of drug such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   2. You meet ONE of the following:
      a. You are 18 years of age or older AND have achieved or maintained at least a 5 percent weight loss of baseline body weight
      b. You are 12 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat)

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA (CONTINUED)

USE THIS CRITERIA FOR BENEFIT EXCLUSION OF WEIGHT LOSS

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for renewal:

A. The request is to reduce the risk of cardiovascular death, heart attack, and stroke (a type of brain damage)
B. You have cardiovascular disease (such as prior heart attack, prior stroke, carotid artery stenosis of at least 50 percent [the blood vessel that transports blood to the brain is blocked], symptomatic peripheral arterial disease [PAD])
C. Wegovy will be used in addition to a reduced calorie diet and increased physical activity
D. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of drug such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
E. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event (such as a non-fatal myocardial infarction [heart attack], non-fatal stroke [a type of brain damage]):
    1. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (a type of brain damage caused by broken blood vessels in the brain)
    2. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
    3. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

NOTE: Your plan does NOT cover Wegovy when it is only used for weight loss or weight management.

Commercial Effective: 07/01/24

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SETMELANOTIDE

Generic	Brand				
SETMELANOTIDE ACETATE	IMCIVREE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The request is for chronic weight management
B. You are 6 years of age or older
C. You have a diagnosis of obesity (a condition where you have higher than normal body fat) that is caused by ONE of the following:
   1. Bardet-Biedl syndrome (BBS: a genetic disorder)
   2. A deficiency in ONE of the following:
      a. Pro-opiomelanocortin (POMC: type of gene)
      b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
      c. Leptin receptor (LEPR: type of gene)
D. **If your obesity is caused by a POMC, PCSK1, or LEPR deficiency, approval also requires:**
   1. Confirmed genetic testing shows variants (changes) in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic (causing disease), likely pathogenic, or of uncertain significance (VUS)

RENEWAL CRITERIA

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

A. You have a diagnosis of obesity (a condition where you have higher than normal body fat) that is caused by ONE of the following:
   1. Bardet-Biedl syndrome (BBS: a genetic disorder)
   2. A deficiency in ONE of the following:
      a. Pro-opiomelanocortin (POMC: type of gene)
      b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
      c. Leptin receptor (LEPR: type of gene)
B. You meet ONE of the following:
   1. You are 18 years of age or older AND have lost at least 5% of your baseline body weight
   2. You are 6 to 17 years of age AND have lost at least 5% of your baseline body mass index (BMI: a tool for evaluating body fat)

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SILDENAFIL IV

Generic	Brand				
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
F. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

RENEWAL CRITERIA

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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SILDENAFIL SUSPENSION

Generic	Brand				
SILDENAFIL CITRATE	REVATIO, LIQREV, SILDENAFIL CITRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. **If you are 1 to 17 years of age, approval also requires:**
    1. You are requesting Revatio (sildenafil) suspension
    2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
    3. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
        a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
        b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
        c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
    4. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
    5. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
    6. You are unable to swallow pills AND you have tried crushed sildenafil tablets

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

C. **If you are 18 years of age or older, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
   5. If you are requesting Revatio (sildenafil) suspension, you are unable to swallow pills AND you have tried crushed sildenafil tablets
   6. If you are requesting Liqrev suspension, you are unable to swallow Revatio (sildenafil) tablets AND you have tried generic sildenafil powder for suspension

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. **If you are 1 to 17 years of age, approval also requires:**
   1. You are requesting Revatio (sildenafil) suspension
   2. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   3. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

C. **If you are 18 years of age or older, approval also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   2. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Commercial Effective: 07/01/24

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SILDENAFIL TABLET

Generic	Brand				
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. **If you are 1 to 17 years of age, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

C. **If you are 18 years of age or older, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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SILDENAFIL TABLET

RENEWAL CRITERIA

Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 1 year of age or older
C. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
D. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Commercial Effective: 07/01/24

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SIMVASTATIN 80

Generic	Brand				
EZETIMIBE/ SIMVASTATIN	VYTORIN				
SIMVASTATIN	ZOCOR, SIMVASTATIN				

GUIDELINES FOR USE

Our guideline named **SIMVASTATIN 80 (VYTORIN, ZOCOR)** requires the following rule(s) be met for approval:

A. You have been taking the medication for at least 12 months

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Commercial Effective: 05/14/21

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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 have tried or have a contraindication to (harmful for you to use) simvastatin tablets
B. You have dysphagia (difficulty swallowing), difficulty swallowing tablets, or a feeding tube (such as a G-tube or J-tube)
C. Requests for zero-dollar cost share also require 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: 07/01/24

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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 a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

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 (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
B. You have demonstrated a clinical benefit compared to pre-treatment baseline
C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

Commercial Effective: 07/01/24

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SIROLIMUS TOPICAL

Generic	Brand				
SIROLIMUS	HYFTOR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)
B. You are 6 years of age or older

RENEWAL CRITERIA

Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for renewal:

A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)

Commercial Effective: 08/29/22

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. Idiopathic hypersomnia (IH: a type of sleep disorder)
   2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep disorder)

B. You are not concurrently on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   4. You tried and failed or have a contraindication (harmful for) to armodafinil OR modafinil

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

D. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. If you are 7 to 17 years old, you tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine, dextroamphetamine, or methylphenidate)
   6. If you are 18 years or older, you tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
      a. Generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.)
      b. Armodafinil OR modafinil

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SODIUM/CALCIUM/MAG/POT OXYBATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. You are not concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

C. **If you have narcolepsy, renewal also requires you meet ONE of the following:**
   1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

D. **If you have idiopathic hypersomnia, renewal also requires you meet ONE of the following**:
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

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Commercial Effective: 01/01/23

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SODIUM OXYBATE-LUMRYZ

Generic	Brand				
SODIUM OXYBATE	LUMRYZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

B. **If you have cataplexy with narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You had a trial of generic sodium oxybate
   4. You had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])
   5. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

C. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

4. You have excessive daytime sleepiness (EDS) persisting for at least 3 months
5. You have an Epworth Sleepiness Scale (ESS: questionnaire used to assess daytime sleepiness) score of greater than 10
6. You had a trial of or contraindication to (harmful for you to use) generic sodium oxybate
7. Your diagnosis is confirmed by ONE of the following:
   a. You have a Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND at least 2 early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   b. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less AND at least one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   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)
8. **If you are 7 to 17 years old, approval also requires:**
   a. You had a trial of or contraindication to (harmful for you to use) a generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
9. **If you are 18 years or older, approval also requires:**
   a. You had a trial of or contraindication to (harmful for you to use) a generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   b. You had a trial of or contraindication to (harmful for you to use) armodafinil (Nuvigil) or modafinil (Provigil)

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for renewal:

A. You have narcolepsy (a type of sleep condition)
B. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
C. 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 (ESS: questionnaire used to assess daytime sleepiness) scores by at least 25 percent compared to baseline
    3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep) compared to baseline

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Commercial Effective: 10/14/24

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SODIUM OXYBATE-XYREM

Generic	Brand				
SODIUM OXYBATE	XYREM, SODIUM OXYBATE				

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:

A. You have ONE of the following diagnoses:
   1. Idiopathic hypersomnia (IH: a type of sleep disorder)
   2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   3. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), or Restoril (temazepam)

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do NOT have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM (rapid eye movement) sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   4. You have tried and failed or have a contraindication (harmful for) to armodafinil (Nuvigil) OR modafinil (Provigil)
   5. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

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INITIAL CRITERIA (CONTINUED)

D. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a tricyclic anti-depressant (such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months
   4. You have an Epworth Sleepiness Scale (tool to measure sleepiness) score of more than 10
   5. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND two or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test showing an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing low levels of a chemical that help with staying awake)
   6. If you are 7 to 17 years old, you have tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], or methylphenidate [Ritalin])
   7. If you are 18 years or older, you have tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
      a. Generic typical stimulant (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
      b. Armodafinil (Nuvigil) OR modafinil (Provigil)
      c. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

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SODIUM OXYBATE-XYREM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], or Restoril [temazepam]

C. **If you have narcolepsy, renewal also requires ONE of the following:**
   1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   2. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep)

D. **If you have idiopathic hypersomnia, renewal also requires ONE of the following:**
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

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Commercial Effective: 06/12/23

SODIUM PHENYLBUTYRATE

Generic	Brand			
SODIUM PHENYLBUTYRATE	BUPHENYL, PHEBURANE, SODIUM PHENYLBUTYRATE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
B. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
C. The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction
D. Your disorder cannot be managed by dietary protein restriction or amino acid supplementation alone
E. **If your request is for Pheburane or Olpruva, approval also requires:**
    1. You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder
    2. You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

RENEWAL CRITERIA

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced a clinical benefit from baseline (for example you have normal fasting glutamine levels, low-normal fasting ammonia levels, mental status clarity)

