This is a complete list of drugs that have written coverage determination policies. Drugs on this list do not indicate that this particular drug will be covered under your medical or prescription drug benefit. Prior Authorization for individual drugs and categories of drugs may be required to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the drug formulary. Please verify drug coverage by checking your formulary and member handbook. Additional restrictions and exclusions may apply. If you have questions, please contact Providence Health Plan Customer Service at 503-574-8200 or 1-800-898-8174 (TTY: 711). Service is available five days a week, Monday through Friday, between 8 a.m. and 6 p.m.
ACNE MEDICATIONS

MEDICATION(S)
ACNUETANE, ACNE CONTROL CLEANSER, ACNE FOAMING WASH, ACNE MEDICATION 10% GEL, ACNE MEDICATION 5% GEL, ACNE TREATMENT 10% GEL, CVS ACNE TREATMENT 10% GEL, ACNECLEAR, ADADEAPALENE 0.1% GEL, ADADEAPALENE 0.3% GEL, CVS ADADEAPALENE 0.1% GEL, ADVANCED EXFOLIATING CLEANSER, AMNESTEEM, ATRALIN, AVITA 0.025% CREAM, BENZA CLIN, BENZAMYCIN, BENZOYL PEROXIDE 10% GEL, BENZOYL PEROXIDE 10% WASH, BENZOYL PEROXIDE 5% GEL, BENZOYL PEROXIDE 5% WASH, BENZOYL PEROXIDE 6% CLEANSER, PR BENZOYL PEROXIDE 7% WASH, BP, BP WASH 10% LIQUID, BP WASH 5% LIQUID, BP WASH 7% LIQUID, CLARAVIS, CLEAN-CLEAR CONTINUOUS CONTROL, CLEOCIN T, CLINDACIN ETZ 1% PLEDGET, CLINDACIN P, CLIND PH-BENZOYL PEROX 1.2-5%, CLINDAMYCIN PH 1% GEL, CLINDAMYCIN PH 1% SOLUTION, CLINDAMYCIN PHOS 1% PLEDGET, CLINDAMYCIN PHOSP 1% LOTION, CLINDAMYCIN-BENZOYL PEROXIDE, DAYLOGIC ACNE FOAMING WASH, DAYLOGIC ACNE TREATMENT, DIFFERIN 0.1% GEL, EFFACLAR ADADEAPALENE, ERY, ERYGEL, ERYTHROMYCIN 2% GEL, ERYTHROMYCIN 2% SOLUTION, ERYTHROMYCIN-BENZOYL PEROXIDE, FOAMING ACNE FACE WASH, ISOTRETINOIN 10 MG CAPSULE, ISOTRETINOIN 20 MG CAPSULE, ISOTRETINOIN 30 MG CAPSULE, ISOTRETINOIN 40 MG CAPSULE, KLA RON, MYORISAN, NEUAC GEL, PAC NEX, PANOXYL 10% ACNE FOAMING WASH, PERSA-GEL, RETIN-A 0.01% GEL, RETIN-A 0.025% CREAM, RETIN-A 0.05% CREAM, RETIN-A 0.1% CREAM, SODIUM SULFACETAMIDE 10% LOTN, SULFACETAMIDE SOD 10% TOP SUSP, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.05% CREAM, TRETINOIN 0.05% GEL, TRETINOIN 0.1% CREAM, ZENATANE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Preferred products may be approved when one of the following conditions are met (must be supported by chart notes):
   a. Documentation of acne fulminans
   b. Documentation of acne conglobata with recurrent abscesses or communicating sinuses
   c. Documentation of severe cystic acne with persistent or recurrent inflammatory nodules and cysts AND ongoing scarring

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
ACUTE HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)
BERINERT, FIRAZYR, ICATIBANT, KALBITOR, RUCONEST, SAJAZIR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria (1-2) must be met:
1. Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following:
a. For HAE Type I and Type II, documentation of the following (per laboratory standard):
i. Serum C4 below the lower limit of normal,
   AND
   ii. One of the following:
      1. C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal, or
      2. C1-INH function less than 50 percent of the lower limit of normal
b. For HAE with normal C1-INH or HAE Type III:
   i. Confirmed Factor 12 (FXII), ANGPT1, PLG, or KNG1 gene mutation
      OR
   ii. Positive family history for HAE and attacks that lack response with high dose antihistamines or corticosteroids.
2. For coverage of Berinert®, Kalbitor®, Firazyr®, or Ruconest®: Documentation of trial and failure or contraindication to generic icatibant

For patients established on the requested therapy, all of the following criteria (1-2) must be met:
1. Documentation must be provided showing benefit of therapy with reduction of length and severity of HAE attack episodes.
2. For coverage of Firazyr®: Documentation of trial and failure or contraindication to generic icatibant

For quantities exceeding the formulary quantity limit: Documentation of frequent HAE attacks defined as greater than or equal to two attacks per month on average.

AGE RESTRICTION
Kalbitor® - 12 years and older
Firazyr® - 18 years and older
Ruconest® - 13 years and older
PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an immunologist or an allergist.

COVERAGE DURATION
Initial authorization will be approved for up to six months. Reauthorization will be approved for up to one year.

OTHER CRITERIA
N/A
MEDICATION(S)
ADAKVEO

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with voxelotor (Oxbryta®)

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed medical history or diagnosis of sickle cell disease
2. Patient has experienced at least two (2) sickle cell-related pain crises in the prior year
3. Documentation that patient meets one of the following:
   a. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least six (6) months
   b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six (6) months
   c. Patient has had an intolerance or contraindication to hydroxyurea (For many patients myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments)

Reauthorization: Documentation that the number or severity of sickle cell-related pain crises has decreased from baseline

AGE RESTRICTION
May be approved for patients 16 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of sickle cell disease.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 year

OTHER CRITERIA
N/A
MEDICATION(S)
ADBRY

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with another therapeutic immunomodulator (TIM) agent

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet all of the following criteria:
1. Diagnosis of severe atopic dermatitis (for adults 21 years of age and older) as defined by all the following:
   a. Documentation that patient is having functional impairment as indicated by one of the following:
      i. Dermatology Life Quality Index (DLQI) of at least 11
      ii. Children’s Dermatology Life Quality Index (CDLQI) of at least 13
      iii. Severe score on other validated tool
   b. One of the following:
      i. At least 10% of body surface area involved
      ii. Hand, foot, face, or mucous membrane involvement
2. Documentation of inadequate efficacy, intolerable side effects, or contraindication to at least one of the following:
   a. Four-week trial of a combination of moderate to high potency topical corticosteroid and a topical non-steroidal agent
   b. Oral immunomodulator (such as cyclosporine, methotrexate, oral corticosteroid)

For reauthorization, all the following criteria must be met:
1. Documentation of response to therapy indicating improvement or stabilization of condition
2. If the request is for four 150 mg syringes per 28 days, one of the following must be met:
   a. Patient has not achieved clear or almost clear skin in the last six months
   b. Individual weighs greater than 100 kg

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
ADDYI

COVERED USES
N/A

EXCLUSION CRITERIA
Sexual dysfunction without a diagnosis listed above.

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following must be met:
1. Patient is female and pre-menopausal
2. Patient must have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD, ICD-10 code F52.0)
3. Documentation that the patient’s condition is NOT due to any of the following:
   a. A co-existing medical or psychiatric condition,
   b. Problems within the relationship, or
   c. The effects of a medication or other drug substance

Reauthorization requires documentation of all the following:
1. Patient continues to be pre-menopausal
2. Documentation of positive response to the medication

AGE RESTRICTION
Approved for ages 18 years and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
AEMCOLO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. Rifamycin is not covered if documentation shows diarrhea that is complicated by fever or blood in stool.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for a 3-day treatment course

OTHER CRITERIA
N/A
MEDICATION(S)
ALBENDAZOLE 200 MG TABLET, ALBENZA, EMVERM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For the treatment of pinworms (Enterobius vermicularis):
   i. Documented trial, failure, intolerance, or contraindication to pyrantel pamoate (available over the counter)
   OR
2. For diagnoses other than pinworm (Enterobius vermicularis):
   i. Must be FDA approved or be a medically accepted indication (such as guideline directed therapy or
      compendia supported as listed in either the American Hospital Formulary System or Drugdex).
   ii. Diagnosis of parasite species must be confirmed through validated laboratory testing/identification. If
      laboratory confirmation is not possible, must be prescribed by or in consultation with an infectious disease
      specialist.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
See “Required Medical Information”

COVERAGE DURATION
Initial authorization and reauthorization will be approved for three months.

OTHER CRITERIA
N/A
MÉDICATION(S)
ALINIA, NITAZOXANIDE 500 MG TABLET

COBERTED USES
N/A

EXCLUSION CRITERIA
Treatment of diarrhea due to Cryptosporidium parvum in HIV-infected or immunodeficient patients.

REQUIRED MEDICAL INFORMATION
For diarrhea caused by Cryptosporidium:
1. Confirmed diagnosis of Cryptosporidium parvum

For diarrhea caused by Giardia:
1. Confirmed diagnosis of Giardia
AND
2. Documentation of trial and failure, intolerance, or contraindication to tinidazole

For diagnoses other than listed above:
1. Must be FDA approved or be a medically accepted indication (guideline directed therapy or compendia supported as listed in either the American Hospital Formulary System or Drugdex).
2. Must be prescribed by or in consultation with an infectious disease specialist or gastroenterologist.
3. Length of coverage will be three to 10 days depending on appropriate treatment duration for the diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For diarrhea caused by Cryptosporidium parvum in patients without HIV and diarrhea caused by Giardia lamblia: authorization will be approved for three days.

For all other indications: authorization will be approved for three to 10 days depending on diagnosis.

OTHER CRITERIA
ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)
ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of:
1. One of the following:
   a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 micromol/L (approximately 50 mg/dL by nephelometry or 80mg/dL by immunodiffusion)
   b. Patient has one of the following high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null)

   AND

2. Diagnosis of emphysema with one of the following:
   a. Forced expiratory volume per one second (FEV-1) of 35 to 65% of predicted volume
   b. Rapid lung function decline as evidence by reduction of FEV-1 of 100 mL/year or greater

   AND

3. Documentation that the patient has never smoked or has abstained from smoking for at least the previous six months

Reauthorization requires documentation of positive clinical response to therapy (e.g., reduction in exacerbations, reduced progression of emphysema as assessed by computed tomography (CT) densitometry, slowing of FEV-1 decline)

QUANTITY LIMIT:
60 mg/kg infused every seven days, subject to audit.
Note: Dose may be rounded down to the nearest gram (500 mg for Aralast®) within 10% of calculated dose.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Initial authorization will be approved for six months and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
ANTI-AMYLOID MONOCLONAL ANTIBODIES

MEDICATION(S)
ADUHELM, LEQEMBI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Monoclonal antibodies directed against amyloid is not considered medically necessary and will not be covered due to insufficient evidence of a clinical benefit and safety concerns.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
N/A
ANTIFUNGAL AGENTS

MEDICATION(S)
CRESEMBA 186 MG CAPSULE, ITRAConAZOLE 10 MG/ML SOLUTION, ITRAConAZOLE 100 MG CAPSULE, ITRAConAZOLE 100 MG/10 ML CUP, NOXAFIL 300 MG POWDERMIX SUSP, NOXAFIL 40 MG/ML SUSPENSION, NOXAFIL DR 100 MG TABLET, POSAConAZOLE 200 MG/5 ML SUSP, POSAConAZOLE DR 100 MG TABLET, SPORANOX, VFEND, VIVJOA, VORICONAZOLE 200 MG TABLET, VORICONAZOLE 40 MG/ML SUSP, VORICONAZOLE 50 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For oropharyngeal or esophageal candidiasis (itraconazole solution, posaconazole, and voriconazole only):
   a. For itraconazole solution: Documented failure, intolerance, or contraindication to fluconazole
   b. For voriconazole or posaconazole: Documented failure, intolerance, or contraindication to fluconazole and itraconazole solution

   Note: itraconazole capsules are not covered for this indication. Their use is not supported by Infectious Diseases Society of America (IDSA) guidelines, as they were considered less effective than fluconazole.

2. For the treatment of invasive Aspergillus or disseminated Candida infections:
   a. Confirmed diagnosis (Fungal culture and other relevant laboratory studies [including histopathology] must be documented)
   b. For posaconazole or isavuconazonium: Documented failure, intolerance, or contraindication to voriconazole

3. For the treatment of blastomycosis or histoplasmosis, itraconazole may be covered:
   a. For voriconazole or posaconazole: Documented failure, intolerance, or contraindication to itraconazole

4. For prophylaxis of invasive Aspergillus or Candida infections: posaconazole or voriconazole may be covered for severely immunocompromised patients. For example:
   a. Hematopoietic stem cell transplant recipient with graft-versus-host disease
   b. Current diagnosis of cancer currently undergoing chemotherapy or radiation
   c. HIV/AIDS
   d. Lung transplant or high risk non-lung solid organ transplant recipients

5. For onychomycosis (itraconazole only):
a. Documentation of diagnosis confirmed by fungal diagnostic test:
   AND
b. Documented failure, intolerance, or contraindication to generic terbinafine
   AND
c. One of the following criteria must be met:
   i. Patient has a relevant comorbidity (such as immunocompromised condition, severe circulatory disorder, or diabetes)
   ii. Infection resulting in recurrent cellulitis or functional impairment (such as pain-limiting normal activity)
6. For dermatomycosis (itraconazole only):
   a. Documentation of trial and failure, intolerance, or contraindication to topical therapy, terbinafine, or griseofulvin to treat the condition
7. For treatment of mucormycosis: isavuconazonium or posaconazole may be covered
8. For empiric antifungal therapy in patients with febrile neutropenia: itraconazole, voriconazole or posaconazole may be covered
9. For recurrent vulvovaginal candidiasis (RVVC) (oteseconazole only) must meet all the following criteria:
   a. Documentation that therapy is aligned with FDA approved indication (specifically, patient is a female who is NOT of reproductive potential)
   b. Documentation of three or more episodes of symptomatic vulvovaginal candidiasis
   c. Documentation of compatible clinical symptoms (such as vulvovaginal irritation, burning, pruritus, characteristic discharge, or edema/erythema)
   d. Documented failure, intolerance, or contraindication to BOTH of the following:
      i. A 7- to 14-day topical azole course
      ii. An oral fluconazole dose (specifically, oral fluconazole given every third day for a total of three doses)

For reauthorization:
Documentation supporting continued use of the requested agent for the intended diagnosis (such as continued active disease, length of therapy is supported by literature or guidelines, for prophylaxis patient continues to be severely immunocompromised)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, one of the following:
• Infectious disease specialist
• Hematologist
• Oncologist
• Pulmonologist
Prescriber restrictions apply for all indications except:
• Onychomycosis
• Dermatomycosis
  • If requesting itraconazole, oropharyngeal or esophageal candidiasis

**COVERAGE DURATION**
For prophylaxis of invasive Aspergillus or Candida infections: initial authorization and reauthorization will be approved for one year

For recurrent vulvovaginal candidiasis (RVVC): initial authorization and reauthorization will be approved for six months.

For other covered uses: Initial authorization will be approved for three months. Reauthorization will be approved for up to one year.

**OTHER CRITERIA**
N/A
ANTIMALARIAL AGENTS

MEDICATION(S)
COARTEM, DARAPRIM, PYRIMETHAMINE 25 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
Use for prophylaxis against malaria

REQUIRED MEDICAL INFORMATION
For treatment of acute malaria (Coartem® only):
1. Documentation of acute, uncomplicated infection caused from the species Plasmodium falciparum
2. Documentation that the infection was acquired in a chloroquine- or mefloquine-resistant area

For the treatment of toxoplasmosis (pyrimethamine only):
1. Documentation of Toxoplasma encephalitis infection in a pregnant or immunocompromised patient. AND
2. Documentation that the patient will be using pyrimethamine with leucovorin and sulfadiazine, or clindamycin if the patient cannot tolerate sulfadiazine

For the prevention of toxoplasmosis (pyrimethamine only):
1. Documentation that the patient has HIV with a CD4 count less than 100 cells/uL AND
2. Documented intolerance or contraindication to prophylaxis with trimethoprim-sulfamethoxazole

For reauthorization: documentation that that the patient’s CD4 count remains below 200 cells/uL

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For treatment of malaria or toxoplasmosis: authorization will be for 3 months
For prophylaxis against toxoplasmosis: Initial authorization and reauthorization will be approved for one year
OTHER CRITERIA
N/A
### ARIKAYCE

#### MEDICATION(S)
ARIKAYCE

#### COVERED USES
N/A

#### EXCLUSION CRITERIA
N/A

#### REQUIRED MEDICAL INFORMATION
1. Documentation of a confirmed diagnosis of Mycobacterium avium complex (MAC) lung infection by MAC-positive sputum or bronchoscopy cultures

AND

2. Documentation that the patient is unable to achieve negative sputum cultures after a minimum of 6 consecutive months of a standard guideline-based therapy (GBT). Guideline-based therapy is a three-drug oral antibiotic regimen composed of a macrolide (clarithromycin or azithromycin), ethambutol and rifamycin (rifabutin).

AND

3. Documentation that organism is susceptible to amikacin

Reauthorization requires documentation of negative sputum cultures.

#### QUANTITY LIMIT:
28 vials per month (8.4 ml/day)

#### AGE RESTRICTION
Approved for 18 years and older

#### PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist, or pulmonologist

#### COVERAGE DURATION
Initial authorization and reauthorization will be approved for 6 months

#### OTHER CRITERIA
N/A
EXCLUSION CRITERIA
Belimumab will not be approved if any of the following are present:
1. Severe active central nervous system lupus
2. Current use of other biologic immunomodulator
3. Documentation of previous use of dialysis in the past 12 months or currently using dialysis
4. Concurrent use of voclosporin (Lupkynis®) or anifrolumab (Saphnelo®)

REQUIRED MEDICAL INFORMATION
For patients initiating therapy for Systemic Lupus Erythematosus (SLE) and active lupus nephritis, all the following must be met:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist
   AND
2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following:
   a. Positive Antinuclear antibody (ANA)
   b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
   c. Positive anti-Smith (Anti-Sm)
   d. Positive anti-Ro/SSA and anti-La/SSB antibodies
   AND
3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:
   a. For SLE without Active Lupus Nephritis:
      i. Oral corticosteroid(s)
      ii. Azathioprine
      iii. Methotrexate
      iv. Mycophenolate mofetil
   b. Hydroxychloroquine
   c. Chloroquine
   d. Cyclophosphamide
b. For SLE with Active Lupus Nephritis:
   i. mycophenolate for induction followed by mycophenolate for maintenance, OR
   ii. cyclophosphamide for induction followed by azathioprine for maintenance.
4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

For patients established on therapy, the following criteria must be met:
1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction of renal related events)
2. Patient currently receiving standard therapy for SLE and active lupus nephritis

AGE RESTRICTION
Age five years and older for IV infusion
Age 18 years and older for subcutaneous injection

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a rheumatologist, nephrologist or a provider with experience treating SLE or lupus nephritis

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
BOTULINUM TOXIN

**MEDICATION(S)**
BOTOX, BOTOX COSMETIC, DYSPORT, JEUVEAU, MYOBLOC, XEOMIN

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
- When the above criteria are not met, botulinum toxin is considered investigational and not covered.
- Botulinum toxin is considered cosmetic and is not covered for the treatment of glabellar lines and/or fine wrinkles on the face.
  - PrabotulinumtoxinA (Jeuveau®) will not be covered as it is only FDA approved for the treatment of glabellar lines and/or fine wrinkles on the face.

**REQUIRED MEDICAL INFORMATION**
OnabotulinumtoxinA (Botox®) may be covered for the following indications when criteria are met:

1. Chronic migraine headaches in adults when all of the following is met:
   a. Documentation of at least 15 headache days per month with headaches lasting four hours or longer
   b. Documentation of trial and failure, intolerance, or contraindication to at least TWO of the following classes used for migraine prevention. Trial and failure is defined as inadequate response following a minimum three months of consistent use.
      i. Antidepressants (e.g., amitriptyline, venlafaxine)
      ii. Beta-blockers (e.g., metoprolol, propranolol, timolol)
      iii. Antiepileptics (e.g., divalproex, valproate, topiramate)
   c. For patients established on a Calcitonin Gene Related Peptide (CGRP) receptor antagonist for migraine prophylaxis, combination therapy with Botox® may be considered medically necessary if the following criteria are met:
      i. The patient has been established on, and adherent to, CGRP prophylaxis therapy (e.g., Aimovig®, Emgality®, Ajovy®) for at least six months and has a documented improvement in frequency and/or severity of migraine headaches
      ii. Patient continues to have at least 15 headache days per month with headaches lasting four hours or longer, despite use of CGRP prophylaxis monotherapy
   d. Reauthorization for Botox® monotherapy or combination therapy with CGRP for prophylaxis will require documentation of a 30% reduction in headache days from baseline.

2. Spasticity in patients at least two years of age
3. Cervical dystonia in adults
4. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
5. Severe axillary hyperhidrosis in adults after documented trial and failure, intolerance or contraindication
to topical agents

- Note: The safety and effectiveness of onabotulinumtoxinA for hyperhidrosis in other body areas have not been established.

6. Overactive bladder in adults with:
   - Symptoms of urge urinary incontinence, urgency, and frequency
   - Documented trial and failure, intolerance, or contraindication to at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)

7. Urinary incontinence in patients at least five years of age:
   - Due to detrusor overactivity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
   - Documented trial and failure, intolerance, or contraindication at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)

8. Excessive salivation due to advanced Parkinson’s disease

9. Hemifacial spasm

10. Chronic anal fissure when all of the following is met:
    - Prescribed by, or in consultation with, a gastroenterologist or colorectal surgeon
    - Documentation of trial and failure, intolerance, or contraindication to at least six weeks of therapy with either topical nitrates or topical calcium channel blockers
    - One of the following:
      - Documentation that the patient is not a good candidate for surgery or appropriate medical rationale is provided for avoiding surgery
      - Botox® is to be used in conjunction with fissurotomy
      - The use of Botox® in combination with sphincterotomy or anal advancement flap is considered experimental and investigational and will not be covered

11. Spastic dysphonia (laryngeal dystonia) for adductor type when prescribed by, or in consultation with, a specialist in laryngology

12. Achalasia in patients ineligible for definitive treatments, such as pneumatic dilation, surgical myotomy or peroral endoscopic myotomy (POEM)
    - The use of Botox® in combination with pneumatic dilation is considered experimental and investigational and will not be covered

AbobotulinumtoxinA (Dysport®) may be covered for the following indications:

1. Spasticity in patients two years of age and older
2. Cervical dystonia in adults
3. Blepharospasm in adults

IncobotulinumtoxinA (Xeomin®) may be covered for the following indications:

1. Chronic sialorrhea in patients two years and older
2. Upper limb spasticity in patients at least two years of age
3. Cervical dystonia in adults
4. Blepharospasm in adults
RimabotulinumtoxinB (Myobloc®) may be covered for the following indications:

1. Cervical dystonia in adults
2. Chronic sialorrhea in adult patients

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for one year

**OTHER CRITERIA**
N/A
BRAND OVER GENERIC

MEDICATION(S)
GLEEVEC, TECFIDERA, ZYTIGA

COVERED USES
N/A

EXCLUSION CRITERIA
Brand formulations will not be approved solely due to financial reasons (e.g., patient has coupon card for brand formulation).

REQUIRED MEDICAL INFORMATION
One of the following criteria must be met:
1. Patient has a documented allergy to an excipient found in all generic manufacturers' products
2. Patient has had a therapeutic failure to the generic formulation. This is defined as the patient taking the medication as prescribed for an adequate duration, a trial on multiple generic manufacturers' products, and the therapeutic failure cannot be attributed to inadequate dosing
3. Documented medical rationale for requiring use of brand name formulation over therapeutically equivalent generic formulation. If the rationale provided is related to the Food & Drug Administration's definition of generic bioequivalence, high-quality medical literature must be provided showing there are clinically meaningful differences between the specific formulations in terms of efficacy and/or safety.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
CABENUVA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For new starts:
1. Patient must have a confirmed diagnosis of human immunodeficiency virus type -1 (HIV-1)
2. Patient has been stable and adherent with their current antiviral regimen for a minimum of six months (adherence may be confirmed by pharmacy claims)
3. Patient has a recent viral HIV-1 RNA of less than 50 copies/mL on current oral antiviral regimen
4. Documentation that patient does not have a history of treatment failure

For continuation of therapy:
1. Documentation that patient has been adherent with therapy
2. Documentation that patient has maintained a viral HIV-1 RNA of less than 50 copies/mL

AGE RESTRICTION
May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist

COVERAGE DURATION
Initial authorization for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
CABLIVI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Criteria:
1. Diagnosis of acquired thrombotic thrombocytopenic purpura
2. Documentation that therapy will be given in combination with plasma exchange therapy
3. Documentation that therapy will be given in combination with immunosuppressive therapy (such as glucocorticoids, rituximab)

Reauthorization criteria:
If the request is for a new treatment cycle:
1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (such as glucocorticoids, rituximab)
3. Documentation that length of therapy post plasma exchange will not exceed 58 days
4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange.
If request is for treatment extension:
1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency
3. Documentation that length of therapy post plasma exchange will not exceed 58 days

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist or hematologist
COVERAGE DURATION
Initial authorization will be approved for 30 days. Reauthorization will be approved up to a total duration of 58 days post-plasma-exchange.

OTHER CRITERIA
N/A
CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS

MEDICATION(S)
AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, AJOVY SYRINGE, EMGALITY PEN, EMGALITY SYRINGE, NURTEC ODT, QULIPTA, UBRELVY, VYEPTI

COVERED USES
N/A

EXCLUSION CRITERIA
Use in combination with botulinum toxin therapy

REQUIRED MEDICAL INFORMATION
1. For initial authorization, the following indication-specific criteria must be met:
   a. For migraine prophylaxis (chronic and episodic), Emgality®, Aimovig®, Ajovy®, Vyepti®, Nurtec ODT®, or Qulipta® may be covered if ALL the following criteria are met:
      i. Diagnosis of migraine headaches with at least four migraine headache days per month, AND
      ii. Documentation of inadequate response, defined as minimal to no improvement after at least six weeks of consistent use, to at least one prophylactic medication from each of the following categories, or intolerance/contraindication to each of the following classes:
         • Anticonvulsants (specifically divalproex, valproate, or topiramate)
         • Beta-blockers (specifically metoprolol, propranolol, or timolol)
         • Antidepressants (specifically amitriptyline or venlafaxine)
      AND
      iii. Documentation that member has not received a botulinum toxin injection in the past two months, AND
   iv. Documentation that headaches are not due to medication overuse
   v. For non-preferred agents (Vyepti®, Nurtec ODT®, Qulipta®, Emgality®): Documentation of inadequate response, intolerance, or contraindication to the preferred products Aimovig® and Ajovy®

 b. For episodic cluster headaches, Emgality® may be covered if ALL the following criteria are met:
    i. A history of at least four cluster headache attacks per week
    ii. A history of cluster headaches for more than one month
    iii. Documentation that headaches are not due to medication overuse
    iv. Documentation of inadequate response, defined as minimal to no improvement after at least six weeks of therapy, to two of the following prophylactic medications:
       • Verapamil
       • Melatonin
       • Lithium
       • Prednisone
       • Sub occipital steroid injection
• Topiramate
c. For the acute treatment of migraine headaches, Nurtec ODT® or Ubrelvy® may be covered if the following criteria are met:
i. Failure of two different triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) or documented contraindication to the use of triptans, such as:
   • Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal’s angina)
   • History of stroke or transient ischemic attack (TIA)
   • Peripheral vascular disease
   • Ischemic bowel disease
   • Uncontrolled hypertension
   • History of hemiplegic or basilar migraine
ii. If the patient also has chronic migraines, the following additional criteria must be met:
   • Patient has a history of at least four migraines per month, AND
   • Patient is using preventative migraine therapy (excluding other CGRP inhibitors)

2. For patients established on the requested therapy, the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy
a. For migraine management:
   i. Documentation that headaches are not due to medication overuse
   ii. Documented reduction in migraine headache frequency and/or intensity from baseline
b. For cluster headaches:
   i. Documentation that headaches are not due to medication overuse
   ii. Documentation of a reduction of at least eight cluster headaches per month

3. For quantity limit exception requests:
a. For migraine prophylaxis: doses above the FDA maximum recommended dose will not be covered
   i. Qulipta® will be allowed at a quantity of one tablet per day if coverage for migraine prophylaxis is approved.
b. For acute treatment of migraines:
   i. The safety and efficacy of treating more than eight migraine headaches per month with ubrogepant has not been established, quantities to treat more than eight migraine headaches will not be covered.
   ii. Quantities of up to 18 tablets per month of rimegepant may be covered if the patient is on prophylactic therapy (e.g. divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, or venlafaxine) and the patient is still experiencing more than two headache days per week.

AGE RESTRICTION
May be covered for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist or headache specialist
**COVERAGE DURATION**
Initial authorization will be approved for six months.

Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

**OTHER CRITERIA**
N/A
MEDICATION(S)
CAMBIA, DICLOFENAC POT 50 MG POWDR PKT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For authorization, all the following criteria (1-3) must be met:
1. Confirmed diagnosis of episodic or chronic migraine headaches
2. Inadequate response to at least one generic triptan (such as sumatriptan, rizatriptan, naratriptan) or contraindication to all triptan medications
3. Inadequate response to diclofenac tablets/capsules, or medical rationale provided why patient cannot use diclofenac tablets/capsule

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
CAMZYOS

MEDICATION(S)
CAMZYOS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization requires documentation of all the following:
1. Clinical diagnosis of hypertrophic cardiomyopathy (HCM), defined as left ventricular hypertrophy (LVH) in the absence of another cardiac, systemic, or metabolic disease capable of producing the magnitude of hypertrophy evident, and evidence of one of the following as measured by any imaging technique:
   a. Left ventricle wall thickness of 15 mm or greater OR
   b. Left ventricle wall thickness of 13 mm or greater with family history of HCM or in conjunction with a positive genetic test
2. New York Heart Association (NYHA) class II, III, or IV
3. Left ventricular ejection fraction (LVEF) 55% of greater
4. Left ventricular outflow tract (LVOT) peak gradient 50 mmHg or greater at rest or with provocation
5. Documented trial and failure, intolerance, or contraindication to two of the following:
   a. A formulary generic non vasodilating beta blocker (such as propranolol, metoprolol, atenolol, bisoprolol)
   b. A formulary generic calcium channel blocker (verapamil or diltiazem)
   c. Disopyramide

Reauthorization requires documentation of a positive clinical response, as evidenced by at least one of the following:
1. Improvement in symptoms (such as dyspnea, fatigue, chest pain, palpitations, dizziness, fainting) OR
2. NYHA class reduction

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a cardiologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.
OTHER CRITERIA
N/A
CFTR MODULATORS

MEDICATION(S)
KALYDECO, ORKAMBI, SYMDEKO, TRIKAFTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For ivacaftor (Kalydeco®):
• Diagnosis of cystic fibrosis with documentation of at least one copy of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to ivacaftor (See package insert)

For lumacaftor-ivacaftor (Orkambi®):
• Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene

For tezacaftor-ivacaftor (Symdeko™):
• Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to tezacaftor-ivacaftor based on clinical evidence and/or in vitro data (See package insert)

For elexacaftor-tezacaftor-ivacaftor (Trikafta™):
• Diagnosis of cystic fibrosis with documentation of at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to elexacaftor-tezacaftor-ivacaftor based on in vitro data (See package insert)

AGE RESTRICTION
Ivacaftor (Kalydeco®): four months or older
Lumacaftor/Ivacaftor (Orkambi®): one year or older
Tezacaftor/Ivacaftor (Symdeko™): six years or older
Elexacaftor/Tezacaftor-ivacaftor (Trikafta™): two years or older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
OTHER CRITERIA
N/A
CHENODAL

MEDICATION(S)
CHENODAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For use in gallstone dissolution:
1. Documentation that the patient is not a candidate for surgery
   AND
2. Documentation of failure of an adequate trial of six months duration, contraindication, or intolerance to
   ursodiol
   AND
3. Documentation that dose does not exceed 16 mg/kg/day (current body weight must be provided)
   AND
4. For Medicaid only: Documentation of evidence of cholecystitis (gallstones without cholecystitis is
   unfunded)

For use in cerebrotendinous xanthomatosis: Documentation of confirmed diagnosis.

Reauthorization: Documentation of positive clinical response to therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For use in gallstone dissolution, must be prescribed by, or in consultation with, a gastroenterologist.

For use in cerebrotendinous xanthomatosis, must be prescribed by, or in consultation with, a genetics or
metabolism specialist.

COVERAGE DURATION
Initial authorization will be for six months. Reauthorization will be for one year.
Maximum total duration of therapy authorized for treatment of gallstones will be two years.
OTHER CRITERIA
N/A
CHOLBAM

MEDICATION(S)
CHOLBAM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Documentation of baseline liver function tests (LFTs)
AND
2. For bile acid synthesis disorder: documentation of a single enzyme defect
3. For peroxisomal disorder, including Zellweger spectrum disorders, both of the following criteria must be met:
   a. Documentation of manifestations of at least one of the following:
      i. Liver disease (e.g., jaundice, elevated serum transaminases)
      ii. Steatorrhea
      iii. Complications from decreased fat-soluble vitamin absorption (such as poor growth)
      AND
   b. The medication will be used as adjunctive therapy
For Reauthorization: Documentation of positive clinical response, as evidenced by an improvement in LFTs

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with medical geneticist, pediatric gastroenterologist, hepatologist, or other specialist experienced in treating inborn errors of metabolism.

COVERAGE DURATION
Initial authorization for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
CHOLESTATIC PRURITUS AGENTS

MEDICATION(S)
BYLVAY, LIVMARLI

COVERED USES
N/A

EXCLUSION CRITERIA
1. History of liver transplant
2. Decompensated cirrhosis
3. History of surgical interruption of enterohepatic circulation, such as partial external biliary diversion surgery (For Livmarli® only)
4. Molecular genetic testing indicates PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-2, protein (For Bylvay® only)

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following criteria must be met:
1. Documentation of moderate-to-severe pruritus AND
2. Documentation that drug-induced pruritis has been ruled out AND
3. Documentation of trial and failure, contraindication, or intolerance to ALL of the following systemic medications for pruritis associated with cholestasis:
   a. Ursodiol
   b. Cholestyramine
   c. Rifampin
4. Indication-specific criteria, as outlined below:
   a. For Cholestatic pruritus in patients with confirmed diagnosis of Alagille syndrome (ALGS), Livmarli® may be approved with documentation of cholestasis, as indicted by at least one of the following:
      i. Total serum bile acid greater than three times the upper limit of normal (ULN) for age, or
      ii. Conjugated bilirubin greater than 1 mg/dL, or
      iii. Fat soluble vitamin deficiency that is otherwise unexplainable, or
      iv. Gamma Glutamyl Transferase (GGT) greater than three times ULN for age, or
      v. Intractable pruritus explainable only by liver disease
   b. For Progressive Familial Intrahepatic Cholestasis (PFIC), Bylvay® may be approved when the following criteria are met:
      i. Documentation of genetically confirmed PFIC type 1 or 2 (formerly known as Byler disease or syndrome) (note: gene mutations affiliated with PFIC include the ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND
      ii. Documentation that serum bile acids at least 100 micromol/L
For reauthorization: documentation of response to therapy, defined as both of the following:
1. Improvement in pruritus
2. Reduction in serum bile acids from baseline, defined as:
   a. For Livmarli®: at least 50% reduction
   b. For Bylvay®: at least 70% reduction

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hepatologist or gastroenterologist.