Commercial Effective: 07/01/24

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SOD PHENYLBUTYRATE-TAURURSODIOL

Generic	Brand				
SOD PHENYLBUTYRAT /TAURURSODIOL	RELYVRIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

RENEWAL CRITERIA

Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for renewal:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. You do not require invasive ventilation (inserting a breathing tube into your throat)
C. You have improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS: a tool for evaluating functional status])

Commercial Effective: 10/24/22

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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 virus (HCV: liver inflammation caused by a type of virus)
B. You have genotype 2 or 3 infection (types of hepatitis C virus) and are 3 to 17 years of age OR you have genotype 1, 2, 3, or 4 infection (types of hepatitis C virus) and are 18 years of age or older
C. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
D. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
E. You will NOT use Sovaldi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. John's wort, Aptivus [tipranavir]/ritonavir)
F. You will NOT use Sovaldi concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
G. **If you have genotype 2 infection, approval also requires:**
    1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
    2. Sovaldi will be used with ribavirin
    3. You meet ONE of the following:
        a. You are 3 to 17 years of age
        b. You are 18 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

H. **If you have genotype 3 infection, approval also requires:**
   1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   2. Sovaldi will be used with ribavirin
   3. You meet ONE of the following:
      a. You are 3 to 17 years of age
      b. You are 18 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

I. **If you have genotype 1 infection, approval also requires:**
   1. You are 18 years of age or older
   2. You are treatment-naïve (no prior treatment)
   3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   4. Sovaldi will be used with peginterferon alfa and ribavirin OR Sovaldi will be used with ribavirin if you have a contraindication to (harmful for you to use) interferon
   5. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa

J. **If you have genotype 4 infection, approval also requires:**
   1. You are 18 years of age or older
   2. You are treatment-naïve (no prior treatment)
   3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   4. Sovaldi will be used with peginterferon alfa and ribavirin
   5. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa

K. **If Sovaldi will be used to prevent post-transplant HCV reinfection (getting infected again with HCV after transplant), approval also requires:**
   You have hepatocellular carcinoma (HCC: a type of liver cancer)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

L. **If you had a previous treatment failure with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir), approval also requires:**
   1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage and scarring)
   2. Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

M. Sovaldi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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Commercial Effective: 07/22/24

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SOFOSBUVIR/VELPATASVIR

Generic	Brand			
SOFOSBUVIR/ VELPATASVIR	EPCLUSA, SOFOSBUVIR/ VELPATASVIR			

GUIDELINES FOR USE

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

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have genotype 1, 2, 3, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You will NOT use Epclusa concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV [human immunodeficiency virus] regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. John's wort)
G. You will NOT use Epclusa concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

H. You meet ONE of the following:
   1. You do not have cirrhosis (liver damage and scarring)
   2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
   3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (moderate or severe liver impairment; Child-Pugh B or C [a score that evaluates the severity of liver damage]), and you meet ONE of the following:
      a. You will use Epclusa with ribavirin
      b. You have a contraindication to (harmful for you to use) ribavirin
      c. You have failed prior treatment with a sofosbuvir-based regimen (such as sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin
      d. You have failed prior treatment with an NS5A inhibitor-based regimen (such as Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin
      e. You received a liver transplant (replaced your liver), are treatment-experienced (failed prior treatment), AND Epclusa will be used with ribavirin

I. Epclusa will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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Commercial Effective: 07/22/24

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand			
SOFOSBUVIR/VELPATASVIR/ VOXILAPREVIR	VOSEVI			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 18 years of age or older
C. You have genotype 1, 2, 3, 4, 5 or 6 infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Vosevi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. John's wort, HIV (human immunodeficiency virus) regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz)
H. You will NOT use Vosevi concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
I. **If you are treatment-naïve (no prior treatment), approval also requires**:
    1. You have genotype 3 infection
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms)
    3. You have NS5A resistance-associated substitution (RAS) Y93H polymorphism (variations in a type of hepatitis C virus protein)

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

J. **If you are treatment-experienced (failed prior treatment), approval also requires**:
   1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   2. You meet ONE of the following:
      a. You have failed a full course of a regimen containing an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a direct-acting antiviral (such as Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant (replaced your liver or kidney)
      b. You have failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])
      c. You have failed prior treatment with Vosevi AND Vosevi will be used with ribavirin

K. Vosevi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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Commercial Effective: 07/22/24

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SOFPIRONIUM

Generic	Brand				
SOFPIRONIUM BROMIDE	SOFDRA				

GUIDELINES FOR USE

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

A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You have primary axillary hyperhidrosis as evidenced by focal (limited to a particular area of the body), visible, excessive sweating of at least 6 months duration with all secondary causes (caused by another medical condition) ruled out
D. You have tried a prescription strength aluminum chloride product (such as Drysol)
E. You have tried the preferred topical anticholinergic medication: Qbrexza (glycopyrronium tosylate)
F. You will NOT use Sofdra concurrently (at the same time) with other topical anticholinergics used for primary axillary hyperhidrosis (such as Qbrexza [glycopyrronium tosylate])
G. You have at least two of the following:
    1. Symptoms occur bilaterally (on both sides of the body)
    2. Symptoms impair daily activities
    3. You have at least one episode per week
    4. Onset occurred before you turn(ed) 25 years old
    5. You have a family history of primary axillary hyperhidrosis
    6. Symptoms do not occur during sleep

Commercial Effective: 08/01/24

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SOLIFENACIN SUSPENSION

Generic	Brand				
SOLIFENACIN SUCCINATE	VESICARE LS				

GUIDELINES FOR USE

Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:

A. You have neurogenic detrusor overactivity (type of bladder dysfunction)
B. You are 2 years of age or older
C. You had a trial of or contraindication (harmful for) to TWO of the following:
    1. Anticholinergics (such as oxybutynin)
    2. Beta-3 agonists (such as mirabegron)
D. You are unable to swallow oral solifenacin tablets

Commercial Effective: 01/01/22

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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:**
   - 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)
   - You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   - 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)

(*Initial criteria continued on the next page)*

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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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SOMAPACITAN-BECO

Generic	Brand				
SOMAPACITAN-BECO	SOGROYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   2. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
   4. You meet ONE of the following:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

C. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You 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

D. Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMAPACITAN-BECO

RENEWAL CRITERIA

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   2. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
   4. You meet ONE of the following:
      a. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty

C. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)

D. Renewal request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 07/01/24

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SOMATROGON-GHLA

Generic	Brand				
SOMATROGON-GHLA	NGENLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
E. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Skytrofa (lonapegsomatropin-tcgd) or Sogroya (somapacitan-beco)
F. You meet ONE of the following:
    1. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
    2. Your height velocity is less than the 25th percentile for your age
    3. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
G. Request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

SOMATROGON-GHLA

RENEWAL CRITERIA

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for renewal:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
E. You meet ONE of the following:
    1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
    2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
F. Renewal request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 07/01/24

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SOMATROPIN - GENOTROPIN

Generic	Brand				
SOMATROPIN	GENOTROPIN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure associated with Turner syndrome (TS: a type of gene condition)
- Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
- Growth failure born small for gestational age (SGA)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have growth failure associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth failure due to Prader-Willi syndrome (PWS), approval also requires:
- You have a confirmed genetic diagnosis of Prader-Willi syndrome
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

If you have growth failure born small for gestational age (SGA), **approval also requires:**
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You had no catch-up growth by age 2 years
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Genotropin will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA

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

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure associated with Turner syndrome (TS: a type of gene condition)
- Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
- Growth failure born small for gestational age (SGA)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have short stature associated with Turner syndrome or growth failure born small for gestational age, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth failure due to Prader-Willi syndrome, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have experienced improvement in body composition

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Genotropin will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 01/01/24

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SOMATROPIN - HUMATROPE

Generic	Brand				
SOMATROPIN	HUMATROPE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

You have ONE of the following:

- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
- Growth failure born small for gestational age (SGA)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:

- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

If you have short stature associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have short stature or growth failure with SHOX gene deficiency, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth failure born small for gestational age, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You had no catch-up growth by age 2 to 4 years
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

If you have growth hormone deficiency, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Humatrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - HUMATROPE

RENEWAL CRITERIA

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

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
- Growth failure born small for gestational age (SGA)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have short stature associated with Turner syndrome, short stature or growth failure with SHOX deficiency, or growth failure born small for gestational age, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Humatrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 01/01/24

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SOMATROPIN - NORDITROPIN

Generic	Brand				
SOMATROPIN	NORDITROPIN FLEXPRO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   2. Short stature associated with Turner syndrome (TS: a type of gene condition)
   3. Short stature associated with Noonan syndrome (a type of gene condition)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you are a child with short stature born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You had no catch-up growth by age 2 to 4 years
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN - NORDITROPIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

(Renewal criteria continued on next page)

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SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you are a child with short stature born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had improvement in body composition