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
CIBINQO

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with another therapeutic immunomodulator (TIM) agent

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet all of the following criteria:
1. Diagnosis of severe atopic dermatitis (for adults 21 years of age and older) as defined by all the following:
   a. Documentation that patient is having functional impairment as indicated by one of the following:
      i. Dermatology Life Quality Index (DLQI) of at least 11
      ii. Children’s Dermatology Life Quality Index (CDLQI) of at least 13
      iii. Severe score on other validated tool
   b. One of the following:
      i. At least 10% of body surface area involved
      ii. Hand, foot, face, or mucous membrane involvement
2. Documentation of inadequate efficacy, intolerable side effects, or contraindication to at least one of the following:
   a. Four-week trial of a combination of moderate to high potency topical corticosteroid and a topical non-steroidal agent
   b. Oral immunomodulator (such as cyclosporine, methotrexate, oral corticosteroid)

Reauthorization requires documentation of response to therapy indicating improvement or stabilization of condition

AGE RESTRICTION
May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.
OTHER CRITERIA
N/A
CONSTIPATION AGENTS

MEDICATION(S)
AMITIZA, IBSRELA, LINZESS, LUBIPROSTONE, MOTEGRITY, MOVANTIK, RELISTOR, SYMPROIC,
TRULANCE, ZELNORM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For children less than 21 years of age:
1. The diagnosis is a funded diagnosis per the Prioritized List of Healthcare Service or documentation is provided outlining constipation is impacting the patient’s health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)
2. Documented trial and failure, intolerance, or contraindication to at least two preferred products such as bisacodyl, docusate, lactulose, polyethylene glycol 3350 (available without restriction),
For adults 21 years of age and older: Documentation that all the following criteria are met:
1. The diagnosis is a funded diagnosis per the Prioritized List of Healthcare Service. Chronic constipation caused by a funded condition or adversely affecting a funded condition may be covered (subject to additional criteria below)
Note: disorders of function of stomach and other functional digestive disorders which includes constipation and Irritable Bowel Syndrome are NOT funded (ICD-10: K3183-3184, K310, R1110, K30, K3189, K319, K314-315, K312, K589, K591, K594, K5900-5902, K5909, K910-911, K9189, K598-599, R159, R150, R152)
2. For all requests, the patient must have an FDA labeled indication for the requested agent.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
CONTINUOUS GLUCOSE MONITORS FOR PERSONAL USE

MEDICATION(S)
DEXCOM G4 RECEIVER, DEXCOM G4 TRANSMITTER, DEXCOM G5 RECEIVER, DEXCOM G5 TRANSMITTER, DEXCOM G5-G4 SENSOR, DEXCOM G6 RECEIVER, DEXCOM G6 SENSOR, DEXCOM G6 TRANSMITTER, DEXCOM G7 RECEIVER, DEXCOM G7 SENSOR, DEXCOM RECEIVER, FREESTYLE LIBRE 14 DAY READER, FREESTYLE LIBRE 14 DAY SENSOR, FREESTYLE LIBRE 2 READER, FREESTYLE LIBRE 2 SENSOR, FREESTYLE LIBRE 3 SENSOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
I. Continuous glucose monitors may be considered medically necessary and covered for the management of insulin-dependent diabetes when all the following criteria are met:
A. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and
B. The patient is currently using insulin therapy. This may be verified by pharmacy claim(s) for insulin within the previous 120 days.

II. Continuous glucose monitors may be considered medically necessary and covered for patients experiencing post-bariatric hypoglycemia (PBH) when all the following criteria are met:
C. Other causes of hypoglycemia have been ruled out (such as malnutrition, adverse events from medications, dumping syndrome, or insulinoma), and
D. The patient is experiencing severe hypoglycemia episodes or hypoglycemia unawareness

Replacement of Continuous Glucose Monitors
I. Upgrade or replacement of continuous glucose monitor systems may be considered medically necessary and covered when there is documentation that one or more of the device components meet all of the following criteria (A.-C.):
A. Are no longer functional, and
B. Are not under warranty, and
C. Cannot be repaired.

II. Upgrade or replacement of continuous glucose monitor systems is considered not medically necessary and not covered when criterion II above is not met.

Upon approval, concurrent use of test strips will be limited to:
• Dexcom G6/Dexcom G7/Freestyle Libre 2/Libre 3: 50 test strips per 90-day supply
  o An additional 50 test strips per 90 days may be approved with documentation that the patient has low blood glucose levels requiring verification at least two times per week (See Diabetic DME policy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
CORLANOR

MEDICATION(S)
CORLANOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chronic heart failure in adults, all the following must be met:
1. Symptoms consistent with New York Heart Association (NYHA) Class II, III, or IV
2. Left ventricular ejection fraction (LVEF) of 35% or less
3. Documentation that patient is currently in normal sinus rhythm with resting heart rate of at least 70 beats per minute (bpm)
4. On maximally tolerated guideline-directed therapy including all the following, unless contraindicated or intolerant:
   a. Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol)
   b. SGLT-2 (specifically empagliflozin or dapagliflozin)
   c. One of the following:
      i. Angiotensin-converting enzyme (ACE) inhibitor, such as lisinopril,
      ii. Angiotensin II receptor blocker (ARB), such as losartan,
      iii. Angiotensin receptor-neprilysin inhibitor (ARNI), such as sacubitril/valsartan (Entresto®)
5. On maximally tolerated therapy with the following, as clinically appropriate:
   a. Aldosterone antagonists for patients with symptoms despite maximally tolerated therapy above
   b. Diuretic therapy for symptomatic patients with persistent volume overload
6. Documentation that the patient has been hospitalized for worsening heart failure in the previous 12 months

For inappropriate sinus tachycardia (IST):
1. Documentation of one of the following:
   a. Sinus rhythm and resting heart rate (HR) greater than 100 bpm (with a mean HR greater than 90 bpm over 24 hours)
   b. A rapid, stable, symptomatic increase in resting HR greater than 25 bpm when moving from a supine to a standing position or in response to physiological stress. Symptoms may include palpitations, shortness of breath, or dizziness.
2. Documentation that other causes of sinus tachycardia have been ruled out (such as thyroid disease,
3. Documentation that inappropriate sinus tachycardia is causing significant functional impairment or distress, such as presyncope, headache, dyspnea

For heart failure, due to dilated cardiomyopathy (DCM), in pediatric patients, all the following criteria must be met:

1. Documentation that patient has stable (for at least four weeks) and symptomatic heart failure (NYHA Class II to IV)
2. Left ventricular ejection fraction (LVEF) of 45% or less
3. Documentation that patient is currently in normal sinus rhythm with a resting heart rate (HR) as follows:
   a. 6–12 months: HR at least 105 bpm
   b. 1–3 years: HR at least 95 bpm
   c. 3–5 years: HR at least 75 bpm
   d. 5–18 years: HR at least 70 bpm

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or electrophysiologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
MEDICATION(S)
CALCIPOTRIENE-BETAMETHASONE, ENSTILAR, TACLONEX, WYNZORA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUARED MEDICAL INFORMATION
All of the following must be met:

1. Diagnosis of severe psoriasis (for adults 21 years of age and older) as defined by all the following:
   a. Documentation that patient is having functional impairment as indicated by one of the following:
      i. Dermatology Life Quality Index (DLQI) of at least 11
      ii. Children’s Dermatology Life Quality Index (CDLQI) of at least 13
      iii. Severe score on other validated tool
   b. Documentation of one of the following:
      i. At least 10% of body surface area involved
      ii. Hand, foot, face, or mucous membrane involvement
2. Documentation of inadequate efficacy, intolerable side effects, or contraindication to the following:
   a. For mild to moderate psoriasis (children less than 21 years of age only), two of the following:
      i. Four-week trial of moderate to high potency topical corticosteroid
      ii. Four-week trial of topical vitamin D analogues (calcitriol, calcipotriene)
      iii. Eight-week trial of tazarotene
      iv. Eight-week trial of calcineurin inhibitor (tacrolimus, pimecrolimus)
   b. For severe psoriasis: Four-week trial of at least two high to super-high potency topical corticosteroids

AGE RESTRICTION
Enstilar: 12 years of age and older
Taclonex: 12 years of age and older
Wynzora: 18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
OTHER CRITERIA
N/A
CRYSVITA - MEDICAL BENEFIT

MEDICATION(S)
CRYSVITA

COVERED USES
N/A

EXCLUSION CRITERIA
Pediatric patients with an estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73m2 or adult patients with creatinine clearance (CLcr) less than 30 mL/min.

REQUIRED MEDICAL INFORMATION
Initial authorization for new starts all of the following criteria must be met:
1. One of the following diagnoses:
   a. Diagnosis of X-linked hypophosphatemia (XLH) supported by ONE or more of the following:
      i. Confirmed PHEX mutation in the patient or a directly related family member with appropriate X-linked inheritance
      ii. Elevated Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL
   b. Clinical diagnosis of tumor-induced osteomalacia (TIO) and all of the following:
      i. Associated with tumors that cannot be identified or curatively resected
      ii. FGF23 level of at least 100 pg/mL, and
2. Documentation that serum phosphorus level is below the normal range for age, (use laboratory-specific reference ranges if available, otherwise, see appendix for ranges), and
3. One of the following:
   a. Patient’s epiphyseal plate has NOT fused, or
   b. Patient meets all of the following:
      i. Patient’s epiphyseal plate has fused, and
      ii. Patient is experiencing clinical signs and symptoms of disease (e.g., limited mobility, musculoskeletal pain, bone fractures), and
4. Failure of calcitriol with an oral phosphate agent, unless contraindicated or clinically significant adverse effects are experienced, and
5. Documentation of patient’s current weight and that dosing is in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for X-linked hypophosphatemia all of the following criteria must be met:
1. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
2. Documentation of at least one of the following responses to therapy:
a. Improvement in skeletal deformities
b. Healing of fracture or pseudofractures
c. Reduction in number of fractures/pseudofractures
d. Increase in growth velocity, and

3. Documentation of patient’s current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for hypophosphatemia in tumor induced osteomalacia (TIO) all of the following criteria must be met:
1. Documentation that tumor continues to be unidentifiable or unresectable
2. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
3. Documentation of at least one of the following responses to therapy:
   a. Improvement in skeletal deformities
   b. Healing of fracture or pseudofractures
   c. Reduction in number of fractures/pseudofractures
   d. Increase in growth velocity, and
4. Documentation of patient’s current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders.

COVERAGE DURATION
Initial authorization will be approved for six months and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
DALIRESP

MEDICATION(S)
DALIRESP, ROFLUMILAST

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. A confirmed diagnosis of severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations
   AND
2. Trial (of at least 60 days) and failure, contraindication or intolerance to maintenance treatment with triple therapy including a long-acting beta2 agonist (LABA), long-acting antimuscarinic agonist (LAMA), and an inhaled corticosteroid (ICS).
Note: Use of ICS may be waived if documentation is provided that patient has low likelihood of a beneficial ICS response with blood eosinophils less than 100 cells per microliter.

Reauthorization will require documented positive response to therapy (e.g., reduction in exacerbations, positive change from baseline in post-bronchodilator FEV1)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for 12 months
Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
DENAVIR/SITAVIG/XERESE/ZOVIRAX

MEDICATION(S)
ACYCLOVIR 5% CREAM, ACYCLOVIR 5% OINTMENT, DENAVIR, PENCICLOVIR 1% CREAM, SITAVIG, XERESE, ZOVIRAX 5% CREAM, ZOVIRAX 5% OINTMENT

COVERED USES
N/A

EXCLUSION CRITERIA
1. Genital or mucocutaneous herpes simplex
2. Suppressive therapy (greater than 10 days course)
3. Retreatment with acyclovir buccal tablets (Sitavig®) for the same episode of cold sore infection

REQUIRED MEDICAL INFORMATION
For herpes labialis (cold sores):
1. Documented trial and failure, intolerance or contraindication to a generic oral antiviral medication
2. For acyclovir buccal tablets (Sitavig®), acyclovir cream (Zovirax® cream), acyclovir/hydrocortisone cream (Xerese®), or penciclovir cream (Denavir®): Documented trial and failure, contraindication or intolerance to acyclovir ointment. Trial and failure is defined as no improvement in lesions 10 days after starting treatment.

QUANTITY LIMIT:
The following quantities will be approved per rolling 365-day period
1. Sitavig® - two 50mg tablets
2. Xerese® - 10 grams
3. Denavir® - 10 grams
4. Acyclovir 5% cream (Zovirax®) - 10 grams
5. Acyclovir 5% ointment (Zovirax®) - 30 grams

Additional quantities may be approved based on medical necessity. Medications being used as suppressive therapy is not considered medically necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
MEDICATION(S)
DESCOVY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of one of the following:
1. Patient has an allergy or intolerance to emtricitabine/tenofovir disoproxil fumarate
2. Patient has presence of, or at high risk for, osteopenia or osteoporosis
3. Patient has renal impairment or a high risk for renal impairment (i.e., older age, hypertension, diabetes, nephrotoxic medications)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
DIACOMIT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met:
1. Documentation of seizures associated with Dravet Syndrome (DS)
2. Documentation of inadequate control on clobazam, topiramate or valproate (unless contraindicated), despite optimized therapy
3. Documentation that stiripentol will be used in combination with clobazam
4. Dose will not exceed 50 mg/kg (up to maximum 3,000 mg) per day
5. Baseline absolute neutrophil count (ANC) above 1,900 cells per microliter and platelet count above 150,000 cells per microliter

For reauthorization or if patient is currently established on therapy (Note: starting on samples will not be considered established on therapy) all of the following criteria must be met:
1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
2. Dose will not exceed 50 mg/kg (up to maximum 3,000 mg) per day
3. Documentation of absolute neutrophil count (ANC) above 1,900 cells per microliter and platelet count above 150,000 cells per microliter taken within the past six months

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with a neurologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for six months.

OTHER CRITERIA
N/A
DISPOSABLE INSULIN PUMPS

MEDICATION(S)
OMNIPOD 5 G6 INTRO KIT (GEN 5), OMNIPOD 5 G6 PODS (GEN 5), OMNIPOD CLASSIC PODS (GEN 3), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4)

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
I. Disposable insulin pumps may be considered medically necessary and covered for the treatment of insulin-dependent diabetes when one of the following criteria are met:
A. The request is for a patient with Type 1 diabetes, or
B. All the following:
   1. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and
   2. The patient has been on a program of multiple daily injections of insulin (at least two injections per day), and
   3. Documented history of inadequate glycemic control despite compliance with frequent self-monitoring (four or more blood glucose readings per day or use of continuous glucose monitor) and patient has any of the following problems controlling blood glucose level:
      i. Documented hypoglycemia unawareness, or
      ii. Documented recurring episodes (two or more events) of clinically significant hypoglycemia (less than 54 mg/dl) or fasting hyperglycemia (greater than 150 mg/dl), or
      iii. Glycosylated hemoglobin level (HbA1C) greater than 7%, or
      iv. History of recurring, symptomatic hypoglycemia, or
      v. Fasting blood sugars frequently exceeding 200 mg/dL, or
      vi. History of severe glycemic fluctuations, or
      vii. Documented need for more than five daily injections of insulin.
B. For requests for V-go: failure of Omnipod or medical rationale provided for use of this pump over Omnipod

Replacement of Disposable Insulin Pumps
II. Upgrade or replacement of existing insulin pump may be considered medically necessary and covered when there is documentation that one or more of the device components meet all the following criteria (A.-C.):
A. Are no longer functional, and
B. Are not under warranty, and
C. Cannot be repaired.

III. Upgrade or replacement of existing insulin pump is considered not medically necessary and not covered when criterion II above is not met.

Note: The Omnipod pump Personal Diabetes Manager (PDM) is supplied by the manufacturer for most Commercial patients, so patients should be referred to Insulet Corporation for free starter kit or for replacement at 1-800-591-3455.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

**OTHER CRITERIA**
N/A
DPP4 INHIBITORS

MEDICATION(S)
GLYXAMBI, JANUMET, JANUMET XR, JANUVIA, JENTADUETO, JENTADUETO XR, KOMBIGLYZE XR, ONGLYZA, QTERN, STEGLUJAN, TRADJENTA, TRIJARDY XR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, ALL the following criteria are required:
1. Documentation of trial and failure, contraindication, or intolerance to metformin therapy, at the maximum effective dose of 2000 mg/day. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.
   AND
2. Documented trial and failure to one of the following medication classes, or intolerance/contraindication to all classes listed below (trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy):
   a. Sulfonylurea (such as glimepiride),
   b. Thiazolidinedione (such as pioglitazone),
   c. Sodium-glucose co-transporter 2 (SGLT2) inhibitor (such as empagliflozin),
   d. Glucagon-like peptide-1 (GLP-1) receptor agonist (such as liraglutide, exenatide, semaglutide),
   AND
3. A documented HbA1c (obtained within the last six months) that is greater than or equal to 7% and less than or equal to 10%,
   AND
4. For non-preferred DPP-4 inhibitors (sitagliptin, linagliptin, saxagliptin): Documented trial and failure, intolerance, or contraindication to alogliptin. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
DRONABINOL

MEDICATION(S)
DRONABINOL, MARINOL, SYNDROS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For nausea and vomiting associated with cancer chemotherapy:
1. Documentation of trial and failure, contraindication or intolerance to one of the following formulary 5HT-3 receptor antagonist: ondansetron (available as tablet, orally disintegrating tablet, or oral solution) or granisetron tablet.
AND
2. Documentation of trial and failure, contraindication or intolerance to one of the following formulary medications unless contraindicated: promethazine, prochlorperazine, chlorpromazine, or metoclopramide.
AND
3. For coverage of dronabinol oral solution (Syndros®), documentation that the patient is unable to swallow generic dronabinol oral capsule.

For anorexia with weight loss in patients with AIDS:
1. Documentation that patient is currently taking anti-retroviral therapy
AND
2. If patient is less than 65 years of age: Documentation of trial and failure, contraindication, or intolerance to megestrol (Megace®)
AND
3. For coverage of dronabinol oral solution (Syndros®), documentation that the patient is unable to swallow generic dronabinol oral capsule.

Reauthorization requires documentation of successful response to the medication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Nausea/vomiting with chemotherapy: Initial authorization and reauthorization will be approved for six (6) months.
AIDS wasting: Initial authorization and reauthorization will be approved for three (3) months.

OTHER CRITERIA
N/A
MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with another therapeutic immunomodulator (TIM) agent

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet the following indication-specific criteria:

For moderate-severe atopic dermatitis, all the following must be met:
1. For Commercial for initial authorization, all the following must be met:
a. Patient has a minimum body surface area (BSA) involvement of at least 10% or involvement of the palms of the hands and/or soles of the feet,
b. Documented inadequate response to one of the following or contraindication to all therapies:
   i. Systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) for at least three months
   ii. Both of the following:
      a) Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least four weeks
      b) Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least four weeks

2. For Medicaid for initial authorization, all the following must be met:
   1. Diagnosis of severe atopic dermatitis as defined by all the following:
a. Documentation that patient is having functional impairment as indicated by one of the following:
   i. Dermatology Life Quality Index (DLQI) of at least 11
   ii. Children's Dermatology Life Quality Index (CDLQI) of at least 13
   iii. Severe score on other validated tool
b. One of the following:
   i. At least 10% of body surface area involved
   ii. Hand, foot, face, or mucous membrane involvement
2. Documentation of inadequate efficacy, intolerable side effects, or contraindication to at least one of the following:
a. Four-week trial of a combination of moderate to high potency topical corticosteroid and a topical non-steroidal agent
b. Oral immunomodulator (such as cyclosporine, methotrexate, oral corticosteroid)

For moderate to severe asthma:
1. For initiation of therapy, all the following criteria (a-c) must be met:
   a. Confirmed diagnosis of one of the following (i or ii):
      i. Eosinophilic asthma, defined as one of the following:
         a) A blood eosinophil count of at least 150 cells/microliter while on high-dose inhaled corticosteroids or daily oral corticosteroids
         b) Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion while on high-dose inhaled corticosteroids or daily oral corticosteroids
         c) The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids
         d) Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
      ii. Corticosteroid dependent asthma, defined as consistent treatment with oral corticosteroids for the past six months (5 mg to 35 mg of prednisone/prednisolone (or equivalent). This may be verified by pharmacy claims information.
   b. Documentation of adherence to treatment with maximally tolerated doses of the following medications (this may be verified by pharmacy claims information), unless intolerance or contraindication to all therapies:
      i. Inhaled corticosteroid plus
      ii. One of the following:
         a) A long-acting inhaled beta 2-agonist (LABA)
         b) A leukotriene receptor antagonist (LTRA)
         c) A long-acting muscarinic antagonist (LAMA)
   c. Documentation inadequate asthma control despite above therapy, defined as one of the following:
      i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score more than 1.5
      ii. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
      iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months
2. For continuation of therapy: documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

For Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all the following must be met for initial authorization:
1. Evidence of nasal polyposis by direct examination, endoscopy, or sinus computed tomography (CT) scan
2. Documentation of inadequate response to a three-month trial of intranasal corticosteroids (such as fluticasone) or a documented intolerance or contraindication to ALL intranasal corticosteroids
3. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with dupilumab
For Eosinophilic Esophagitis (EoE), all the following must be met for initial authorization:
1. Diagnosis of eosinophilic esophagitis, defined as all of the following:
   a. Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF)
   b. Symptoms of esophageal dysfunction such as dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting
2. Patient weighs at least 40 kg
3. Patient had an inadequate response to one of the following therapies, or has an intolerance/contraindication to all of the following therapies:
   a. Eight weeks of a proton pump inhibitor
   b. Eight weeks of a topical glucocorticoid (e.g., fluticasone inhaler, swallowed budesonide)

For Prurigo Nodularis (PN), all the following must be met for initial authorization:
1. Presence of firm, nodular lesions
2. Documentation of itching which has lasted for at least six weeks
   a. Patient had an inadequate response, intolerance, or contraindication to moderate to high potency topical corticosteroid for at least two weeks (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%)
3. For Medicaid only: Diagnosis of severe prurigo nodularis (for adults 21 years of age and older) as defined by all the following:
   a. Documentation that patient is having functional impairment as indicated by one of the following:
      i. Dermatology Life Quality Index (DLQI) of at least 11
      ii. Children’s Dermatology Life Quality Index (CDLQI) of at least 13
      iii. Severe score on other validated tool
   b. One of the following:
      i. At least 10% of body surface area involved
      ii. Hand, foot, face, or mucous membrane involvement

For reauthorization for all indications: Documentation of response to therapy indicating improvement or stabilization of condition

AGE RESTRICTION
The patient’s age must be within FDA labeling for the requested indication

PRESCRIBER RESTRICTION
• Moderate-to-severe atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
• Eosinophilic and corticosteroid dependent asthma: Must be prescribed by, or in consultation with, an
asthma specialist (such as a pulmonologist, immunologist, or allergist)
• Chronic rhinosinusitis with nasal polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist
• Eosinophilic Esophagitis: Must be prescribed by, or in consultation with, an allergist and/or a gastroenterologist
• Prurigo Nodularis: Must be prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION
• For atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis: Initial authorization will be approved for six months. Reauthorization will be approved for one year.
• For asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
DURYSTA

MEDICATION(S)
DURYSTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The following criteria must be met:
1. The patient is not receiving re-treatment of eye(s) previously treated with bimatoprost intracameral implant (Durysta®)
2. Trial and failure, intolerance or contraindication to at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes, one of which is an ophthalmic prostaglandin (for example, bimatoprost, latanoprost, or travoprost)

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by an ophthalmologist

COVERAGE DURATION
Authorization will be approved for six months. Approval will be for a one-time use in each treated eye (one implant per treated eye, a total of two implants per patient)

OTHER CRITERIA
N/A
**EGRIFTA**

**MEDICATION(S)**
EGRIFTA SV

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
1. Diagnosis of HIV-associated lipodystrophy
   AND
2. Documentation of patient's waist circumference
   a. Waist circumference greater than or equal to 37.4 inches (95 cm) for males
   b. Waist circumference greater than or equal to 37 inches (94 cm) for females
   AND
3. Documentation of waist-to-hip ratio
   a. Waist-to-hip ratio greater than or equal to 0.94 for males
   b. Waist-to-hip ratio greater than or equal to 0.88 for females
   AND
4. Documentation of a body mass index (BMI) greater than 20 kilograms per meter squared
   AND
5. Documentation of fasting blood glucose (FBG) of less than or equal to 150 mg/dL (8.33 mmol/L)
   AND
6. Documentation that patient has been on a stable regimen of antiretrovirals for at least eight (8) weeks

Reauthorization will require documentation of clinical improvement (e.g., decrease in waist circumference, improvement in visceral adipose tissue).

**AGE RESTRICTION**
Adults 18 years of age and older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for six months.
OTHER CRITERIA
N/A
MEDICATION(S)
ELIDEL, PIMECROLIMUS, PROTOPIC, TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

COVERED USES
N/A

EXCLUSION CRITERIA
Requests for coverage for rosacea will not be approved due to the lack of evidence supporting their effectiveness and safety in these conditions.

REQUIRED MEDICAL INFORMATION
For atopic dermatitis, psoriasis, oral lichen planus, and vitiligo: Diagnosis of severe disease as defined by all the following:

1. Documentation that patient is having functional impairment as indicated by one of the following:
   a. Dermatology Life Quality Index (DLQI) of at least 11
   b. Children’s Dermatology Life Quality Index (CDLQI) of at least 13
   c. Severe score on other validated tool
2. One of the following:
   a. At least 10% of body surface area involved
   b. Hand, foot, face, or mucous membrane involvement

Reauthorization requires documentation of reduction or stabilization from baseline of flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification or affected BSA

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization for six months. Reauthorization for 12 months.

OTHER CRITERIA
N/A
EMFLAZA

MEDICATION(S)
EMFLAZA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. The patient has a diagnosis of Duchenne Muscular Dystrophy (prescriber must provide genetic test to confirm diagnosis)
2. Documentation of one of the following:
a. The patient has tried prednisone for at least six months and has experienced one of the following clinically significant adverse events: cushingoid appearance, central (truncal obesity), weight gain of at least 10% body weight over a 6-month period or diabetes and/or hypertension that is difficult to manage according to the prescribing physician
OR
b. The patient has tried prednisone and has experienced psychiatric/behavioral issues (such as abnormal behavior, aggression, or irritability)
i. The psychiatric/behavioral issues persisted beyond the first six weeks of treatment with prednisone AND
ii. A change in timing of prednisone administration (such as changing from morning to evening has been attempted but was unsuccessful in resolving issues
3. The dose requested is within FDA labeled dosing based on the patient’s weight (patient’s weight must be provided) AND dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension)

Re-authorization:
1. Documentation of clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function
2. The dose requested is within FDA labeled dosing based on the patient’s weight (updated weight must be provided) AND dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension)

AGE RESTRICTION
Two years and up
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a provider that specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
EMPAVELI

MEDICATION(S)
EMPAVELI

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent therapy with another FDA-approved product for PNH, meaning Soliris® or Ultomiris®, unless the member is in a four-week period of cross-titration between Soliris® and Empaveli®

REQUIRED MEDICAL INFORMATION
Paroxysmal Nocturnal Hemoglobinuria (PNH):
1. For initiation of therapy (patients not established on therapy), all the following must be met:
   a. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycophaspatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
   b. Severe disease as defined by at least one of the following (i or ii):
      i. Documented history of thrombosis, OR
      ii. Documentation of at least 10% PNH type III red cells AND at least one of the following:
         1. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
         2. Disabling fatigue
         3. End-organ complications
         4. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
      5. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
2. For patients currently on eculizumab (Soliris®) or ravulizumab (Ultomiris®) switching to pegcetacoplan (Empaveli®) the following must be met:
   a. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1a above) and severe disease (criteria 1b above). However, this can be based on patient’s history prior to starting eculizumab or ravulizumab.
3. For patients already established on the requested therapy, the following must be met for continuation of therapy:
   a. Documentation of reduced LDH levels, reduced transfusion requirements, increase in hemoglobin levels, or improvement in PNH related symptoms

AGE RESTRICTION
May be approved for patients aged 18 years and older.

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation with, a hematologist/oncologist or nephrologist

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for up to one year.

**OTHER CRITERIA**
N/A
MEDICATION(S)
ENJAYMO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy (new start), all the following must be met:
1. Diagnosis of primary cold agglutinin disease (CAD) by all the following:
   a. Chronic hemolysis, confirmed by low levels of haptoglobin, and high levels of unconjugated bilirubin and lactate dehydrogenase
   b. Positive direct antiglobulin (Coombs) test for C3d. (Note: a positive is graded as a 1+, 2+, or 3+)
   c. Cold agglutinin titer of 1:64 or higher at 4 degrees Celsius
   d. Presence of one or more symptom associated with CAD such as symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria
2. History of blood transfusion within the previous six months
3. Hemoglobin of 10 g/dL or less
4. Dose and frequency are in accordance with FDA-approved labeling

For patients that are established on therapy, all the following must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
1. Diagnosis of cold agglutinin disease
2. Documentation of successful response to therapy defined as an increase in hemoglobin level or reduced transfusion requirements
3. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist or an oncologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for a year.
OTHER CRITERIA
N/A
ENSPRYNG

MEDICATION(S)
ENSPRYNG

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as both of the following:
   a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions)
   AND
   b. Anti-AQP4 antibody positive
2. Documentation that other alternative diagnoses have been excluded (e.g. Multiple Sclerosis)
3. For Commercial members: Trial and failure, intolerance or contraindication to rituximab
4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
3. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
For Commercial members: Must be prescribed by, or in consultation with, a neurologist or ophthalmologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.
OTHER CRITERIA
N/A
ENZYME REPLACEMENT THERAPY_MEDICAL BENEFIT

MEDICATION(S)
ALDURAZYME, BRINEURA, CEREZYME, ELAPRASE, ELEYSO, FABRAZYME, KANUMA, LAMZEDE, LUMIZYME, MEPSEVII, NAGLAZYME, NEXVIAZYME, VIMIZIM, VPRIV, XENPOZYME 20 MG VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy (new starts to therapy) all the following criteria must be met:
1. Documentation of FDA-labeled indication for the requested product
2. Dosing is within FDA-labeled guidelines.
3. For avalglucosidase alfa (Nexviazyme®) only: Patients weighing less than 30 kg must have a documented trial, failure, intolerance or contraindication to alglucosidase alfa (Lumizyme®)
4. For olipudase alfa (Xenpozyme®) only, the following additional criteria apply:
   a. Clinical presentation must be consistent with acid sphingomyelinase deficiency (ASMD) type B OR ASMD type A/B
   b. Spleen volume of six multiples of normal (MN) or more for adults OR five MN or more for those less than 18 years old
   c. For adults only, diffusing capacity of the lungs for carbon monoxide (DLco) equal to 70% or less of predicted normal value
   d. The following are excluded from coverage:
      i. Use of invasive ventilatory support, or noninvasive ventilatory support while awake for greater than 12 hours a day
      ii. Acute or rapidly progressive neurological abnormalities and/or genotypes associated with ASMD type A, meaning homozygous for SMPD1 gene mutations R496L, L302P, and fs330 or any combination of these three mutations
5. For cerliponase alfa (Brineura®) only, the following additional criteria must be met:
   a. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) confirmed by both of the following:
      i. Deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity (in a sample of leukocytes, fibroblasts, dried blood spot or saliva)
      ii. Genetic testing revealing one pathogenic mutation on each parental allele of TPP1/CLN2 gene
   b. Documentation of symptomatic disease (such as, seizures, changes in gait, falls, difficulty in ambulating, loss of language/delay in language development, visual failures)
   c. Baseline Motor Domain of the CLN2 Clinical Rating Scale score of at least one
Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines and exceptions will be considered on a case-by-case basis.

For patients currently established on the requested therapy, all the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.

1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms).
   a. For olipudase alfa (Xenpozyme®) only, documentation of improvement in at least one of the following: spleen volume, liver volume, platelet count, DLco or forced vital capacity (FVC)
   b. For cerliponase alfa (Brineura®) only, documentation of both of the following:
      i. No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale
      ii. Motor Domain of the CLN2 Clinical Rating Scale score remains above zero

2. Dosing is within FDA-labeled guidelines

Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis.

AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a hepatologist, endocrinologist, medical geneticist, cardiologist, pulmonologist, neurologist, or bone and mineral specialist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
EPIDIOLEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For New Starts:
1. Documentation that patient has one of the following:
   a. Seizures associated with Lennox-Gastaut syndrome (LGS)
   b. Seizures associated with Dravet syndrome (DS)
   c. Tuberous sclerosis complex (TSC)
2. Documented trial, failure, intolerance or contraindication to two of the following for the seizure type:
   a. For DS: clobazam, valproate/valproic acid or topiramate
   b. For LGS: lamotrigine, valproate/valproic acid, topiramate or rufinamide
   c. For TSC: clobazam, levetiracetam, topiramate or valproate/valproic acid
3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
4. Baseline liver function tests must be documented
5. Dose will not exceed:
   a. 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome
   b. 25 mg/kg/day in tuberous sclerosis complex

For Patients Established on Therapy:
1. Documentation of periodic liver function tests
2. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
3. Dose continues to not exceed 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome or 25 mg/kg/day in tuberous sclerosis complex

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescriber by or in consultation with a neurologist
COVERAGE DURATION
Initial authorization will be approved for six months and reauthorization will be approved for one year

OTHER CRITERIA
N/A
ERYTHROPOIESIS STIMULATING AGENTS (ESAS)

MEDICATION(S)
ARANESP, EPOGEN, MIRCERA, PROCRIT, RETACRIT

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with uncontrolled hypertension

REQUIRED MEDICAL INFORMATION
For patients initiating therapy:
1. All diagnoses, with the exception of 2e (preoperative use in patients scheduled for elective non-cardiac, nonvascular surgery), must have documented Hemoglobin (HGB) levels of less than or equal to 10g/dl within the 30 days prior to initiation of therapy
AND
2. Must meet all of the listed criteria below for each specific diagnosis:
   a. Treatment of Anemia in Chronic Kidney Disease (CKD)
      i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%
   b. Treatment of anemia in patients with cancer:
      i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%
      AND
      ii. One of the following clinical scenarios:
         1. Patient has comorbid chronic kidney disease
         2. Patient undergoing palliative treatment
   c. Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis
      i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%
      ii. Must have documented current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL
   d. Anemia associated with zidovudine-treated HIV-infection patients
      i. Documented current (within last three months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml
      ii. Zidovudine dose is less than or equal to 4200 mg/week
e. Preoperative use in patients scheduled for elective noncardiac and nonvascular surgery, all of the following criteria must be met:
   i. Member has preoperative HGB between 10 and 13 g/dL
   ii. The surgery has a high-risk for perioperative blood loss (for example, expected to lose more than two units of blood)
   iii. Patient is unwilling to donate autologous blood pre-operatively
f. Mircera only: For the treatment of pediatric patients 5 to 17 years of age who are on hemodialysis and converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
   i. Documented hemodialysis for at least eight weeks
   ii. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy
   iii. Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

For patients established on therapy (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
1. Documentation of continued medical necessity (such as ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12 g/dl within previous 30 days

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization and reauthorization will be for one year

**OTHER CRITERIA**
N/A
MEDICATION(S)
ESBRIET, OFEV, PIRFENIDONE

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with pirfenidone (Esbriet®) or nintedanib (Ofev®)

REQUIRED MEDICAL INFORMATION
Initial Authorization:
For Idiopathic Pulmonary Fibrosis (IPF)
1. Diagnosis of Idiopathic Pulmonary Fibrosis
   a. Note: Confirmed by exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, drug toxicity, or connective tissue disease
   AND
2. Presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) or histological pattern of probable or indeterminate UIP and diagnosis is supported by lung biopsy
3. For Ofev® and Esbriet® capsule: Documentation of medical rationale for use over generic pirfenidone tablets

For Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (Ofev® only):
1. Confirmed diagnosis of systemic sclerosis
   AND
2. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography

For other chronic fibrosing interstitial lung diseases with a progressive phenotype (Ofev® only):
1. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography
   AND
2. One of the following criteria:
   a. Relative decline in FVC of at least 10% of predicted value (as reported by spirometry performed on two different dates within the last two years)
   b. Relative decline in FVC of at least 5% of predicted value combined with worsening of respiratory symptoms
   c. Relative decline in FVC of at least 5% of predicted value combined with increased extent of fibrotic changes on chest imaging
d. Increased extent of fibrotic changes on chest imaging combined with worsening of respiratory symptoms
e. Increased fibrotic changes on HRCT

Reauthorization:
Documentation of positive clinical response to pirfenidone (Esbriet®) or nintedanib (Ofev®), such as slowed
rate or lack of declining lung function (FVC and DLCO) and improved or stable respiratory symptoms (for
example cough and dyspnea).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For all indications: Must be prescribed by or in consultation with a pulmonologist

For SSc-ILD only: Must be prescribed by or in consultation with a pulmonologist or rheumatologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
**EUCRISA**

**MEDICATION(S)**
EUCRISA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
1. For mild to moderate atopic dermatitis (for patients less than 21 years of age), the following criteria must be met:
   a. Documentation that the condition is of sufficient severity that it impacts the patient’s health (such as quality of life, function, growth, development, ability to participate in school, perform activities of daily living)
   b. Documentation of inadequate efficacy, intolerable side effects, or contraindication to BOTH of the following:
      i. Two-week trial of low to high potency topical corticosteroid
      ii. Two-week trial of topical calcineurin inhibitors (tacrolimus or pimecrolimus)
2. For severe atopic dermatitis, this medication will not be covered as it is only FDA-approved for mild to moderate disease

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

**OTHER CRITERIA**
N/A
EVRYSDI

MEDICATION(S)
EVRYSDI

COVERED USES
N/A

EXCLUSION CRITERIA
1. Use in combination with nusinersen (Spinraza®) therapy
2. Concomitant use with, or following, gene therapy for SMA (such as onasemnogene abeparvovec)
3. Tracheostomy or invasive ventilator support in the absence of an acute reversible illness

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria must be met:
1. Confirmed genetic diagnosis of spinal muscular atrophy (SMA) Type 1, 2, 3 or presymptomatic
2. Baseline assessment with an age-appropriate tool that establishes baseline motor ability must be submitted (such as HINE-2, HFSME, CHOP-INTEND, MFM-32)
3. Requested dose is within FDA labeling

For patients established on therapy, all the following must be met:
1. Confirmed genetic diagnosis of spinal muscular atrophy (SMA) Type 1, 2, 3 or presymptomatic
2. Documentation of positive response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (for example, stabilization or improvement in motor function test scores performed at baseline)
3. Requested dose is within FDA labeling

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A
EXON-SKIPPING THERAPIES FOR DUCHENNE MUSCULAR DYSTROPHY

MEDICATION(S)
AMONDYS-45, EXONDYS-51, VILTEPSO, VYONDYS-53

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
Exon-skipping therapies for Duchene Muscular Dystrophy are not considered medically necessary and will not be covered due to the lack of clinical evidence of improved outcomes and safety.
REQUIRED MEDICAL INFORMATION

For initiation of therapy for multiple sclerosis (MS), all the following criteria (1-3) must be met:

1. Must have one of the following confirmed diagnoses:
   a. Relapsing-remitting multiple sclerosis (RRMS)
   b. Secondary progressive multiple sclerosis (SPMS)
   c. Clinically isolated syndrome (CIS)

2. Documentation of ONE of the following:
   a. Inadequate response (after at least six months of continuous therapy) or intolerance to generic dimethyl fumarate or generic glatiramer OR
   b. FDA labeled contraindication to BOTH generic dimethyl fumarate and generic glatiramer

3. Documentation of active disease after an adequate trial (defined as at least six months of continuous therapy) of at least one of the following preferred agents unless all are contraindicated OR medical rationale why therapies cannot be tried is provided. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.
   a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
   b. Interferon-beta 1b (Betaseron®)
   c. Teriflunomide (Aubagio®)
   d. Fingolimod (Gilenya®)
   e. Ozanimod hydrochloride (Zeposia®)
   f. Siponimod (Mayzent®)
   g. Cladribine (Mavenclad®)
   h. Ofatumumab (Kesimpta®)

For patients established on therapy for at least three months, documentation of positive clinical response to therapy must be provided.

Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
FENTANYL CITRATE

MEDICATION(S)
ACTIQ, FENTANYL CIT 100 MCG BUCCAL TB, FENTANYL CIT 200 MCG BUCCAL TB, FENTANYL CIT 400 MCG BUCCAL TB, FENTANYL CIT 600 MCG BUCCAL TB, FENTANYL CIT 800 MCG BUCCAL TB, FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG, FENTORA, LAZANDA, SUBSYS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of all the following:
1. Treatment of breakthrough cancer pain (prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer)
   AND
2. Failure of or intolerance to other oral or parenteral short-acting narcotic formulary agents used for breakthrough pain
   AND
3. Pain is not controlled with long-acting narcotic analgesics
   AND
4. For Fentora®, Lazanda® and Subsys®:
   a. Documented trial and failure, contraindication, or intolerance to generic fentanyl citrate lozenge/troche

Reauthorization:
1. Documentation that patient continues to have breakthrough cancer pain (prescriber MUST submit recent chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer)
   AND
2. Documentation of successful response to the medication

AGE RESTRICTION
Fentanyl citrate lozenge/troche: Approved for 16 years or older Fentora®, Lazanda®, Subsys®: Approved for 18 years or older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist or pain specialist
COVERAGE DURATION
Initial authorization for six months. Reauthorization for one year.

OTHER CRITERIA
N/A
FERTILITY AND RELATED MEDICATIONS

MEDICATION(S)
CETRORELIX ACETATE, CETROTIDE, CHORIONIC GONAD 10,000 UNIT VL, CHORIONIC GONAD 12,000 UNIT VL, CHORIONIC GONAD 6,000 UNIT VL, FOLLISTIM AQ, FYREMADEL, GANIRELIX ACETATE, GONAL-F, GONAL-F RFF, GONAL-F RFF REDI-JECT, MENOPUR, NOVAREL, OVIDREL, PREGNYL

COVERED USES
N/A

EXCLUSION CRITERIA
1. Hypogonadism, unrelated to infertility
2. Cryptorchidism

REQUIRED MEDICAL INFORMATION
1. For fertility preservation, preferred gonadotropins and Lupron® may be covered if the patient’s benefit covers fertility preservation, meeting one of the following scenarios (a or b):
   a. The patient’s benefit covers fertility preservation ONLY when due to treatment for cancer and the following criteria are met:
      i. The gonadotropin will be used for retrieval and storage of eggs and/or sperm
      ii. The patient will be undergoing treatment for cancer that is expected to cause irreversible infertility as recommended by evidence-based guidelines such as the National Comprehensive Cancer Network (NCCN),
   b. The patient’s benefit covers fertility preservation for any reason (such as egg/sperm storage)
2. For treatment of infertility, preferred gonadotropins and Lupron® may be covered if the patient’s benefit covers the planned infertility treatment [e.g., intrauterine insemination (IUI) vs. in vitro fertilization (IVF)].
3. Non-preferred therapies may be covered when criteria 1 or 2 above are met and subject to the following criteria:
   a. For Gonal-F®: documented inadequate response, intolerance, or contraindication to Follistim AQ®
   b. For Ovidrel®: documented inadequate response, intolerance, or contraindication to Novarel®, Pregnyl®, or generic chorionic gonadotropin
   c. For Cetrotide®: documented inadequate response, intolerance, or contraindication to Ganirelix®

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Authorization will be approved for one year

OTHER CRITERIA
N/A
FINTEPLA

MEDICATION(S)
FINTEPLA

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome

REQUIRED MEDICAL INFORMATION
For New Starts:
1. Documentation that patient has one of the following:
   a. seizures associated with Dravet syndrome (DS)
   b. seizures associated with Lennox-Gastaut syndrome (LGS)
2. Documented trial, failure, intolerance, or contraindication to two of the following:
   a. For DS: clobazam, valproate/valproic acid, or topiramate
   b. For LGS: lamotrigine, valproate/valproic acid, topiramate, or rufinamide

For Patients Established on therapy:
Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy

AGE RESTRICTION
Must be 2 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist.

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
FIRDAPSE

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with a history of seizures

REQUIRED MEDICAL INFORMATION
Initial authorization (all the following must be met):
1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS), and
2. Documentation of confirmatory diagnostic test results including:
   a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise OR
   b. Positive anti-P/Q type voltage-gated calcium channel antibody test, and
3. Documentation of symptomatic disease, such as dyspnea or muscle weakness
4. Member has been evaluated for malignancy and treated for malignancy, if present. (Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy)

Reauthorization:
1. Documentation of improvement or stabilization of muscle weakness from baseline

AGE RESTRICTION
The patient’s age must be within FDA labeling for the requested indication.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial approval will be approved for three months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
MEDICATION(S)
GATTEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy (patients not established on therapy), all the following must be met:
1. An initial nutritional assessment has been completed by a registered dietitian who has determined that oral/enteral nutrition is not sufficient to meet nutritional goals
2. Member is stable and dependent on parenteral support (fluids, electrolytes and/or nutrients) delivered at least three times per week
3. Teduglutide (Gattex®) has been made part of a treatment plan established by a Gastroenterologist or a hospital Metabolic Support Team:
   a. Member evaluation indicates the possibility of success with treatment
   b. Parameters have been defined to identify goals and measure improvement

For patients already established on therapy, the following must be met:
(Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy)
1. Documentation that parenteral nutrition support requirement has decreased since initiation of teduglutide

AGE RESTRICTION
Approved for one year and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
Initial authorization will be approved for six months, and reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
GIVLAARI

MEDICATION(S)
GIVLAARI

COVERED USES
N/A

EXCLUSION CRITERIA
Use post liver transplant

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met:
1. Confirmed diagnosis of acute hepatic porphyria [i.e., acute intermittent porphyria, hereditary corproprhyria, variegate porphyria, aminolevulinic acid (ALA) dehydratase deficient porphyria] AND
2. One of the following:
   a. Active disease defined as two (2) documented porphyria attacks within the past six (6) months which required either hospitalization, urgent care visit, or intravenous hemin administration, or
   b. Patient is currently receiving treatment with prophylactic hemin to prevent porphyria attacks
3. Documentation that patient will not receive concomitant prophylactic hemin treatment while on therapy with givosiran therapy
4. Documentation that patient’s dosing is in accordance with FDA labeling (patient’s current weight must be included in documentation) and is subject to audit

Reauthorization requires documentation of one of the following:
1. Reduction in the number or severity of porphyria attacks
2. Reduction in number of hospitalizations due to acute porphyria attacks
3. Decreased hemin administration from baseline

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist

COVERAGE DURATION
Initial authorization will be approved for 6 months.
Reauthorization will be approved for 1 year.
OTHER CRITERIA
N/A
**GNRH ANTAGONISTS**

**MEDICATION(S)**
MYFEMBREE, ORIAHNN, ORILISSA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
1. Patient has osteoporosis or severe hepatic impairment
2. Undiagnosed abnormal uterine bleeding

**REQUIRED MEDICAL INFORMATION**
For endometriosis (Orilissa® and Myfembree® only):
Initial Authorization
1. Confirmed diagnosis of endometriosis  
AND  
2. Documentation that patient has moderate to severe pain associated with endometriosis  
AND  
3. Documentation that patient has failed a three-month trial of hormonal contraceptives unless they are not tolerated, or contraindicated

Reauthorization:
1. Request is for the 150 mg daily dose and total duration will not exceed 24 months  
AND  
2. Documentation of a positive response to therapy (e.g., reduction in pain)

For management of heavy menstrual bleeding associated with uterine leiomyomas/fibroids (Oriahnn® and Myfembree® only):
Initial Authorization
1. Documentation of confirmed diagnosis of uterine fibroids (e.g., ultrasound), AND  
2. Documentation of heavy menstrual bleeding  
AND  
3. Documentation that patient has failed a three-month trial of hormonal contraceptives unless they are not tolerated, or contraindicated

Reauthorization:
1. Total treatment duration will not exceed 24 months  
AND
2. Documentation of a positive response to therapy (e.g., reduction in bleeding)

AGE RESTRICTION
Approved for patients 18 years and older

PRESCRIBER RESTRICTION
Must be written by on in consultation with an obstetrician-gynecologist (OB-GYN)

COVERAGE DURATION
• Orilissa® 150 mg once daily: Initial authorization for six months. Reauthorization for up to 18 months. No reauthorization beyond 24 months.
• Orilissa® 200 mg twice daily: Initial authorization for six months. No reauthorization.
• Oriahnn® and Myfembree®: Initial authorization for six months. Reauthorization for up to 18 months. No reauthorization beyond 24 months.

OTHER CRITERIA
N/A
GONADOTROPIN RELEASING HORMONE AGONISTS

MEDICATION(S)
CAMCEVI, ELIGARD, FENSOLVI, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE DEPOT,
LUPRON DEPOT, LUPRON DEPOT-PED, SUPPRELIN LA, SYNAREL, TRELSTAR, TRIPTODUR,
VANTAS, ZOLADEX

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of male infertility

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. For oncological indications, gonadotropin releasing hormone agonists may be covered if the following criteria are met:
a. Use is for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

2. For uterine leiomyomata (fibroids), leuprolide acetate may be covered if one of the following criteria (a or b) are met:
a. Request is for use prior to surgery to improve anemia caused by fibroids and one of the following criteria (i or ii) are met:
i. Request is for a Medicaid member
ii. Both of the following criteria:
   • Documented trial, failure, intolerance, or contraindication to at least 30 days of therapy with iron supplementation alone
   • Documentation that leuprolide acetate will be used in combination with iron supplementation
b. Request is for use prior to surgery to reduce the size of fibroids and the following criteria are met:
i. Documentation that surgical removal of fibroids is planned within four months

3. For endometriosis, leuprolide acetate, goserelin acetate, or nafarelin acetate may be covered if the following criteria (a and b) are met:
a. Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel syndrome, interstitial cystitis, urinary tract disorders)
b. For Synarel® (nafarelin acetate): Documented trial and failure to leuprolide acetate

4. For endometrial thinning/dysfunctional uterine bleeding, goserelin acetate may be covered if the following
criteria are met:

a. Documentation for use prior to endometrial ablation

5. For central precocious puberty, gonadotropin releasing hormone agonists may be covered if one of the following criteria (a, b, or c) are met:

a. Request is for a Medicaid member
b. Request is for a one-time dose for diagnostic purposes
c. All of the following criteria:
   i. Documentation of a history of early onset of secondary sexual characteristics (age eight years and under for females or nine years and under for males)
   ii. Confirmation of diagnosis by one of the following:
      • Pubertal response to a GnRH or GnRH analog (such as leuprolide) stimulation test [e.g., stimulated peak luteinizing hormone (LH) of approximately 4.0 to 6.0 IU/L and/or elevated ratio of LH/follicle-stimulating hormone at 0.66 or greater (reference range may vary depending on assay)]
      • Pubertal level of basal LH levels (0.2 IU/L or greater)
      • Bone age advanced one year beyond the chronological age
   iii. For Synarel®: Documented trial and failure or contraindication/intolerance to both of the following:
      • Leuprolide acetate
      • Triptodur® or Supprelin LA®