Commercial Effective: 11/01/22

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SOMATROPIN - NUTROPIN

Generic	Brand				
SOMATROPIN	NUTROPIN AQ NUSPIN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROPIN (Nutropin AQ)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

If you have growth failure secondary to chronic kidney disease, approval also requires:
- You have NOT undergone a renal (kidney) transplantation
- Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
- Your height or growth velocity is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

If you have short stature associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Nutropin AQ will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA

Our guideline named **SOMATROPIN (Nutropin AQ)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have growth failure secondary to chronic kidney disease, renewal also requires:
- You have not had a renal (kidney) transplantation
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have short stature associated with Turner syndrome, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Nutropin AQ will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 01/01/24

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SOMATROPIN - OMNITROPE

Generic	Brand				
SOMATROPIN	OMNITROPE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
- Growth failure born small for gestational age (SGA)
- Growth failure associated with Turner syndrome (TS: a type of gene condition)
- Growth hormone deficiency (GH: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

If you have growth failure due to Prader-Willi syndrome, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have a confirmed genetic diagnosis of Prader-Willi Syndrome
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)

If you have growth failure born small for gestational age, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You had no catch-up growth by age 2 years
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth failure associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

If you have growth hormone deficiency, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Omnitrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - OMNITROPE

RENEWAL CRITERIA

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

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
- Growth failure born small for gestational age (SGA)
- Growth failure associated with Turner syndrome (TS: a type of gene condition)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have growth failure due to Prader-Willi syndrome, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have experienced improvement in body composition

If you have growth failure born small for gestational age or growth failure associated with Turner syndrome, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Omnitrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - SAIZEN

Generic	Brand				
SOMATROPIN	SAIZEN, SAIZEN-SAIZENPREP				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

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SOMATROPIN - SAIZEN

INITIAL CRITERIA (CONTINUED)

If you have growth hormone deficiency, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)

Request for Saizen will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - SAIZEN

RENEWAL CRITERIA

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Saizen will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 01/01/24

SOMATROPIN - SEROSTIM

Generic	Brand				
SOMATROPIN	SEROSTIM				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist OR infectious disease specialist (doctor who specializes in the treatment of infections)
D. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
E. You have had an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
F. You have had an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
G. Alternative causes of wasting have been ruled out. Alternative causes may include:
    1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    2. Diarrhea
    3. Inadequate energy (caloric) intake
    4. Malignancies (tumors)
    5. Opportunistic infections (an infection that can occur because of a weakened immune system)
H. You meet ONE of the following criteria for weight loss:
    1. 10% unintentional weight loss over 12 months
    2. 7.5% unintentional weight loss over 6 months
    3. 5% body cell mass (BCM) loss within 6 months
    4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
    5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
    6. BMI less than 18.5 kg per meter squared

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SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
   1. You meet one of the following criteria for low testosterone:
      a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
      b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
      c. A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

RENEWAL CRITERIA

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

A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
B. You have NOT received more than 24 weeks of therapy within the plan year
C. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
D. You have shown clinical benefit in muscle mass and weight as indicated by at least a 10 percent increase in weight or BCM (body cell mass) from baseline (Note: current and baseline weight must be documented including dates of measurement)
E. You are on HIV anti-retroviral therapy

Commercial Effective: 01/01/23

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SOMATROPIN - ZOMACTON

Generic	Brand				
SOMATROPIN	ZOMACTON				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

You have ONE of the following:

- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Short stature born small for gestational age (SGA)
- Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:

- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You meet ONE of the following criteria:
  - Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

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SOMATROPIN - ZOMACTON

INITIAL CRITERIA (CONTINUED)

If you have short stature associated with Turner syndrome, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have short stature born small for gestational age, **approval also requires:**
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- You had no catch-up growth by age 2 to 4 years
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have short stature or growth failure with SHOX deficiency, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

If you have growth hormone deficiency, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
- You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Request for Zomacton will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN - ZOMACTON

RENEWAL CRITERIA

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

You have ONE of the following:
- Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
- Short stature associated with Turner syndrome (TS: a type of gene condition)
- Short stature born small for gestational age (SGA)
- Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
- Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:
- You are a pediatric patient
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
- You meet ONE of the following:
  - Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

If you have short stature associated with Turner syndrome, short stature born small for gestational age, or short stature or growth failure with SHOX deficiency, renewal also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
- Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

If you have growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Request for Zomacton will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Commercial Effective: 01/01/24

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SOMATROPIN - ZORBTIVE

Generic	Brand				
SOMATROPIN	ZORBTIVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have short bowel syndrome (the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. Therapy is prescribed by or in consultation with a gastroenterologist (digestive system doctor)
C. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
D. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences

RENEWAL CRITERIA

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

A. You have short bowel syndrome (the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. You have not been on the requested medication for 4 weeks

Commercial Effective: 11/01/22

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SONIDEGIB

Generic	Brand				
SONIDEGIB PHOSPHATE	ODOMZO				

GUIDELINES FOR USE

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

A. You have locally advanced basal cell carcinoma (BCC: type of skin cancer).
B. You are 18 years of age or older
C. This is a recurrence (disease returns) of basal cell carcinoma after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
D. Baseline serum creatine kinase (CK: type of lab test) and serum creatinine levels have been obtained before starting therapy
E. If you are a female of reproductive potential, you must verify your pregnancy status before starting therapy

Commercial Effective: 01/01/22

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SORAFENIB

Generic	Brand			
SORAFENIB TOSYLATE	NEXAVAR, SORAFENIB TOSYLATE			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery)
   3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned or spread, is getting worse and is not responding to a type of treatment)

Commercial Effective: 07/18/22

SOTATERCEPT-CSRK

Generic	Brand				
SOTATERCEPT-CSRK	WINREVAIR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    4. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    5. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    6. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You meet ONE of the following:
    1. You have been on background PAH therapy (for at least 3 months) with at least TWO of the following medications from different drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
    2. You are on ONE medication from one of the following drug classes, AND you have a contraindication to (harmful for you to use) or intolerance (side effect) to ALL of the other drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

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SOTATERCEPT-CSRK

RENEWAL CRITERIA

Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Commercial Effective: 07/01/24

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SOTORASIB

Generic	Brand				
SOTORASIB	LUMAKRAS				

GUIDELINES FOR USE

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

A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes, or has spread to other parts of the body)
B. You are 18 years of age or older
C. Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
D. You have received at least one prior systemic therapy (treatment that targets the entire body)

Commercial Effective: 11/25/24

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SPARSENTAN

Generic	Brand				
SPARSENTAN	FILSPARI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You are 18 years of age or older
C. You are at risk of disease progression (worsening)
D. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
E. Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
F. You have proteinuria (increased levels of protein in the urine) of at least 1 g/day
G. You have an eGFR (a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
H. You have tried or have a contraindication to (harmful for you to use) an angiotensin converting enzyme inhibitor (ACE-I: such as lisinopril, enalapril) or an angiotensin receptor blocker (ARB: such as losartan, valsartan) for at least 12 weeks
I. Filspari will NOT be used concurrently (at the same time) with ACE-I (such as lisinopril, enalapril), an ARB (such as losartan, valsartan), an endothelin receptor antagonist (such as ambrisentan, bosentan), or aliskiren

RENEWAL CRITERIA

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

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You meet ONE of the following:
    1. You had a reduction in proteinuria (increased levels of protein in the urine)
    2. You have improvement or stable kidney function compared to baseline
C. Filspari will NOT be used concurrently (at the same time) with angiotensin converting enzyme inhibitor (ACE-I: such as lisinopril, enalapril), an angiotensin receptor blocker (ARB: such as losartan, valsartan), an endothelin receptor antagonist (such as ambrisentan, bosentan), or aliskiren

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SPESOLIMAB-SBZO - SQ

Generic	Brand				
SPESOLIMAB-SBZO	SPEVIGO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for approval:

A. You have a diagnosis of generalized pustular psoriasis (GPP: a type of skin condition)
B. You are 12 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
E. You have a history of GPP as defined by the presence of sterile, macroscopically visible pustules (blisters with non-infectious pus that can be seen with the naked eye) on non-acral skin (skin in areas of the body such as arms and legs) (per ERASPEN [European Rare and Severe Psoriasis Expert Network] diagnostic criteria)
F. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

RENEWAL CRITERIA

Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of generalized pustular psoriasis (GPP: a type of skin condition)
B. You have shown a clinical response to therapy
C. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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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 (a rare type of seizure)
B. You are 6 months of age or older AND weighs 7kg or more
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. You are currently being treated with clobazam (a type of seizure drug)
E. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivatives, clobazam, topiramate

RENEWAL CRITERIA

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

A. You have seizures associated with Dravet syndrome (a rare type of seizure)
B. You are currently being treated with clobazam (type of seizure drug)

Commercial Effective: 08/29/22

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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 advanced renal cell carcinoma (RCC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of imatinib mesylate (Gleevec), unless there is a medical reason why you cannot (contraindication)

D. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor is progressive (getting worse) and well-differentiated

E. **If the request is for 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: 09/06/21

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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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TADALAFIL-ADCIRCA, ALYQ

Generic	Brand				
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
E. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

RENEWAL CRITERIA

Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Commercial Effective: 07/01/24

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TADALAFIL-TADLIQ

Generic	Brand				
TADALAFIL	TADLIQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TADALAFIL-TADLIQ (Tadliq)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You will NOT use Tadliq concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
E. You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
F. You are unable to swallow tadalafil tablets

RENEWAL CRITERIA

Our guideline named **TADALAFIL-TADLIQ (Tadliq)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You will NOT use Tadliq concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
C. You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Commercial Effective: 07/01/24

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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/Cl] ratio of at least 1.5 or grade 2 or greater localization to the heart using the Perugini grade 1-3 scoring system
   2. 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

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TALAZOPARIB

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 ONE of the following diagnoses:
   1. Human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (cancer that does not have a type of protein and has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   2. HRR gene-mutated (abnormal change in the homologous recombination repair gene) 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. You are 18 years of age or older

C. **If you have breast cancer, approval also requires:**
   1. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*: a type of gene mutation [abnormal change]) as confirmed by a Food and Drug Administration-approved test
   2. You have been treated with chemotherapy in the neoadjuvant (drugs used to treat cancer given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
   3. If you have hormone receptor (HR)-positive breast cancer, you had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

D. **If you have prostate cancer, approval also requires:**
   1. Talzenna will be used in combination with Xtandi (enzalutamide)
   2. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Talzenna will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron-Depot [leuprolide], Zoladex [goserelin], Supprelin [histrelin], Firmagon [degarelix])

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TAPINAROF

Generic	Brand				
TAPINAROF	VTAMA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have plaque psoriasis (a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
E. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
F. You had a trial of or contraindication (harmful for) to TWO of the following (from different categories):
    1. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

RENEWAL CRITERIA

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

A. You have plaque psoriasis (a type of skin condition)
B. You have achieved or maintained clear or minimal disease
C. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

Commercial Effective: 06/15/22

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TASIMELTEON

Generic	Brand			
TASIMELTEON	HETLIOZ, HETLIOZ LQ, TASIMELTEON			

GUIDELINES FOR USE

Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD) (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 the capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting brand Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz LQ oral suspension if you are 3 to 15 years old
   3. You have previously tried and failed maximally-tolerated melatonin therapy

Commercial Effective: 02/01/23

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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

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Commercial Effective: 07/13/20

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TBO-FILGRASTIM

Generic	Brand				
TBO-FILGRASTIM	GRANIX				

GUIDELINES FOR USE

Our guideline named **TBO-FILGRASTIM (Granix)** requires the following rule(s) be met for approval:

A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor)
D. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
E. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym

Commercial Effective: 11/01/22

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TEDUGLUTIDE

Generic	Brand			
TEDUGLUTIDE	GATTEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. You are 1 year of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
D. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

RENEWAL CRITERIA

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

A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
C. You have achieved at least a 20 percent reduction in parenteral support (administration of nutrition through a vein) compared to baseline
D. You have NOT achieved enteral autonomy (you still need nutrition through a tube)

Commercial Effective: 10/01/24

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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 (loose stool caused by a type of tumor)
B. You are 18 years of age or older
C. Xermelo will be used in combination with a somatostatin analog (such as octreotide)
D. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor) or gastroenterologist (doctor who treats digestive conditions)
E. You have been receiving a stable dose of long-acting somatostatin analog therapy (such as Sandostatin LAR [octreotide] or Somatuline Depot [lanreotide]) for a minimum of 3 months, unless you have a contraindication (it is harmful for you to use)
F. You have diarrhea that is inadequately controlled as defined by having at least four bowel movements per day

Commercial Effective: 07/01/24

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TEMOZOLOMIDE

Generic	Brand				
TEMOZOLOMIDE	TEMODAR , TEMOZOLOMIDE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Anaplastic astrocytoma (type of brain tumor)
   2. Glioblastoma multiforme (type of tumor affecting brain or spine)
   3. Small cell lung cancer (SCLC: a type of lung cancer)
   4. Metastatic melanoma (type of skin cancer)

B. **If you have metastatic melanoma, approval also requires:**
   1. You are not concurrently (at the same time) using an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

RENEWAL CRITERIA

NOTE: For the diagnoses of Anaplastic astrocytoma, Glioblastoma multiforme, or Small cell lung cancer (SCLC), please refer to the Initial Criteria section.

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

A. You have metastatic melanoma (type of skin cancer)
B. You are not concurrently (at the same time) using an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

Commercial Effective: 07/01/22

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TENAPANOR

Generic	Brand				
TENAPANOR HCL	IBSRELA				

GUIDELINES FOR USE

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

A. You have irritable bowel syndrome with constipation (IBS-C: a type of bowel disease)
B. You are 18 years of age or older
C. You had a trial of the preferred agents: lubiprostone AND Linzess

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Commercial Effective: 07/01/22

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TEPOTINIB

Generic	Brand				
TEPOTINIB HCL	TEPMETKO				

GUIDELINES FOR USE

Our guideline named **TEPOTINIB (Tepmetko)** 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. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

Commercial Effective: 10/09/21

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TERIFLUNOMIDE

Generic	Brand			
TERIFLUNOMIDE	AUBAGIO, TERIFLUNOMIDE			

GUIDELINES FOR USE

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

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Commercial Effective: 04/17/23

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TERIPARATIDE

Generic	Brand			
TERIPARATIDE	FORTEO, TERIPARATIDE			

GUIDELINES FOR USE

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

You have ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition in women after menopause)
- Primary or hypogonadal (low level of sex hormones) osteoporosis (a type of bone condition) in a male patient
- Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)

You meet ONE of the following:
- You are at high risk for fractures defined as ONE of the following:
  - You have a history of osteoporotic (i.e., fragility, low trauma) fracture(s)
  - You have two or more risk factors for a fracture (such as a history of multiple recent low trauma fractures, bone marrow density [BMD: a type of lab test] T-score less than or equal to -2.5, corticosteroid [such as prednisone] use, or use of GnRH analogs [such as Synarel (nafarelin)])
  - You have had no prior treatment for osteoporosis AND you have a FRAX (test for your risk of fractures) score of at least 20 percent for any major fracture OR at least 3 percent for a hip fracture
- 2. You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine
- You had a trial of, intolerance (side effect), or contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

You meet ONE of the following:
- You have received a total of 24 months of cumulative treatment with Forteo (teriparatide) AND remain at or have returned to having a high risk for fracture
- You have received less than 24 months of cumulative treatment with Forteo (teriparatide)

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TESAMORELIN

Generic	Brand			
TESAMORELIN ACETATE	EGRIFTA , EGRIFTA SV			

GUIDELINES FOR USE

Our guideline named **TESAMORELIN (Egrifta, Egrifta SV)** requires the following rule(s) be met for approval:

A. You have human immunodeficiency virus (HIV: a type of immune disorder) with lipodystrophy (abnormal distribution of fat in the body)
B. You are 18 years of age or older
C. The requested medication is being used for the reduction of excess abdominal fat
D. You are currently receiving treatment with a protease inhibitor (PI: a type of drug), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI: a type of drug), OR an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

Commercial Effective: 04/01/22

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TESTOSTERONE

Generic	Brand				
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO, TESTOSTERONE				

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. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   2. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

C. If the request is for Androderm, Fortesta, Natesto or Striant, you had a trial of or contraindication (harmful for) to TWO preferred agents: testosterone cypionate and intramuscular [injected into the muscle] testosterone enanthate

D. **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

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TESTOSTERONE

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. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **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

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Commercial Effective: 10/09/23

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TESTOSTERONE CYPIONATE

Generic	Brand				
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE CYPIONATE (Depo-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. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, approval also requires:**
   1. You are 16 years of age or older
   2. 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 with primary or secondary hypogonadism, approval also requires:**
   1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   2. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

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TESTOSTERONE CYPIONATE

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE CYPIONATE (Depo-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. 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. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

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Commercial Effective: 08/28/23

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TESTOSTERONE ENANTHATE

Generic	Brand				
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. If you are 40 years of age or older, approval also requires that your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   3. If the request is for Xyosted, approval also requires:
      a. You are 18 years of age or older
      b. The requested medication is being used for testosterone replacement therapy

C. **If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:**
   1. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

(Initial criteria continued on next page)

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

D. **If you are a female with metastatic breast cancer, approval also requires:**
   2. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
   3. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

E. **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 the treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:**
   1. You have NOT received more than two 6-month courses of testosterone replacement therapy
   2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

D. **If you are a female with metastatic breast cancer, renewal also requires:**
   1. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
   2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

E. **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 the treatment of gender dysphoria may be approved

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Commercial Effective: 04/01/24

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TESTOSTERONE UNDECANOATE

Generic	Brand				
TESTOSTERONE UNDECANOATE	JATENZO, KYZATREX, TLANDO, UNDECATREX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. You are 18 years of age or older
   2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   3. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, OR you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   4. If the request is for Jatenzo, Tlando, or Undecatrex, you had a trial of or contraindication to (harmful for you to use) TWO preferred medications: intramuscular testosterone cypionate and intramuscular testosterone enanthate

C. **If you have gender dysphoria, approval also requires:**
   1. You are 16 years of age or older
   2. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. Your symptoms have improved compared to baseline and you have tolerated treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you have gender dysphoria, renewal also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

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Commercial Effective: 10/21/24

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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 have cystic fibrosis (CF: a type of lung disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You meet ONE of the following:
    1. You are homozygous (have two copies of the same gene) for the F508del-CFTR (cystic fibrosis transmembrane conductance regulator: a type of gene) mutation (abnormal change)
    2. You have at least ONE of the following mutations (abnormal change) in the CFTR gene:

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N	I148T	P67L	R352Q	T1053I
D110E	F508del	I175V	P205S	R352W	V201M
D110H	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I

D443Y	F1052V	I618T	Q237H	R751L	V754M
D443Y; G576A; R668C	F1074L	I807M	Q359R	R792G	V1153E
D579G	F1099L	I980K	Q1291R	R933G	V1240G
D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

RENEWAL CRITERIA

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

A. You have cystic fibrosis (CF: a type of lung disorder)
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 a less than expected decline in FEV1 (forced expiratory volume: amount of air exhaled in one second)
    2. You have improved, maintained, or demonstrated a less than expected decline in BMI (body mass index: a tool for evaluating body fat)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 07/01/24

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TEZEPELUMAB-EKKO

Generic	Brand				
TEZEPELUMAB-EKKO	TEZSPIRE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:

A. You have severe asthma (a type of lung condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (lung/breathing) medicine
D. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
E. You meet ONE of the following:
    1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months OR at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months
    2. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma
F. You will NOT use Tezspire concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 (anti-interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

A. 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 (such as albuterol)
   3. Increase in percent predicted FEV1 (amount of air exhaled in one second) from pretreatment baseline
   4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

B. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline

C. You will NOT use Tezspire concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 (anti-interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

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Commercial Effective: 01/01/24

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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 (a type of blood cancer)
   2. Erythema nodosum leprosum (ENL: a type of immune condition)
   3. Anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)
   4. Waldenström's macroglobulinemia (a type of blood cancer)

B. **If you have multiple myeloma, approval also requires:**
   1. Thalomid will be used in combination with dexamethasone

C. **If you have anemia due to myelodysplastic syndrome, approval also requires:**
   1. You have been previously treated for anemia due to myelodysplastic syndrome

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Commercial Effective: 04/01/22

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TIRZEPATIDE - ZEPBOUND

Generic	Brand				
TIRZEPATIDE	ZEPBOUND				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The request is for weight loss OR weight loss management
B. You are 18 years of age or older
C. You have evidence of active enrollment in an exercise and caloric reduction program, which may include other optional weight loss/behavioral modification programs
D. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Ozempic [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
E. You meet ONE of the following:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You have a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

RENEWAL CRITERIA

Our guideline named **TIRZEPATIDE - ZEPBOUND** requires the following rule(s) be met for renewal:

A. The request is for weight loss OR weight loss management
B. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of drug such as Victoza [liraglutide], Ozempic [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
C. You have achieved or maintained at least a 5 percent weight loss of baseline body weight

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TIVOZANIB

Generic	Brand				
TIVOZANIB HCL	FOTIVDA				

GUIDELINES FOR USE

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

A. You have relapsed or refractory advanced renal cell carcinoma (type of kidney cancer that returned or no longer responds to treatment)
B. You are 18 years of age or older
C. You previously received two or more systemic therapies (such as Cabometyx, Keytruda, Opdivo)

Commercial Effective: 07/01/21

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TOBRAMYCIN INHALED

Generic	Brand				
TOBRAMYCIN	BETHKIS, TOBRAMYCIN				
TOBRAMYCIN IN 0.225% SOD CHLOR	TOBI, TOBRAMYCIN				
TOBRAMYCIN	TOBI PODHALER				
TOBRAMYCIN/NEBULIZER	KITABIS PAK, TOBRAMYCIN				

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)
D. **If the request is for Tobi Podhaler, approval also requires ONE of the following:**
   1. You had a trial and failure of or contraindication (harmful for) to ONE generic inhaled tobramycin product
   2. You are not able to tolerate the prolonged administration of nebulizers

Commercial Effective: 01/01/22

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TOCILIZUMAB - SQ

Generic	Brand			
TOCILIZUMAB SQ	ACTEMRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older

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INITIAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure or fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors [a type of blood pressure medication]), recurrent aspiration (something enters the airways accidentally) 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)

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), 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.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

D. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

E. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

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TOCILIZUMAB-AAZG - SQ

Generic	Brand				
TOCILIZUMAB-AAZG	TYENNE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure or fluid overload, drug-induced lung toxicity (lung damage due to side effects of drugs such as cyclophosphamide, methotrexate, ACE-inhibitors [a type of blood pressure medication]), recurrent aspiration (something enters the airways accidentally) such as from GERD (acid reflux), pulmonary vascular disease (a condition affecting blood vessels in the lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in the lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease (such as mixed connective tissue disease)

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

D. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

(Renewal criteria continued on next page)

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA (CONTINUED)

E. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as 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:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Enbrel etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam, diclofenac)
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

F. **If you have polyarticular course juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

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TOFACITINIB

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:
   6. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   7. Psoriatic arthritis (PsA: a type of skin and joint condition)
   8. Ankylosing spondylitis (AS: a type of joint condition)
   9. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   10. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

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

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have ankylosing spondylitis, renewal also requires**:
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

F. **If you have polyarticular course juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Xeljanz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 09/01/24

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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. Therapy is prescribed by or in consultation with a nephrologist (kidney specialist)
D. You do not have end-stage renal disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis

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: 04/01/23

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TOPIRAMATE

Generic	Brand				
TOPIRAMATE	EPRONTIA				

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)
   3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   4. Migraine

B. You are unable to take oral tablets or capsules

C. **If you have partial-onset seizures or primary generalized tonic-clonic seizures, approval also requires:**
   1. Eprontia will be used as initial monotherapy OR adjunctive therapy (drugs taken together with)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication (harmful for) to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
      b. You are 6 years of age or older AND had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

D. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. Eprontia will be used as adjunctive therapy (drugs taken together with)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication (harmful for) to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
      b. You are 6 years of age or older AND had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, or topiramate ER sprinkle

E. **If you have migraines, approval also requires:**
   1. You are 12 years of age or older
   2. Eprontia will be used as preventative treatment of migraines
   3. You had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

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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

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TORSEMIDE

Generic	Brand				
TORSEMIDE	SOAANZ				

GUIDELINES FOR USE

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

A. You have edema (swelling caused by fluid build-up in the body) associated with heart failure (a type of heart condition) or renal (kidney) disease
B. You are 18 years of age or older
C. You had a trial of or contraindication (harmful for) to TWO generic loop diuretics (such as furosemide, bumetanide)

Commercial Effective: 07/01/22

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TOVORAFENIB

Generic	Brand				
TOVORAFENIB	OJEMDA				

GUIDELINES FOR USE

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

A. You have relapsed or refractory low-grade glioma (LGG) (a type of brain cancer that has returned or did not respond to treatment)
B. Your cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation (types of abnormal changes in genes)

Commercial Effective: 06/10/24

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TRALOKINUMAB-LDRM

Generic	Brand				
TRALOKINUMAB-LDRM	ADBRY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:

J. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
K. You are 12 years of age or older
L. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
M. You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
N. You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
O. You will NOT use Adbry concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), Cibinqo (abrocitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
P. You have tried or have a contraindication to (harmful for you to use) ONE of the following:
    6. High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    7. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
    8. Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole])
    9. Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
    10. Phototherapy (light therapy)

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TRALOKINUMAB-LDRM

RENEWAL CRITERIA

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:

E. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
F. You have shown improvement while on Adbry
G. You will NOT use Adbry concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib), Cibinqo (abrocitinib), topical Opzelura (ruxolitinib), Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

Commercial Effective: 10/01/24

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TRAMADOL

Generic	Brand				
TRAMADOL HCL	QDOLO, TRAMADOL HCL				

GUIDELINES FOR USE

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

A. The request is for the management of pain
B. You are 18 years of age or older
C. Your pain is severe enough to require an opioid analgesic (type of pain medication) and alternative treatments are inadequate
D. You had a trial of or contraindication (harmful for) to generic tramadol immediate-release (IR) tablet or a generic tramadol with acetaminophen product
E. You are unable to take oral solid formulations of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