6. For gender-affirming services, gonadotropin releasing hormone agonists may be covered if the following criteria (a and b) are met:

a. Prescribed by or in consultation with an endocrinologist
b. Demonstration that puberty has progressed to a minimum of Tanner Stage 2

For reauthorization:

1. For oncological indications: Documentation of successful clinical response to therapy
2. For uterine leiomyomata (fibroids): Reauthorization will not be authorized. Initial criteria must be met.
3. For endometriosis:
   a. Leuprolide acetate requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g., norethindrone) to help prevent bone mineral density loss.
   b. For Synarel® and Zoladex®: Reauthorization will not be authorized. Treatment is only recommended for up to six months with these agents for endometriosis.
4. For endometrial thinning/dysfunctional uterine bleeding: Reauthorization will not be authorized. Initial criteria must be met.
5. For central precocious puberty:
   a. Clinical response to treatment such as pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level, and
   b. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression
6. For gender-affirming services: Documentation of successful clinical response to therapy

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Oncological Indications: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
Uterine leiomyomata (fibroids): Initial authorization will be approved for three months. No reauthorization.
Endometriosis: For Lupron® and Lupaneta® Pack – authorization/reauthorization will be approved for up to six months (total of 12 months). For Synarel®/Zoladex® initial authorization for up to six months and no reauthorization.
Endometrial thinning/dysfunctional uterine bleeding: Initial authorization will be approved for two months. No reauthorization.
Central precocious puberty: Authorization/reauthorization will be approved for one year
Gender-affirming services: Authorization/reauthorization will be approved for one year

**OTHER CRITERIA**
N/A
MEDICATION(S)
HEMGENIX

COVERED USES
N/A

EXCLUSION CRITERIA
- Current or prior presence of factor IX inhibitors
- HIV not controlled with antiviral therapy (CD4+ counts equal to 200/µL or by a viral load of greater than 200 copies/mL)
- Active hepatitis B or C infection
- Evidence of advanced liver fibrosis (Fibroscan score of 9 kPA or greater)
- ALT, AST, total bilirubin, alkaline phosphatase, or creatinine greater than two times the upper limit of normal
- Previous treatment with gene therapy for the same indication

REQUIRED MEDICAL INFORMATION
Hemgenix® may be approved when all the following criteria are met:
1. Diagnosis of severe or moderately severe hemophilia B, defined by Factor IX level less than 2 IU/dL or less than or equal to 2% of normal
2. Patient is male
3. One of the following:
   a. Patient is currently on a stable dose of factor IX prophylaxis (has been receiving prophylaxis for 2 months of more) with greater than 150 exposure days of factor IX prophylaxis
   b. Current or historical life-threatening hemorrhage
   c. Documentation of repeated, serious spontaneous bleeding episodes
4. Hemgenix® will be administered by or in consultation with a Hemophilia Treatment Center (HTC)

AGE RESTRICTION
May be approved for patients aged 18 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist.

COVERAGE DURATION
Authorization will be limited to one treatment course per lifetime.

OTHER CRITERIA
N/A
HEMLIBRA - MEDICAL BENEFIT

MEDICATION(S)
HEMLIBRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND
2. Diagnosis of hemophilia A (congenital factor VIII deficiency) and documentation of ANY of the following:
   a. Factor VIII inhibitors (defined as at least 5 Bethesda units per milliliter)
   b. Severe hemophilia (defined as pre-treatment factor VIII level less than 1%)
   c. Moderate hemophilia (defined as pre-treatment factor VIII level of 1% to less than 5%) or mild hemophilia (defined as pre-treatment factor VIII level of 5% to less than 40%) with:
      i. One or more spontaneous episodes of bleeding into the central nervous system, large joints (ankles, knees, hips, elbows, shoulders) or other serious, life-threatening bleed

When the above criteria are met, Hemlibra® (emicizumab-kxwh) will be approved for a loading dose of 3 mg/kg once weekly for four weeks, followed by any of the three maintenance dosing regimens below:
   • 1.5 mg/kg once weekly
   • 3 mg/kg every two weeks
   • 6 mg/kg every four weeks

Reauthorization criteria: Documentation of positive clinical response to emicizumab therapy (e.g., reduction in the number/severity of bleeds)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
To be prescribed by, or in consultation with a hematologist.

COVERAGE DURATION
Initial authorization: six months
Reauthorization: Authorization will be approved until no longer eligible with the plan, subject to formulary
and/or benefit changes.

OTHER CRITERIA
N/A
HEPATITIS C-DIRECT ACTING ANTIVIRALS

MEDICATION(S)
EPCLUSA, HARVONI, LEDIPASVIR-SOFOSBUVIR, MAVYRET, SOFOSBUVIR-VELPATASVIR, SOVALDI, VIEKIRA PAK, VOSEVI, ZEPATIER

COVERED USES
N/A

EXCLUSION CRITERIA
All regimens containing a NS3/4a protease inhibitor (e.g., Mavyret, Vosevi, Zepatier and Viekira Pak) are not covered in patients with moderate to severe hepatic impairment (Child-Pugh B or C)

REQUIRED MEDICAL INFORMATION
Prior authorization is NOT required for preferred Direct Acting Antivirals (DAA) regimens for treatment-naive patients with hepatitis C virus.

Mavyret® may be covered for patients undergoing heart transplantation after confirmation donated heart is from a hepatitis C virus (HCV) viremic donor

For treatment-experienced and for non-preferred DAAs, all the following criteria (1-7) must be met:
1. Documentation of confirmed diagnosis of chronic hepatitis C (HCV) infection (B18.2)
2. Documentation of baseline quantitative HCV RNA level
3. Documentation that ALL the following pre-treatment testing has been performed:
   a. Genotype testing in past three years is only required for the following population:
      i. Patients with decompensated cirrhosis
      ii. Patients with prior treatment experience with a direct-acting antiviral (DAA) regimen
      iii. For regimen which is not pan-genotypic (e.g., Harvoni®, Zepatier®)
   b. Cirrhosis status as clinically determined (e.g., clinical, laboratory, or radiologic evidence)
   c. History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience
4. For coverage of non-preferred regimen, the prescriber must submit medical rationale in support of the use of non-preferred drug(s).
5. For coverage of the following regimen, NS5A resistance testing is required to detect any potential resistant variant.
   a. Elbasvir/grazoprevir (Zepatier®) for GT 1a infection
   b. Ledipasvir/sofosbuvir (Harvoni®) for GT 1a treatment-experienced infection
   c. Sofosbuvir/velpatasvir (Epclusa®) for GT 3 in cirrhosis or treatment-experienced infection
6. For coverage of pellet formulation, the prescriber must submit medical rationale in support of its use over
the available tablet formulation (such as use in pediatric patients or inability to swallow)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For patients who have complication of cirrhosis only: Therapy must be prescribed by, OR the patient is in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.

COVERAGE DURATION
Coverage duration will be based on genotype and regimen.

OTHER CRITERIA
N/A
HETLIOZ

MEDICATION(S)
HETLIOZ, HETLIOZ LQ, TASIMELTEON

COVERED USES
N/A

EXCLUSION CRITERIA
Sleep disorders other than Non-24 and SMS.

REQUIRED MEDICAL INFORMATION
For Non-24-Hour Sleep-Wake Disorder (Non-24):
All of the following criteria must be met:
1. Member is totally blind (e.g., no light perception)
2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by:
   a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night
   b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic periods
3. Documented sleep study to exclude other sleep disorders
4. Documentation of symptomatic disease such as excessive daytime sleepiness or fatigue
5. Documented trial and failure, intolerance, or contraindication to an adequate trial (at least 30 days) of melatonin

Reauthorization criteria:
1. Documentation of improvement in social, occupational, and other important areas of functioning
   AND
2. Documentation of entrainment to the 24-hour circadian period

For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS):
All of the following criteria must be met:
1. Documented diagnosis of SMS, as characterized by:
   a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene
2. Documented sleep study to exclude other sleep disorders
3. Documentation of at least one of the following:
   a. difficulties falling asleep
   b. shortened sleep cycles
   c. frequent and prolonged nocturnal awakenings
   d. excessive daytime sleepiness
e. daytime napping

4. Documented trial and failure or contraindication to melatonin dosed at bedtime, or daytime administration of acebutolol combined with melatonin dosed at bedtime.

Reauthorization Criteria:
Documentation of improvement in sleep quality or total sleep time.

AGE RESTRICTION
Non-24: 18 years or older for capsules
SMS: 3-15 years old for suspension and 16 years or older for capsules

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a sleep specialist.

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (FH) AGENTS

MEDICATION(S)
EVKEEZA, JUXTAPID

COVERED USES
N/A

EXCLUSION CRITERIA
1. Concomitant use of therapies on this policy (specifically, Juxtapid or Evkeeza)
2. Current pregnancy
3. Diagnosis of Heterozygous familial hypercholesterolemia or other hyperlipidemia disorders

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following must be met:
1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by either genetic or clinical confirmation, as outlined below:
   a. Genetic confirmation: biallelic functional mutations in the low density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin/kexin type 9 (PCSK9) or LDL receptor adapter protein 1 (LDLRAP1) genes
   b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL or treated LDL-C greater than or equal to 300 mg/dL and one of the following:
      i. Presence of xanthomas before the age of 10 years, or
      ii. Evidence of heterozygous familial hypercholesterolemia in both parents such as documented history of elevated LDL-C greater than or equal to 190 mg/dL prior to lipid-lowering therapy
2. Current use of all of the following therapies:
   a. High-intensity statin therapy, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily, unless contraindicated or documented statin intolerance
   b. Ezetimibe, unless contraindicated or prior intolerance
   c. PCSK-9 inhibitor (such as, evolocumab), unless contraindicated or prior intolerance
3. Documentation of LDL cholesterol levels (taken within the last six months) of greater than 100 mg/dL despite at least six months of use of the therapies outlined above

Initial reauthorization requires documentation of at least a 30% reduction in LDL cholesterol levels from pre-treatment levels

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist

**COVERAGE DURATION**
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

**OTHER CRITERIA**
N/A
HORMONE REPLACEMENT THERAPY

MEDICATION(S)
ANDRODERM, ANDROGEL 1.62%(1.25G) GEL PCKT, ANDROGEL 1.62%(2.5G) GEL PCKT, AVEED, FORTESTA, JATENZO, NATESTO, TESTOPEL, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 100 MG PELLET, TESTOSTERONE 200 MG PELLET, TLANDO, XYOSTED

COVERED USES
N/A

EXCLUSION CRITERIA
Use for improvement of sexual signs and symptoms (such as decreased libido, sexual dysfunction)

REQUIRED MEDICAL INFORMATION
Hormone replacement therapy is considered medically necessary if all the following criteria are met:
1. One of the following diagnoses:
   a. Gender dysphoria or gender identity disorder (diagnosis codes F64.0, F64.1, F64.8, or F64.9)
   OR
   b. Diagnosis of primary or secondary (hypogonadotropic) hypogonadism
2. For testosterone replacement: Documented inability to reach therapeutic levels or experiencing fluctuations in levels (resulting in symptoms) of the following:
   a. For topical products: Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump)
   b. For injectable products: Generic injectable testosterone cypionate
   c. For oral products: Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump) AND Kyzatrex® (testosterone undecanoate capsule)
   d. For all other products including pellets and nasal products: Must try two of the following:
      i. Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump)
      ii. Generic injectable testosterone cypionate
      iii. Kyzatrex® (testosterone undecanoate capsule)
3. For estrogen replacement: The use of a subcutaneous pellet formations of estrogen is considered investigational for all indications.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
ACTHAR, CORTROPHIN

COVERED USES
N/A

EXCLUSION CRITERIA
All other indications beside infantile spasms are not considered medically necessary and are excluded for coverage.

REQUIRED MEDICAL INFORMATION
For infantile spasm:  H.P. Acthar Gel® will be approved for one month of therapy at the following dose: 75 units/m(2) injected intramuscularly twice daily

Reauthorization will require medical rationale for continuing treatment, as recommended treatment duration is for 2 weeks followed by two-week taper to avoid adrenal insufficiency.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization/reauthorization will be approved for one month.

OTHER CRITERIA
N/A
MEDICATION(S)
GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SAIZEN-SAIZENPREP, SEROSTIM, SKYTROFA, ZOMACTON, ZORBTIVE

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of idiopathic short stature.

REQUIRED MEDICAL INFORMATION
For ALL non-preferred growth hormone (GH) requests, documentation must be provided showing that the patient has intolerance, FDA labeled contraindication, or hypersensitivity to all preferred growth hormone product(s) that is not expected to occur with the requested non-preferred agent (medical record required). Requests for lonapegsomatropin (Skytrofa®) to improve compliance or to reduce dosing frequency are considered not medically necessary.

For initial authorization requests, must meet criteria listed below for each specific diagnosis:
1. Growth Hormone Deficiency (GHD): Must have documentation of BOTH of the following:
   a. Goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition improvements, etc)
   b. One of the following:
      i. Serum GH level less than 5 ng/mL on stimulation testing with either glucagon or insulin
      ii. Removal/destruction of pituitary
      iii. Panhypopituitarism since birth

2. Noonan Syndrome (NS), Prader-Willi Syndrome (PWS), Short stature homeobox-containing (SHOX) deficiency, Turner Syndrome (TS):
   a. Documented confirmation of diagnosis through genetic testing
   b. Goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition improvements, etc)

3. All Other FDA-Approved Indications (Growth Failure Secondary to Chronic Kidney Disease (CKD), HIV associated wasting/cachexia, Idiopathic Short Stature (ISS), Short Bowel Syndrome (SBS), Small for Gestational Age (SGA)):
   a. Goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition improvements, etc)
For reauthorization requests:
1. For continuation of GH therapy initiated in patients less than 18 years of age to improve growth velocity or height: Must have documentation of ONE of the following:
   a. Growth velocity of at least 2 cm per year
   b. BOTH of the following:
      i. Provider attestation that benefits of therapy continue to outweigh the risks
      ii. Improvement from baseline as assessed by prescribing provider

2. For all other requests for continuation of GH therapy:
   a. Documentation of improvement from baseline as assessed by the prescribing provider

AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
GH therapy must be prescribed by, or in consultation with the appropriate provider specialist listed by indication below:
  • Adult GHD: endocrinologist
  • Growth Failure Secondary to CKD: pediatric endocrinologist or pediatric nephrologist
  • HIV Associated Wasting/Cachexia: specialist in the management of HIV
  • SBS: gastroenterologist
  • All other indications: pediatric endocrinologist

COVERAGE DURATION
• Authorization for SBS will be approved for a maximum of four weeks.
• Authorization for HIV-associated wasting/cachexia will be approved for a maximum of 12 months.
• Initial authorization and reauthorization for other indications will be approved for up to one year.

OTHER CRITERIA
N/A
IL-5 INHIBITORS

MEDICATION(S)
CINQAIR, FASENRA, FASENRA PEN, NUCALA

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with anti-IL5 (such as mepolizumab, reslizumab, benralizumab), anti-IgE (such as omalizumab), anti-TSLP (such as tezepelumab), or anti-IL4 (such as dupilumab) monoclonal antibodies.