Commercial Effective: 03/14/22

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TRAMETINIB

Generic	Brand			
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST			

GUIDELINES FOR USE

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

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-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 a BRAF V600E or V600K mutation (abnormal change in gene) 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)

(Criteria continued on next page)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene)
   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)

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the oral solution, approval also requires:**
   1. You are unable to swallow Mekinist (trametinib) tablets

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Commercial Effective: 10/01/23

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TREPROSTINIL DPI

Generic	Brand				
TREPROSTINIL	TYVASO DPI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

B. **If you have PAH (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

C. **If you have PH-ILD (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units

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TREPROSTINIL DPI

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

Commercial Effective: 07/01/24

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TREPROSTINIL INHALED

Generic	Brand				
TREPROSTINIL	TYVASO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

B. **If you have PAH (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

C. **If you have PH-ILD (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units

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TREPROSTINIL INHALED

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

Commercial Effective: 07/01/24

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TREPROSTINIL INJECTABLE

Generic	Brand				
TREPROSTINIL SODIUM	REMODULIN, TREPROSTINIL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. **For new start requests of Remodulin (treprostinil), approval also requires ONE of the following:**
    1. You are intermediate or high risk
    2. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
E. **If you are continuing current Remodulin (treprostinil) therapy from a hospital discharge, there is no additional requirement for approval.**

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

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TREPROSTINIL ORAL

Generic	Brand				
TREPROSTINIL DIOLAMINE	ORENITRAM ER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You do NOT have severe hepatic (liver) impairment
E. **For new start requests of Orenitram, approval also requires:**
    1. You have tried or have a contraindication to (harmful for you to use) the preferred oral prostanoid: Uptravi (selexipag)
    2. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
F. **If you are continuing current Orenitram therapy from a hospital discharge, there is no additional requirement for approval.**

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TREPROSTINIL ORAL

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Commercial Effective: 07/01/24

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TRIENTINE CAPSULE

Generic	Brand				
TRIENTINE HCL	SYPRINE, CLOVIQUE, TRIENTINE HCL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
C. You have a Leipzig score (a type of diagnostic score) of 4 or higher
D. You are willing to follow a diet avoiding high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
E. You had a trial of or contraindication (harmful for) to penicillamine (Depen, Cuprimine)

RENEWAL CRITERIA

Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rules be met for renewal:

A. You have Wilson's disease (a type of genetic disorder)
B. You have achieved a free serum copper level (amount of copper in your blood) of less than 10 mcg/dL

Commercial Effective: 10/23/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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TRIENTINE TABLET

Generic	Brand				
TRIENTINE TETRAHYDROCHLORIDE	CUVRIOR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. You are 18 years of age or older
C. You have a prior or current Leipzig score (a type of diagnostic score) of 4 or higher
D. You have a non-ceruloplasmin copper (NCC: a type of test to check copper levels) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE: a type of test to check copper levels) between 100 to 500 mcg per 24 hours
E. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
F. You are willing to maintain a diet that avoids high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
G. You have tried penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
H. You have tried trientine hydrochloride (Syprine)

RENEWAL CRITERIA

Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rules be met for renewal:

A. You have Wilson's disease (a type of genetic disorder)
B. Your body's copper levels are monitored by a non-ceruloplasmin copper (NCC: a type of test to check copper levels) test or 24-hour urinary copper excretion (UCE: a type of test to check copper levels) test

Commercial Effective: 10/30/23

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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 colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lonsurf will be used as a single agent OR in combination with bevacizumab
   3. You had previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) in combination with an anti-VEGF biological therapy such as Zaltrap (ziv-aflibercept) or Cyramza (ramucirumab)
   4. If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You had previous treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

Commercial Effective: 09/01/23

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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 TWO of the following:
    1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
    2. Low enzyme activity in cultured fibroblasts (a type of cell found in the body)
    3. One or more known pathogenic mutations (abnormal changes) in CPT2, ACADVL, HADHA, or HADHB (types of genes)
C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [a type of heart condition])
D. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or physician specialist in medical genetics/inherited metabolic disorders
E. You have tried or have a contraindication to (harmful for you to use) commercial MCT oil (a medical food product)

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 have experienced a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

Commercial Effective: 07/01/24

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TROFINETIDE

Generic	Brand				
TROFINETIDE	DAYBUE				

GUIDELINES FOR USE

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

A. You have Rett syndrome (a type of nervous system disorder)
B. You are 2 years of age or older

Commercial Effective: 07/01/23

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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 ONE of the following diagnoses:
   1. 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
   2. RAS wild-type (a type of gene), HER2-positive unresectable or metastatic colorectal cancer (a type of digestive cancer)

B. **If you have advanced unresectable or metastatic HER2-positive breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have received one or more prior anti-HER2-based treatment (specifically either trastuzumab or trastuzumab with pertuzumab) for metastatic disease
   3. The requested medication will be used in combination with trastuzumab and capecitabine

C. **If you have RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)
   3. The requested medication will be used in combination with trastuzumab

Commercial Effective: 02/06/23

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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:
The request is for the acute (quick onset) treatment of migraines (a type of headache)
You are 18 years of age or older
You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute treatment of migraines
You have tried or have a contraindication (harmful for) to ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

RENEWAL CRITERIA

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for renewal:
The request is for the acute (quick onset) treatment of migraines
You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute treatment of migraines
You meet ONE of the following:
- You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
- You have experienced clinical improvement as defined by ONE of the following:
  - Ability to function normally within 2 hours of dose
  - Headache pain disappears within 2 hours of dose
  - Treatment works consistently in majority of migraine attacks

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UPADACITINIB

Generic	Brand			
UPADACITINIB	RINVOQ			

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 have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   - You are 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   - You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

D. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You have at least TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
   4. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   5. You meet ONE of the following:
      - You were previously on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to Rinvoq
      - You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
      - You have atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
   6. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

F. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

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INITIAL CRITERIA (CONTINUED)

G. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

H. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Cimzia [certolizumab])
   5. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   6. You meet ONE of the following:
      a. You were previously on another biologic and are switching to Rinvoq
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

I. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitors [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitors [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

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UPADACITINIB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

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

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   4. You have shown improvement while on therapy
   5. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

G. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

H. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

I. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitors [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitors [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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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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URSODIOL

Generic	Brand				
URSODIOL	RELTONE, URSODIOL				

GUIDELINES FOR USE

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

E. You have radiolucent, noncalcified gallbladder stones (hardened deposits of bile, that is barely visible on x-ray, in your gallbladder that do not contain calcium)
F. Your gallbladder stones are less than 20 mm in diameter
G. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic (entire body) disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, OR you refuse surgery
H. You have tried generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
I. You are unable to take generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet) formulations

Commercial Effective: 04/01/22

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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 rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe active ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Stelara
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, or genital area

(Initial criteria continued on next page)

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

E. **If you have moderate to severe active ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

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USTEKINUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

C. **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 Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. **If you have moderate to severe Crohn’s disease, renewal also requires:**
   1. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

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VADADUSTAT

Generic	Brand				
VADADUSTAT	VAFSEO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
D. You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 3 months
E. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic kidney disease (CKD)
F. You have a hemoglobin level of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (such as Epogen, Procrit), and you will discontinue ESA therapy before starting Vafseo
G. You will NOT use Vafseo concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Jesduvroq [daprodustat])

RENEWAL CRITERIA

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

A. You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
B. You meet ONE of the following:
    1. You have a hemoglobin level (a type of blood test) of at least 10 g/dL
    2. Your hemoglobin level has increased by at least 2 g/dL from your baseline level

Commercial Effective: 08/05/24

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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 ONE of the following:
   1. Tardive dyskinesia (TD: uncontrolled body movements)
   2. Chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)

B. **If you have tardive dyskinesia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), movement disorder specialist, or psychiatrist (a type of mental health doctor)
   3. Your tardive dyskinesia has been present for at least 3 months
   4. You have a history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

C. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or movement disorder specialist

Commercial Effective: 07/01/24

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VAMOROLONE

Generic	Brand				
VAMOROLONE	AGAMREE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for approval:

G. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
H. You are 2 years of age and older
I. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
J. Your diagnosis of DMD is confirmed by genetic testing
K. You have tried prednisone or prednisolone for at least 6 months
L. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet ALL of the following:
        d. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        e. There is no steroid myopathy (muscle disease due to steroid use)
        f. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
    2. You have experienced a significant adverse effect (such as, weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as, diabetes [a disorder with high blood sugar])

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VAMOROLONE

RENEWAL CRITERIA

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for renewal:

D. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
E. **If you are currently ambulatory (can walk), approval also requires:**
   1. You have shown improvement while on Agamree as measured by a standard set of ambulatory or functional status measures (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
F. **If you are currently non-ambulatory (cannot walk), approval also requires:**
   1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength while on Agamree as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

Commercial Effective: 01/22/24

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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: 04/10/21

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VARENICLINE

Generic	Brand				
VARENICLINE TARTRATE	TYRVAYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have dry eye disease
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
D. You have at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)

RENEWAL CRITERIA

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

A. You have dry eye disease
B. You have demonstrated improvement of dry eye disease

Commercial Effective: 10/01/24

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VEDOLIZUMAB

Generic	Brand				
VEDOLIZUMAB	ENTYVIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

(Initial criteria continued on next page)

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE non-biologic therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You have tried or have a contraindication to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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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VEDOLIZUMAB

RENEWAL CRITERIA

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

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simlandi (adalimumab-ryvk)

C. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Skyrizi (risankizumab-rzaa), Simlandi (adalimumab-ryvk)

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Commercial Effective: 10/01/24

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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 ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed with surgery or has spread to other parts of the body)
   2. Erdheim-Chester Disease (a type of multisystem mutation)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E mutation (a type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
   2. Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

C. **If you have Erdheim-Chester Disease, approval also requires:**
   1. You have a BRAF V600 mutation (a type of gene mutation)

Commercial Effective: 07/01/22

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VENETOCLAX

Generic	Brand			
VENETOCLAX	VENCLEXTA			

GUIDELINES FOR USE

Our guideline named **VENETOCLAX (Venclexta)** requires that the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   3. Newly-diagnosed acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

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

C. **If you have newly-diagnosed acute myeloid leukemia, 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 (a type of therapy to treat cancer)
   2. Venclexta will be used in combination with azacitidine or decitabine or low-dose cytarabine

Commercial Effective: 02/26/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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VERICIGUAT

Generic	Brand				
VERICIGUAT	VERQUVO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You are 18 years of age or older
D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Farxiga, Xigduo XR, Jardiance, Synjardy
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

RENEWAL CRITERIA

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

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

Commercial Effective: 02/15/21

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VIGABATRIN

Generic	Brand				
VIGABATRIN	SABRIL, VIGABATRIN, VIGADRONE, VIGPODER				

GUIDELINES FOR USE

Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Refractory complex partial seizures (a type of seizure)
   2. Infantile spasms (a type of seizure disorder in infancy and childhood)

B. **If you have refractory complex partial seizures, approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive (add-on) therapy
   3. The potential benefits outweigh the risk of vision loss
   4. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   5. You have tried or have a contraindication to (harmful for you to use) THREE antiepileptic medications, at least two of which must be generic (drugs used to treat seizures such as carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam immediate-release/extended-release, gabapentin, zonisamide, topiramate, lamotrigine)

C. **If you have infantile spasms, approval also requires:**
   1. You are 1 month to 2 years of age
   2. The requested medication will be used as monotherapy (one drug treatment)
   3. The potential benefits outweigh the potential risk of vision loss
   4. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

Commercial Effective: 09/01/24

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VIGABATRIN SOLUTION

Generic	Brand				
VIGABATRIN	VIGAFYDE				

GUIDELINES FOR USE

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

A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
B. You are 1 month to 2 years of age
C. Vigafyde will be used as monotherapy (one drug treatment)
D. The potential benefits outweigh the potential risk of vision loss
E. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
F. You have tried or have a contraindication to (harmful for you to use) generic vigabatrin powder for solution

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Commercial Effective: 08/19/24

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VISMODEGIB

Generic	Brand				
VISMODEGIB	ERIVEDGE				

GUIDELINES FOR USE

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

A. You have metastatic basal cell carcinoma or locally advanced basal cell carcinoma (type of skin cancer that has spread in the body or is advanced but has not spread)
B. You are 18 years of age or older
C. **If you have locally advanced basal cell carcinoma, approval also requires:**
   1. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation

Commercial Effective: 01/01/22

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VOCLOSPORIN

Generic	Brand				
VOCLOSPORIN	LUPKYNIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus 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 (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (doctor who specializes in the kidney)
D. The requested medication will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids)

RENEWAL CRITERIA

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

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

Commercial Effective: 02/15/21

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VONOPRAZAN

Generic	Brand				
VONOPRAZAN/AMOXICILLIN	VOQUEZNA DUAL PAK				
VONOPRAZAN/AMOXICILLIN /CLARITH	VOQUEZNA TRIPLE PAK				
VONOPRAZAN FUMARATE	VOQUEZNA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VONOPRAZAN (Voquezna Dual Pak, Voquezna Triple Pak, Voquezna)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. *Helicobacter pylori (H. pylori*: a type of bacteria*)* infection
   2. Erosive esophagitis (a type of digestive disorder)
   3. Non-erosive gastroesophageal reflux disease (a type of digestive disorder)

B. **If you have a *Helicobacter pylori* infection, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) a bismuth-based quadruple regimen (bismuth/tetracycline/metronidazole plus proton pump inhibitor [PPI] [such as omeprazole, lansoprazole])
   3. You meet ONE of the following:
      a. Your request is for Voquezna 20mg in combination with amoxicillin
      b. Your request is for Voquezna 20mg in combination with amoxicillin and clarithromycin
      c. Your request is for Voquezna Dual Pak
      d. Your request is for Voquezna Triple Pak

(Initial criteria continued on the next page)

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VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

C. **If you have erosive esophagitis, approval also requires:**
   1. Your request is for Voquezna
   2. You are 18 years of age or older
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   4. Your diagnosis is confirmed by endoscopy (a procedure to look inside your body, such as Los Angeles Classification of Reflux Esophagitis Grade A-D [a tool to rate the severity of the disease])
   5. You have tried or have a contraindication to (harmful for you to use) TWO proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole) at a maximum dose for 8 weeks each

D. **If you have non-erosive gastroesophageal reflux disease, approval also requires:**
   1. Your request is for Voquezna 10mg
   2. You are 18 years of age or older
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   4. Your diagnosis is confirmed by endoscopy (a procedure to look inside your body) AND you do not have the presence of visible (can be seen) erosion (wearing away) (such as not having Los Angeles Classification of Reflux Esophagitis Grade A-D [a tool to rate the severity of the disease])
   5. You had no previous treatment failure (drug did not work) with Voquezna in the last 12 months
   6. You have tried or have a contraindication to (harmful for you to use) TWO proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks each

RENEWAL CRITERIA

NOTE: For the diagnosis of *Helicobacter pylori* (*H. pylori*) infection or non-erosive gastroesophageal reflux disease, please refer to the Initial Criteria section.

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

A. You have erosive esophagitis (a type of digestive disorder)
B. Your request is for Voquezna
C. You have maintained a clinical response on Voquezna (the treatment is working)

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VORASIDENIB

Generic	Brand				
VORASIDENIB CITRATE	VORANIGO				

GUIDELINES FOR USE

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

A. You have Grade 2 astrocytoma or oligodendroglioma (types of brain cancer)
B. You are 12 years of age or older
C. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation (abnormal changes in types of genes that increase the risk of certain diseases)
D. Voranigo will be used following surgery, including biopsy (removal of cells or tissue from the body for examination), sub-total resection (partial removal of tumor), or gross total resection (complete removal of tumor)

Commercial Effective: 09/01/24

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VOSORITIDE

Generic	Brand				
VOSORITIDE	VOXZOGO				

GUIDELINES FOR USE

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

A. You have achondroplasia (a type of bone condition)
B. You have open epiphyses (the end part of a long bone)

Commercial Effective: 11/13/23

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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 (a type of blood disorder)
B. You are 4 years of age or older
C. Your hemoglobin (a type of blood cell) is less than 10.5 g/dL
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
E. You are having symptoms of anemia (a type of blood condition) which are interfering with activities of daily living
F. You had a trial of or contraindication (harmful for) to hydroxyurea
G. **If the request is for the 300 mg tablets for oral suspension, approval also requires ONE of the following:**
    1. You weigh less than 40 kilograms
    2. You weigh 40 kilograms or more and meet ALL of the following:
        a. You have tried or have a contraindication (harmful for) to Oxbryta 500mg tablets
        b. You are unable to swallow Oxbryta 500mg tablets

RENEWAL CRITERIA

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

A. You have sickle cell disease (a type of blood disorder)
B. You have maintained an improvement in symptoms associated with anemia (a type of blood condition)

Commercial Effective: 01/16/23

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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 ONE of the following:
   1. Mantle cell lymphoma (MCL: a type of blood cancer)
   2. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer that has returned or did not respond to treatment)
   4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   5. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   6. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or did not respond to treatment)

B. **If you have mantel cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received at least ONE prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

C. **If you have Waldenstrom's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older

D. **If you have relapsed or refractory marginal zone lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan, such as rituximab)

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

F. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Brukinsa will be used in combination with Gazyva (obinutuzumab)
   3. Brukinsa will be used after at least TWO lines of systemic therapy (such as lenalidomide with rituximab)

Commercial Effective: 07/01/24

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ZAVEGEPANT

Generic	Brand				
ZAVEGEPANT HCL	ZAVZPRET				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
The request is for the acute (quick onset) treatment of migraines (a type of headache)
You are 18 years of age or older
You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
You have tried or have a contraindication (harmful for) to ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])
You have tried or have a contraindication (harmful for) to TWO of the following medications: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
You are NOT able to tolerate oral medications

RENEWAL CRITERIA

Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
The request is for the acute (quick onset) treatment of migraines (a type of headache)
You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
You meet ONE of the following:
- You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
- You have experienced clinical improvement as defined by ONE of the following:
  - Ability to function normally within 2 hours of dose
  - Headache pain disappears within 2 hours of dose
  - Treatment works consistently in a majority of migraine attacks

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ZERO COPAY OVERRIDE - ASPIRIN

Generic	Brand				
ASPIRIN	ASPIRIN, ASPIRIN EC, VARIOUS				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - ASPIRIN** requires the following rule(s) be met for approval:

Your doctor has provided documentation confirming that your requested drug 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: 01/01/24

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ZERO COPAY OVERRIDE - BOWEL PREP

Generic	Brand				
SOD PICOSULF/MAG OX/CITRIC AC	CLENPIQ				
BISAC/NACL/NAHCO3/KCL/PEG 3350	PEG-PREP				
PEG3350/SOD SULF,BICARB,CL/KCL	GAVILYTE-C, GAVILYTE-G, GOLYTELY COLYTE WITH FLAVOR PACKS, PEG 3350-ELECTROLYTE, PEG 3350 AND ELECTROLYTES				
SODIUM CHLORIDE/NAHCO3/ KCL/PEG	NULYTELY, NULYTELY WITH FLAVOR PACKS, GAVILYTE-N, PEG 3350-ELECTROLYTE, TRILYTE WITH FLAVOR PACKETS				
PEG3350/SOD/SUL/NACL /KCL/ASB/C	MOVIPREP, PLENVU, PEG3350/SOD SUL/NACL/KCL/ASB/C				
PEG 3350/SOD SULF, CHLR/POT/MAG	SUFLAVE				
SODIUM, POTASSIUM,MAG SULFATES	SUPREP, SODIUM, POTASSIUM,MAG SULFATES				
SOD SULF/POT CHLORIDE/MAG SULF	SUTAB				

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ZERO COPAY OVERRIDE - BOWEL PREP

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - BOWEL PREP** requires the following rule(s) be met for approval:
You are 45 to 75 years of age
Your request is for colorectal cancer screening
Your doctor has provided documentation confirming that the requested drug is considered medically necessary for you (considerations may include additional follow-up colonoscopy required after a positive/abnormal screening test)

Commercial Effective: 01/01/24

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ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

Generic	Brand				
ANASTROZOLE	ARIMIDEX, ANASTROZOLE				
EXEMESTANE	AROMASIN, EXEMESTANE				
RALOXIFENE HCL	EVISTA, RALOXIFENE HCL				
TAMOXIFEN CITRATE	TAMOXIFEN CITRATE				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION** requires the following rule(s) be met for approval:

The requested medication is being used for prevention (risk reduction) of breast cancer

You are 35 years of age or older

Your doctor has provided documentation confirming that your requested drug 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: 01/01/24

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

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

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - CONTRACEPTIVE** requires that the following rule(s) be met for approval:

A. Your doctor has provided documentation confirming that 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 [keep up with] the appropriate use)
B. If the request is for an oral contraceptive with a quantity greater than #1 per day, approval also requires that your doctor has provided medical justification as to why the requested quantity is needed for contraception (such as continuous therapy, skipping placebo pills)
C. If the request is for a condom with a quantity greater than #60 per fill, approval also requires that your doctor has provided medical justification as to why the requested quantity is needed for contraception

Commercial Effective: 10/01/24

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ZERO COPAY OVERRIDE - FLUORIDE

Generic	Brand				
FLUORIDE (SODIUM)	FLUORIDE, SODIUM FLUORIDE, LUDENT FLUORIDE				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - FLUORIDE** requires the following rule(s) be met for approval:

You are 6 months to 6 years of age

Your doctor has provided documentation confirming that your requested drug 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: 01/01/24

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ZERO COPAY OVERRIDE - FOLIC ACID

Generic	Brand				
FOLIC ACID	FOLIC ACID, VARIOUS				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - FOLIC ACID** requires the following rule(s) be met for approval:

Your doctor has provided documentation confirming that your requested drug 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: 01/01/24

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

Generic	Brand				
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA, EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE				
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY				
TENOFOVIR DISOPROXIL FUMARATE	VIREAD, TENOFOVIR DISOPROXIL FUMARATE				
EMTRICITABINE	EMTRIVA, EMTRICITABINE				
CABOTEGRAVIR	APRETUDE				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS** requires the following rule(s) be met for approval:

The requested medication is FDA (Food and Drug Administration)-approved for pre-exposure prophylaxis (PrEP) or recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines

You are using the medication for PrEP regardless of your human immunodeficiency virus (HIV) medication use history (such as you have a history of post-exposure prophylaxis medication use)

Your doctor has provided documentation confirming that the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)

Commercial Effective: 01/01/24

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ZERO COPAY OVERRIDE - SMOKING CESSATION

Generic	Brand				
BUPROPION HCL	ZYBAN, BUROPION HCL SR				
VARENICLINE TARTRATE	CHANTIX, VARENICLINE TARTRATE				
NICOTINE	NICOTROL, NICOTROL NS, NICOTINE PATCH, NICODERM CQ, NICOTINE				
NICOTINE POLACRILEX	NICOTINE GUM, NICOTINE LOZENGE, NICORETTE, VARIOUS				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - SMOKING CESSATION** requires the following rule(s) be met for approval:
You are 18 years of age or older
Your doctor has provided documentation confirming that your requested drug 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: 01/01/24

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ZERO COPAY OVERRIDE - STATIN

Generic	Brand				
ROSUVASTATIN CALCIUM	CRESTOR, EZALLOR SPRINKLE, ROSUVASTATIN CALCIUM				
PRAVASTATIN SODIUM	PRAVACHOL, PRAVASTATIN SODIUM				
SIMVASTATIN	ZOCOR, SIMVASTATIN				
ATORVASTATIN CALCIUM	LIPITOR, ATORVASTATIN CALCIUM				
LOVASTATIN, LOVASTATIN EXTENDED-RELEASE	ALTOPREV, LOVASTATIN				
FLUVASTATIN SODIUM , FLUVASTATIN EXTENDED-RELEASE	LESCOL, FLUVASTATIN SODIUM, LESCOL XL, FLUVASTATIN EXTENDED-RELEASE				
PITAVASTATIN CALCIUM	LIVALO, PITAVASTATIN CALCIUM				
PITAVASTATIN MAGNESIUM	ZYPITAMAG, PITAVASTATIN MAGNESIUM				

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - STATIN** requires that the following rules be met for approval:

You are between 40 to 75 years of age without a history of cardiovascular disease (heart disease)

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:

- Aspirin/dipyridamole (Aggrenox)
- Clopidogrel (Plavix)
- Dipyridamole
- Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
- Prasugrel (Effient)
- Praluent Pen
- Repatha
- Ticagrelor (Brilinta)
- Ticlopidine
- Vorapaxar sulfate (Zontivity)

Your doctor has provided documentation confirming that the requested drug 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: 01/01/24

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ZILUCOPLAN

Generic	Brand				
ZILUCOPLAN SODIUM	ZILBRYSQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 18 years of age and older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. Your diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor (AChR) antibody (a type of blood test that shows you have myasthenia gravis)
E. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
F. You had a trial of or contraindication to (harmful for you to use) ONE corticosteroid (such as, prednisone)
G. You meet ONE of the following:
    1. You had a trial of or contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as, azathioprine, cyclophosphamide, methotrexate)
    2. You had a trial of or contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

RENEWAL CRITERIA

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

A. You have generalized myasthenia gravis (gMG: chronic autoimmune disorder)
B. You have had clinical benefit compared to baseline according to validated gMG instruments (such as, the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

Commercial Effective: 01/22/24

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ZONISAMIDE

Generic	Brand				
ZONISAMIDE	ZONISADE				

GUIDELINES FOR USE

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

A. You have partial-onset seizures (a type of seizure)
B. You are 16 years of age or older
C. Zonisade will be used as adjunctive (add-on) treatment
D. You are unable to swallow to zonisamide capsules

Commercial Effective: 01/01/23

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ZURANOLONE

Generic	Brand				
ZURANOLONE	ZURZUVAE				

GUIDELINES FOR USE

Our guideline named **ZURANOLONE (Zurzuvae)** requires the following rule(s) be met for approval:
A. You have postpartum depression (PPD: a type of depression that occurs after giving birth)

Commercial Effective: 01/22/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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