REQUIRED MEDICAL INFORMATION
A. Eosinophilic asthma
1. For patients initiating therapy for eosinophilic asthma, all the following criteria (a-c) must be met:
   a. Confirmed diagnosis of one of the following (i or ii):
      i. Eosinophilic asthma, defined as one of the following:
      ii. A blood eosinophil count of at least 150 cells/microliter while on high-dose inhaled corticosteroids or daily oral corticosteroids
      iii. Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion while on high-dose inhaled corticosteroids or daily oral corticosteroids
      iv. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids
      v. History of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
   b. Documentation of adherence to treatment with maximally tolerated doses of the following medications (this may be verified by pharmacy claims information), unless intolerance or contraindication to all therapies:
      i. Inhaled corticosteroid plus
      ii. One of the following:
         1) A long-acting inhaled beta 2-agonist (LABA)
         2) A leukotriene receptor antagonist (LTRA)
         3) A long-acting muscarinic antagonist (LAMA)
   c. Documentation inadequate asthma control despite above therapy, defined as one of the following:
      i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score more than 1.5
      ii. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
      iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months
   For patients established on therapy for eosinophilic asthma: documentation of response to therapy, such as
lower rate of exacerbations, decreased need for rescue medication, improved quality of life

B. Eosinophilic Granulomatosis with Polyangiitis (EGPA)
1. For patients initiating therapy for EGPA, Nucala (mepolizumab) may be covered if the following criteria are met:
   a. Confirmed diagnosis of EGPA defined as one of the following:
      i. The patient meets four of the following:
         1) Asthma (history of wheezing or diffuse high-pitched rales on expiration)
         2) Eosinophilia (greater than 10% eosinophils on white blood cell differential count)
         3) Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis
         4) Migratory or transient pulmonary infiltrates detected radiographically
         5) Paranasal sinus abnormality
         6) Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas
   b. Documentation of relapsing or refractory disease defined as one of the following:
      i. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent)
      ii. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering off glucocorticoids. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

2. For patients established on therapy for EGPA, Nucala (mepolizumab) may be covered if the following criteria are met: Documentation of response to therapy indicating improvement or stabilization of condition

C. Hypereosinophilic Syndrome (HES)
1. For patients initiating therapy for HES, Nucala (mepolizumab) may be covered if the following criteria are met:
   a. Documentation of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
   b. Blood eosinophil count of 1,000 cells/microliter or higher for at least six months prior to initiation of therapy
   c. Documentation of at least two HES flares in the 12 months prior to initiation of therapy (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)
   d. For Commercial: Documentation of use of conventional HES therapy, including one of the following in the
12 months prior to initiation of therapy:

i. Chronic or episodic oral corticosteroids (OCS)
ii. Immunosuppressive therapy
iii. Cytotoxic therapy

2. For reauthorization for HES, Nucala (mepolizumab) may be covered if the following criteria are met:
   Documentation of response to therapy indicating improvement or stabilization of condition

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. For patients initiating therapy for CRSwNP, Nucala (mepolizumab) may be covered if the following criteria are met:
   a. Evidence of nasal polyposis by direct examination, endoscopy, or sinus computed tomography (CT) scan
   b. Documentation of inadequate response to a three-month trial of intranasal corticosteroids (such as fluticasone) or a documented intolerance or contraindication to ALL intranasal corticosteroids
   c. Documentation that patient will continue standard maintenance therapy (such as nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab

2. For reauthorization for CRSwNP, Nucala (mepolizumab) may be covered if the following criteria are met:
   Documentation of response to therapy indicating improvement or stabilization of condition

AGE RESTRICTION
• Cinqair®: May be approved for patients 18 years of age or older
• Fasenra®: May be approved for patients 12 years of age or older
• Nucala®: May be approved for patients six years of age or older for eosinophilic asthma, 18 years of age and older for EGPA and CRSwNP, and 12 years of age and older for HES

PRESCRIBER RESTRICTION
Eosinophilic Asthma: Must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)

Eosinophilic Granulomatosis with Polyangiitis: Must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist

Hypereosinophilic Syndrome: Must be prescribed by or in consultation with a hematologist, immunologist, pulmonologist, cardiologist, or neurologist

Chronic Rhinosinusitis with Nasal Polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, or pulmonologist

COVERAGE DURATION
Eosinophilic Asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

EGPA, HES, CRSwNP: Initial authorization will be for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
IMCIVREE

COVERED USES
N/A

EXCLUSION CRITERIA
Prior gastric bypass surgery resulting in greater than 10% weight loss that was maintained

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. For Bardet-Biedl syndrome (BBS):
   a. Documented presence of four primary features OR three major features and two minor features
   b. Major features include:
      i. Retinal cone-rod dystrophy
      ii. Postaxial polydactyly
      iii. Cognitive impairment or learning difficulties
      iv. Kidney disease
      v. Central obesity
   c. Minor features include:
      i. Neurologic abnormalities
      ii. Olfactory dysfunction
      iii. Oral/dental abnormalities
      iv. Cardiovascular & other thoraco-abdominal abnormalities
      v. Gastrointestinal abnormalities
      vi. Endocrine/metabolic abnormalities
2. For deficiencies in proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR):
   a. Confirmation that obesity is due to a homozygous, or presumed compound heterozygous variant in at least one of the listed genes (POMC, PCSK1, or LEPR), confirmed by genetic testing
   b. Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
3. For all indications: diagnosis of obesity, defined as either of the following:
   a. For adults: Body mass index (BMI) of greater than or equal to 30
   b. For pediatrics:
      i. For POMC, PCSK1, and LEPR deficiencies: Greater than or equal to the 95th percentile using growth chart assessments
ii. For BBS: Greater than or equal to the 97th percentile using growth chart assessments

For reauthorization, the following must be met:
Documentation of response to therapy, as evidenced by: at least a 5% reduction in baseline body weight
OR at least 5% reduction in baseline BMI for patients with continued growth potential

AGE RESTRICTION
May be approved for patients aged six years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an endocrinologist, pediatric endocrinologist, or geneticist

COVERAGE DURATION
Initial authorization will be approved for four months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
IMMUNE GAMMA GLOBULIN (IGG)

MEDICATION(S)
ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMASTAN, GAMASTAN S-D, Gammagard liquid, Gammagard S-D, Gammaked, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION

Initial Authorization for ALL indications:
1. The medical diagnosis is an FDA approved indication or is listed as a covered medical condition below and any indication specific criteria in the policy is met
AND
2. Requested dosage, frequency and length of therapy are supported by FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines. If request is for a non-standard dose, frequency or length, medical rational should be provided and exceptions will be considered on a case by cases basis. Dosing is subject to audit.

Re-Authorization for ALL indications:
1. Documentation of response to therapy and any indication specific re-authorization criteria listed below is met

Indication-Specific Requirements:

Primary immune deficiency disorders such as agammaglobulinemia, hypogammaglobulinemia (common variable immunodeficiency), Hyper-IgM (X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome
1. The patient has one of the following:
a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy
b. The patient has abnormal Bruton tyrosine kinase (BTK) gene or absence of BTK protein
c. The patient has an absence of B lymphocytes
d. The patient meets all of the following:
i. One of the following:
   1) The patient has selective IgG subclass deficiency [Defined as deficiency of one or more IgG subclasses}
(e.g., IgG1, IgG2, IgG3, or IgG4) more than two standard deviations (SD) below age-specific mean, assessed on two separate occasions during infection free period.

2) The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses.

3) The patient has hypogammaglobulinemia (defined as total IgG less than 700 mg/dL OR more than two SDs below mean for the patient’s age at baseline prior to immune globulin therapy).

ii. The patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (such as inability to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both).

iii. The patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (such as recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics).

Reauthorization:
1. Documentation that treatment has been effective in reducing the number or severity of clinical infections.

Prevention of infections in patients with B-cell chronic lymphocytic leukemia (CLL):
1. Documented pre-treatment endogenous IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient’s age

OR

2. History of recurrent, severe bacterial infections requiring antibiotics and/or hospitalization.

Kawasaki Disease:
1. Documentation that use is for acute treatment given in conjunction with aspirin and within 10 days of the onset of symptoms.

Idiopathic or Immune Thrombocytopenic Purpura (ITP):
(Platelet counts expressed per microliter and should be obtained within the past 30 days)

For children with ITP:
1. Documentation of one of the following:
   a. Platelet count less than 20,000 and significant mucous membrane bleeding
   b. Platelet count less than 10,000 and minor purpura
   c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss.

Pregnant Women with ITP:
1. Documentation of one of the following:
   a. Platelet count is less than 100,000
   b. Past history of splenectomy
   c. Past history of delivered infant with autoimmune thrombocytopenia
Adult Patients with ITP:
1. Documentation of one of the following:
   a. Platelet count of less than 30,000
   b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding
   c. To defer or avoid splenectomy
   d. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss (platelet count goal is generally greater than 50,000)
2. Documentation that IGG product will be used in combination with corticosteroid therapy or corticosteroid therapy is contraindicated

Dermatomyositis and polymyositis:
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
   AND
2. Documented trial, failure, intolerance or contraindication to immunosuppressant therapy (e.g., methotrexate, azathioprine, cyclosporine, 6-mercaptopurine, chlorambucil, cyclophosphamide)
   AND
3. Documentation of severe symptoms/disability despite previous therapy with above agents

Reauthorization: Documented response to therapy

Chronic inflammatory demyelinating polyneuropathy (CIDP):
1. Documentation of severe disability
   AND
2. One of the following:
   a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
   b. Documentation of pure motor CIDP

Autoimmune Hemolytic Anemia:
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
   AND
2. Documented trial, failure, intolerance or contraindication to another conventional therapy for autoimmune hemolytic anemia (e.g., splenectomy, cyclophosphamide, azathioprine, cyclosporine)

Guillain-Barre Syndrome:
1. Documentation that symptom onset is within two weeks or symptoms are severe (such as being unable to ambulate independently)
2. Documented trial, failure, intolerance or contraindication to plasma exchange

Multifocal motor neuropathy:
1. Confirmed diagnosis: motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities
   AND
2. Documentation of severe disease/disability

Multiple Sclerosis:
1. Documentation of relapsing/remitting disease
   AND
2. Documented trial, failure, intolerance or contraindication to at least two conventional therapies (such as glatiramer, interferon beta, dimethyl fumarate)

Myasthenia Gravis:
Myasthenic exacerbation:
1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month:
   a. Difficulty swallowing
   b. Acute respiratory failure
   c. Major functional disability responsible for the discontinuation of physical activity

Refractory disease:
1. Documentation that patient has severely impaired function due to myasthenia gravis
   AND
2. Documented trial, failure, intolerance or contraindication to at least two of the following conventional therapies:
   a. Acetylcholinesterase inhibitors (such as pyridostigmine)
   b. Corticosteroids (such as prednisone, methylprednisolone)
   c. Immunosuppressive agents (such as azathioprine, cyclosporine, mycophenolate)
   d. Plasma exchange

Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:
1. Documentation of one of the following:
   a. Therapy is requested for use within 100 days after transplantation (transplantation date must be documented)
   OR
   b. Documentation that patient has an IgG less than 400 mg/dL with a history of recurrent infections
Autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis
1. Documentation of biopsy proven disease
AND
2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (such as azathioprine, cyclophosphamide, mycophenolate mofetil).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS):
1. Clinical documentation must be provided detailing patient’s primary symptom complex along with baseline clinical testing(s) using validated instrument(s)
AND
2. A clinically appropriate trial of two or more less-intensive treatments was either not effective, not tolerated, or did not result in sustained improvement in symptoms, as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient’s primary symptom complex. For example, treatments may include appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, or short-course antibiotic therapy). These trials may be done concurrently.

Reauthorization in PANDAS/PANS:
1. Documentation that a reevaluation at three months post treatment have been performed by an appropriate specialist
AND
2. Documentation of objective clinically meaningful improvement posttreatment as defined by an improvement in the clinical testing with a validated instrument

Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)
1. Documentation of severe residual deficits following an initial attack, to prevent further disability (for example, to preserve vision in patients with residual monocular blindless after an initial attack)
OR
2. As maintenance treatment for patients who have experienced at least one relapse following an initial attack

Reauthorization for MOGAD: Documented positive response to therapy as demonstrated by recovery of function from previous attack or reduction in frequency or severity of attacks.

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an appropriate specialist (such as a neurologist for multiple sclerosis, immunologist, hematologist or infections disease expert for primary immunodeficiency, neurologist, psychiatrist, or rheumatologist for PANDAS/PANS)

COVERAGE DURATION
Generally, initial authorization is up to six months subject to criteria and reauthorization is up to one year subject to criteria.

OTHER CRITERIA
N/A
INCRELEX

MEDICATION(S)
INCRELEX

COVERED USES
N/A

EXCLUSION CRITERIA
Subjects with secondary forms of Insulin-like growth factor (IGF)-1 deficiency:
• GH deficiency
• Malnutrition
• Hypothyroidism
• Chronic treatment with pharmacologic doses of anti-inflammatory steroids
Concurrent use of growth hormone therapy
Malignant neoplasia

REQUIRED MEDICAL INFORMATION
For Severe primary IGF-1 deficiency:
1. Height standard deviation score of less than or equal to -3.0
AND
2. Basal insulin-like growth factor (IGF)-1 standard deviation score of less than or equal to -3.0
AND
3. Normal or elevated growth hormone (GH) levels.
AND
4. Documentation of open epiphyses by bone radiograph

For Growth hormone (GH) gene deletion
1. Documentation of open epiphyses by bone radiograph
AND
2. Patient has developed neutralizing antibodies to growth hormone

Reauthorization will require evidence that the medication remains effective, growth velocity is above 2.0 cm/year, evidence of open epiphyses, and documentation of expected adult height goal that is not yet obtained.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
INJECTABLE ANTI-CANCER MEDICATIONS

MEDICATION(S)
ABRAXANE, ACTIMMUNE, ADCETRIS, ALIQOPA, ALKERAN 50 MG VIAL, AYUMSYS, ARRANON, ARZERRA, ASPARLAS, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENDeka, BESPONSA, BESREMI, BLENREP, BLINCYTO, BORTEZOMIB 1 MG VIAL, BORTEZOMIB 2.5 MG VIAL, BORTEZOMIB 3.5 MG IV VIAL, BORTEZOMIB 3.5 MG VIAL, BORTEZOMIB 3.5 MG/1.4 ML VIAL, COSELA, CYRAMZA, DACOGEN, DANYELZA, DARZALEX, DARZALEX FASPRO, DECITABINE, ELAHERE, ELZONRIS, EMPLICITI, ENHERTU, EMBRITUX, EVOMELA, FASLODEX, FOLOTYN, FULVESTRANT, FYARRO, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMJUDO, IMLYGIC, ISTODAX, IXEMPRA, JELMYTO, JEMPERLI, JEVTVANA, KADCYLA, KANJINTI, KEYTRUDA, KIMMTRAK, KYPROLIS, LUBTAYO, LUMOXITI, LUNSUMIO, LUTATHERA, MARGENZA, MELPHALAN HCL, MONJUVI, MVASI, MYLOTARG, NELARABINE, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO, OPDUALAG, PAACLITAXEL PROTEIN-BOUND, PADCEV, PEDMARK, PEPAXTO, PERJETA, PESGO, PLUVICTO, POLIVY, PORTRAZZA, POTELIGEO, PRALATREXATE, ROMIDEPSIN, RYBREXANT, RYLAZE, SARCLISA, SYNRIBO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TIVDAK, TORISEL, TRAZIMERA, TREANDA, TRODELVY, VECTIBIX, VEGZELMA, VELCADE, VEDAZA, VIVIMUSTA, VYXEOS, XOFIGO, YERVOY, YONDELIS, ZALTRAP, ZEPZELCA, ZIRABEV, ZYNLONTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For requests for trastuzumab or bevacizumab: Documented trial and failure, intolerance, or contraindication to the use of both preferred biosimilar medications, as follows:
   a. Trastuzumab preferred products: Ogivri® (trastuzumab-dkst) and Kanjinti® (trastuzumab-anns)
   b. Bevacizumab preferred products: Mvasi® (bevacizumab-bvzr) and Zirabev® (bevacizumab-awwb)

For patients established on therapy: documentation of adequate response to the medication must be provided.

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with an oncologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
INSOMNIA AGENTS

MEDICATION(S)
AMBIEN, AMBIEN CR, BELSOMRA, DAYVIGO, DOXEPIN HCL 3 MG TABLET, DOXEPIN HCL 6 MG TABLET, ESZOPICLONE, FLURAZEPAM HCL, HALCION, LUNESTA, QUVIVIQ, RAMELTEON, RESTORIL, ROZEREM, SILENOR, TEMAZEPAM, TRIAZOLAM, ZALEPLON, ZOLPIDEM TARTRATE 1.75 MG TAB SL, ZOLPIDEM TARTRATE 3.5 MG TABLET SL, ZOLPIDEM TARTRATE 10 MG TABLET, ZOLPIDEM TARTRATE 5 MG TABLET, ZOLPIDEM TARTRATE ER

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness (e.g., cancer), OR
2. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all of the following:
   a. Patient is currently being treated for a funded co-morbid condition as indicated by one of the following:
      i. Obstructive sleep apnea: CPAP
      ii. Depression, anxiety, panic disorder, bipolar disorder: antidepressant, antipsychotic, or other appropriate mental health drug
      iii. Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments
   b. Patient has not been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days. If patient has been treated with a sedative in past 30 days, this criteria may be waived if this is a switch in sedative therapy due to intolerance, allergy, or ineffectiveness of prior sedative and notes clearly indicate that the other sedative has been discontinued
   c. Patient has had a documented trial of Cognitive Behavior Therapy (CBT) which must include education on sleep hygiene improvements
   d. For non-preferred drugs: Trial and failure, contraindication, or intolerance to zolpidem AND eszopiclone

Reauthorization:
Patient has a need for continued treatment with a sedative, meeting one of the following:
1. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness (e.g., cancer), OR
2. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all of the following:
   a. Patient is currently being treated for a funded co-morbid condition as indicated by one of the following:
      i. Obstructive sleep apnea: CPAP
      ii. Depression, anxiety, panic disorder, bipolar disorder: antidepressant, antipsychotic, or other appropriate mental health drug
      iii. Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments
   b. Patient has had a positive response to therapy without side effects and noted improvement in the funded condition
   c. If patient is taking a non-benzodiazepine sedative, benzodiazepine, or opioid in combination with the requested sedative the following must be met:
      i. Rationale must be provided addressing need for continuing sedative therapy despite potential risks, AND
      ii. Documentation that the requested sedative, non-benzodiazepine sedative, benzodiazepine, or opioid has been titrated down from the initial authorization OR documentation of a specific tapering plan OR medical rationale for not attempting a taper at this time

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Drug Prior Authorization and Quantity Limit:
• Palliative care services: Initial and reauthorization will be approved up to one year.
• Insomnia for other conditions: Initial and reauthorization will be approved up to one year

OTHER CRITERIA
N/A
INTERLEUKIN-1 INHIBITORS

MEDICATION(S)
ARCALYST, ILARIS

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with another therapeutic immunomodulator (TIM) agent

REQUIRED MEDICAL INFORMATION
1. For all requests, the patient must have an FDA labeled indication for the requested agent or use to treat the indication is supported in drug compendia (such as the American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics’ DRUGDEX® System).
   AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent
   AND
3. One of the following:
   a. For patients already established on the requested agent:
      i. Documentation of positive response to therapy (e.g., improvement or stabilization of clinical symptoms of disease)
   b. For patients not established on the requested agent, must meet ALL of the following criteria according to their diagnosis:
      i. Cryopyrin-Associated Periodic Syndrome (CAPS) includes Familial Cold Autoinflammatory Syndrome (FCS) and Muckle-Wells Syndrome (MCS):
         • Diagnosis confirmed by laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3), also known as CIAS1 (Cold-Induced Autoinflammatory Syndrome-1)
         • Classic symptoms associated with CAPS (such as urticaria-like rash, fever, cold/stress-triggered episodes, sensorineural hearing loss, chronic aseptic meningitis, and skeletal abnormalities).
      ii. Deficiency of Interleukin-1 Receptor Antagonist (DIRA):
         • Diagnosis confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist)
         • Classic symptoms associated with DIRA (such as pustular psoriasis-like rashes, osteomyelitis without bacterial infection, and nail changes)
         • Arcalyst® may be covered if:
            o Current inflammatory remission of DIRA
            o Weight of at least 10 kg
iii. Familial Mediterranean Fever (FMF):
- Diagnosis confirmed by laboratory evidence of genetic mutation in Mediterranean fever gene, MEFV
- Classic symptoms associated with FMF (such as febrile episodes, pain in the abdomen or chest, or arthritis of large joints)
- Documented trial and failure, contraindication, or intolerance to colchicine

iv. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD):
- Laboratory evidence of genetic mutation MVK (mevalonate kinase),
- Classic symptoms associated with HIDS (abdominal pain, lymphadenopathy, aphthous ulcers)

v. Recurrent Pericarditis (RP):
- Diagnosis of RP confirmed by an acute episode of pericarditis followed by a 4–6-week symptom free period prior to the next episode without an identified cause
- Documentation trial and failure, contraindication, or intolerance to NSAIDs or glucocorticoids

vi. Still’s Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), must meet ONE of the following criteria:
- Documentation of trial and failure, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs) OR
- Presence of Macrophage Activation Syndrome

vii. Tumor Necrosis Factor Receptor-Associated Periodic Syndrome (TRAPS):
- Laboratory evidence of genetic mutation TNFRSF1A (Tumor Necrosis Factor Receptor Superfamily), AND
- Classic symptoms associated with TRAPS (such as long-lasting fever episodes, migratory rash, periorbital edema, and myalgia).

AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
INTRANASAL ALLERGY MEDICATIONS

MEDICATION(S)
24 HOUR NASAL ALLERGY, ALLER-CORT, ASTEPRO ALLERGY, AZELASTINE 0.1% (137 MCG) SPRY, AZELASTINE 0.15% NASAL SPRAY, BECONASE AQ, CHILDREN'S ASTEPRO ALLERGY, CHILDREN'S FLONASE SENSIMIST, CHILDREN'S NASACORT, CROMOLYN SODIUM NASAL SPRAY, FLONASE SENSIMIST, FLUNISOLIDE 0.025% SPRAY, IPRATROPIUM 0.03% SPRAY, IPRATROPIUM 0.06% SPRAY, MOMETASONE FUROATE 50 MCG SPRY, NASACORT, NASAL ALLERGY, NASALCROM, NASONEX, OLOPATADINE 665 MCG NASAL SPRY, OMNARIS, PATANASE, QNASL, QNASL CHILDREN, TRIAMCINOLONE 55 MCG NASAL SPR, ZETONNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For authorization, all the following criteria (1-4) must be met:
1. Request is not for intranasal ipratropium or intranasal cromolyn
2. Diagnosis of allergic or non-allergic rhinitis
3. Must meet one of the following (a or b):
   a. Documentation of one of the following co-morbid conditions:
      i. Asthma or reactive airway within the past year
         1) If patient has used an inhaled corticosteroid controller medication for asthma within the past 90 days, intranasal corticosteroid therapy will not be covered (asthma-related outcomes are not improved by the addition of an intranasal corticosteroid to an orally inhaled corticosteroid)
         i. Chronic sinusitis
         ii. Acute sinusitis
         iii. Sleep apnea
      b. Member is under the age of 21 and has documentation that the therapy is expected to improve the patient’s ability to grow, develop or participate in school
4. Documented trial and failure, intolerance, or contraindication to fluticasone nasal spray

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Acute sinusitis comorbid condition: Authorization will be approved for one month
All other comorbid conditions (e.g., asthma, chronic sinusitis): Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
IVERMECTIN

**MEDICATION(S)**
IVERMECTIN 3 MG TABLET, IVERMECTIN POWDER, STROMECTOL

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
Treatment or prevention of COVID-19 infection

**REQUIRED MEDICAL INFORMATION**
N/A

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for one month

**OTHER CRITERIA**
N/A
KERENDIA

MEDICATION(S)
KERENDIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Patient has a diagnosis of type 2 diabetes
2. Patient has evidence of diabetic nephropathy, defined as one of the following:
   a. Estimated glomerular filtration rate (eGFR) of 60 mL/min/1.73m2 or less for at least three months
   b. Persistent moderate to severe albuminuria [urine albumin-to-creatinine ratio (UACR) 30 mg/g or greater, or 0.113 mg/mmol or greater] for at least three months
   c. Moderate to severe proteinuria [urine protein-to-creatinine ratio (UPCR) 200 mg/g or greater] for at least three months
3. Documentation that patient is on a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or an Angiotensin Receptor Blocker (such as losartan), unless all agents in these classes are contraindicated
4. Documentation of one of the following:
   a. Trial of 90 days or more of a Sodium Glucose Co-transporter-2 inhibitor (such as empagliflozin or dapagliflozin)
   b. Contraindication or intolerance to a Sodium Glucose Co-transporter-2 inhibitor

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
KETOROLAC INTRAMUSCULAR INJECTION

MEDIICATION(S)
KETOROLAC 15 MG/ML CARPUJECT, KETOROLAC 15 MG/ML ISECURE SYR, KETOROLAC 15 MG/ML SYRINGE, KETOROLAC 15 MG/ML VIAL, KETOROLAC 30 MG/ML CARPUJECT, KETOROLAC 30 MG/ML SYRINGE, KETOROLAC 30 MG/ML VIAL, KETOROLAC 60 MG/2 ML CARPUJECT, KETOROLAC 60 MG/2 ML SYRINGE, KETOROLAC 60 MG/2 ML VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Request is for one of the following:
   a. Moderately severe acute pain not manageable by oral NSAIDs
   b. Migraine pain not manageable by a formulary triptan (such as frovatriptan, naratriptan, rizatriptan, sumatriptan, Zomig® nasal spray)

   AND

2. Documentation that patient does not have a diagnosis of peptic ulcer disease, gastrointestinal bleed, advanced renal failure, or coagulation disorder

   AND

3. Documentation that ketorolac tromethamine use will not exceed a total of five days of treatment per treatment course (Note: The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed five days)

Reauthorization criteria:
1. Documentation of a positive clinical response to the requested therapy

2. Documentation that ketorolac tromethamine use will not exceed a total of five days of treatment per treatment course (Note: The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed five days)

AGE RESTRICTION
Approved in 17 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
KORLYM

COVERED USES
N/A

EXCLUSION CRITERIA
Current pregnancy

REQUIRED MEDICAL INFORMATION
1. Documentation that the patient has hyperglycemia secondary to endogenous Cushing’s Syndrome (defined as hypercortisolism that is not a result of chronic administration of high dose glucocorticoids), AND
2. Documentation that the patient has type 2 diabetes mellitus or glucose intolerance, AND
3. Documentation that the patient has failed surgery or is not a candidate for surgery

Reauthorization: Documentation that the patient has improved or stable glucose tolerance

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an endocrinologist.

COVERAGE DURATION
Initial authorization for 6 months. Reauthorization for 12 months.

OTHER CRITERIA
N/A
KORSUVA

MEDICATION(S)
KORSUVA

COVERED USES
Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services

EXCLUSION CRITERIA
Use with peritoneal dialysis

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following must be met:
1. Diagnosis of moderate to severe pruritis associated with chronic kidney disease. Moderate to severe pruritis is defined as a score of 4 or higher on the Worst Itching Intensity numerical scale (WI-NRS) or pruritis that is severe enough to impair quality of life
2. Undergoing hemodialysis for at least three months
3. Prescriber attestation that the following have been optimized:
   a. Dialysis
   b. Laboratory abnormalities such as parathyroid, phosphate, magnesium
   c. Use of topical emollients
4. Documented inadequate response to at least two weeks trial of an oral antihistamine, or intolerance/contraindication to antihistamine therapy
5. Documented inadequate response to at least two weeks trial of pregabalin or gabapentin, or intolerance/contraindication to both pregabalin and gabapentin
6. Dose and frequency are in accordance with FDA-approved labeling

For reauthorization, all the following must be met:
1. Undergoing hemodialysis
2. Documentation of positive response to therapy, defined as an improvement of at least three points on the WI-NRS from baseline or improvement in quality of life
3. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged eighteen years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist
COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
KRYSTEXXA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial therapy, all the following criteria must be met:
1. Diagnosis of chronic gout
2. Documentation of inadequate response, intolerance or contraindication to both of the following at maximum medically appropriate doses:
   a. Xanthine oxidase inhibitor (such as allopurinol)
   b. Uricosuric agent (such as probenecid).
   Note: Inadequate response is defined as inability to achieve uric acid levels of less than 6 mg/dL after at least three months of continuous therapy.
3. Documentation of symptomatic gout, as defined by one or more of the following, despite therapies outlined in criterion 2 above:
   a. At least two gout flares per year
   b. Non-resolving tophi

Reauthorization requires documentation of a decreased uric acid level from baseline

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for six months.

OTHER CRITERIA
N/A
MEDICATION(S)
JAVYGTOR, KUVAN, SAPROPTERIN DIHYDROCHLORIDE

COVERED USES
N/A

EXCLUSION CRITERIA
• Doses greater than 20 mg/kg/day will not be approved.
• Use in combination with Palynziq® (pegvalise-pqpx)

REQUIRED MEDICAL INFORMATION
Must meet all of the following criteria for initial authorization:
1. Diagnosis of phenylketonuria (PKU)
   AND
2. Documentation the requested medication will be used in conjunction with a phenylalanine (Phe)-
   restricted diet
   AND
3. Documentation that the patient’s pre-treatment phenylalanine blood levels measured within 90 days prior
to starting therapy is above 6 mg/dL (360 micromol/L) in children less than 12 years of age, or above 10
mg/dL (600 micromol/L) for ages 12 and older.

For Reauthorization:
1. Documented improvement in average blood Phe level from pretreatment baseline, (such as average
blood Phe level decreased by at least 30% for initial reauthorization and remain 30% below pretreatment
baseline for continued authorization thereafter)
   AND
2. Documentation of continued dietary Phe-restriction

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a specialist in metabolic disorders

COVERAGE DURATION
Initial authorization for two months. Reauthorization will be approved until no longer eligible with the plan,
subject to formulary and/or benefit changes.
OTHER CRITERIA
N/A
MEDICATION(S)
LEMTRADA

COVERED USES
N/A

EXCLUSION CRITERIA
In combination with other disease modifying therapy indicated for the treatment of multiple sclerosis

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria (1-4) must be met:
1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis or active secondary progressive disease
2. Documentation of active disease (such as patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial (defined as at least six months of continuous therapy) of ocrelizumab (Ocrevus®)
3. Documentation of active disease after an adequate trial (defined as at least six months of continuous therapy) of at least one of the following additional disease modifying therapies unless all are contraindicated. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.
   a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®) or interferon-beta 1b (Betaseron®)
   b. Generic dimethyl fumarate
   c. Glatiramer acetate (Copaxone®)
   d. Natalizumab (Tysabri®)
   e. Teriflunomide (Aubagio®)
   f. Fingolimod (Gilenya®)
   g. Ozanimod hydrochloride (Zeposia®)
   h. Siponimod (Mayzent®)
   i. Cladribine (Mavenclad®)
   j. Ofatumumab (Kesimpta®)
4. Dose and frequency are in accordance with FDA-approved labeling

For patients established on therapy, all the following must be met:
1. Documentation of positive clinical response to therapy
2. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
LIDOCAINE PATCH

MEDICATION(S)
LIDOCAINE 5% PATCH, LIDODERM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
COVERED USES:
Post-herpetic neuralgia, diabetic peripheral neuropathy, and neuropathic pain

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
LIVTENCITY

MEDICATION(S)
LIVTENCITY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Documentation of history of hematopoietic stem cell or solid organ transplant
2. Documentation of post-transplant cytomegalovirus (CMV) infection/disease with CMV DNA of 2730 IU/mL or greater in whole blood or 910 IU/mL or greater in plasma
3. Documentation that patient is refractory (with or without genotypic resistance), or has an intolerance or contraindication to, treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet

Reauthorization:
1. Documentation is provided to support continued therapy as evidenced by incomplete resolution of clinical symptoms, incomplete virologic clearance, or relapse in CMV infection

AGE RESTRICTION
May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a transplant surgeon, infectious disease specialist, oncologist, hematologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for eight weeks

OTHER CRITERIA
N/A
LONG ACTING OPIOIDS

MEDICATION(S)
BELBUCA, BUPRENORPHINE, BUPRENORPHINE 150 MCG FILM, BUPRENORPHINE 300 MCG FILM, BUPRENORPHINE 450 MCG FILM, BUPRENORPHINE 600 MCG FILM, BUPRENORPHINE 75 MCG FILM, BUPRENORPHINE 750 MCG FILM, BUPRENORPHINE 900 MCG FILM, BUTRANS, DISKETS, FENTANYL 100 MCG/HR PATCH, FENTANYL 12 MCG/HR PATCH, FENTANYL 25 MCG/HR PATCH, FENTANYL 50 MCG/HR PATCH, FENTANYL 75 MCG/HR PATCH, HYDROCODONE BITARTRATE ER, HYDROMORPHONE ER, HYSINGLA ER, METHADONE 40 MG TABLET DISPR, METHADONE HCL 10 MG TABLET, METHADONE HCL 5 MG TABLET, METHADOSE 40 MG TABLET DISPR, NUCYNTA ER, OXYCODONE HCL ER, OXYCONTIN, OXYMORPHONE HCL ER, XTAMPZA ER, ZOHYDRO ER

COVERED USES
N/A

EXCLUSION CRITERIA
• As needed (prn) use
• For treatment of acute pain such as recent injury, sprain, strain, surgery, migraines, or headaches
• Concurrent use with another long-acting opioid

REQUIRED MEDICAL INFORMATION
For ALL requests: chart notes demonstrating assessment of painful conditions within the last six months must be provided with the following:
1. Outline of current treatment regimen including all opioids with daily dose and frequency, all non-opioid therapy, and/or non-pharmacological therapy
2. Comprehensive documentation including an appropriate patient medical history, physical examination, screening for substance use disorder and interacting medications and treatment plan

For patients initiating therapy with a long-acting opioid therapy:
1. The following indication-specific criteria must be met:
   a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease, or severe burns: documentation of all the following:
      i. Active pain directly related to the condition(s) mentioned above
      ii. Inadequate pain relief from current and consistent regimen (of at least two weeks length within the previous 30 days) that includes four or more doses per day of short-acting opioid therapy for around-the-clock management of pain
      iii. Inadequate pain relief, after at least two weeks of consistent use, from a stable dose (within the previous 30 days), of long-acting morphine sulfate therapy or documented contraindication/intolerance to long-acting morphine sulfate therapy
b. For chronic pain, ALL the following must be documented:
   i. Patient has chronic non-malignant pain (lasting longer than three months) that is severe enough to require around-the-clock analgesic therapy
   ii. Pain is not caused by a condition for which opioids are not recommended [such as fibromyalgia, abdominal pain, diabetic neuropathy, Temporomandibular joint (TMJ), headaches, migraines, pelvic pain syndrome]
   iii. Patient has no contraindications to opioid use (including but not limited to untreated substance use disorder, significant respiratory depression, hypercapnia or central apnea or GI obstruction, paralytic ileus)
   iv. Inadequate pain relief from current and consistent regimen (of at least two weeks length within the previous 30 days) that includes four (4) or more doses per day of short-acting opioid therapy for around-the-clock management of pain
   v. Inadequate pain relief, after at least two weeks of consistent use, from a stable dose (after an adequate titration) of long-acting morphine sulfate therapy, or documented contraindication/intolerance to long-acting morphine sulfate therapy
   vi. Adequate use of non-opioid medications such as acetaminophen, NSAIDs, topical therapy (e.g., capsaicin, lidocaine, diclofenac gel), or neuropathic pain medications (e.g., duloxetine, gabapentin, pregabalin, amitriptyline, nortriptyline). This may be verified by on-going use of these medications
   vii. On-going use of non-pharmacological active therapies (such as physical therapy, home or prescribed exercise, acupuncture, Cognitive Behavioral Therapy, counseling, nutrition counseling, weight management)
   viii. There is a pain management agreement and/or treatment/monitoring plan between the prescriber and patient that includes monitoring plans and functional goals that has been reviewed within the previous six months.
   ix. Prescription Drug Monitoring Program has been reviewed and no concerns for initiating long-acting opioid therapy were identified

2. The following drug-specific criteria must be met in addition to the above criteria:
   a. For fentanyl patch: Must be opioid-tolerant, defined as using at least 60 morphine milligram equivalents (MME) per day
   b. For Oxycontin®: Trial and failure of Xtampza ER® [oxycodone extended-release (ER) capsules]
   c. For Nucynta ER®: Documentation of inadequate pain relief from at least a two-week trial of extended-release tramadol
   d. For Belbuca®: Documentation of trial and failure of Butrans® (buprenorphine transdermal)

For patients established on therapy with a long-acting opioid therapy, defined as consistent use for at least three months (may be verified by pharmacy claims):
1. The following indication-specific criteria must be met:
   a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease or severe burns, all the following must be documented:
      i. Positive response to therapy
      ii. Continued active pain directly related to the condition(s) mentioned above
b. For chronic pain, all the following must be documented:
   i. Improvement from baseline in pain control/level of functioning, or no worsening of pain control
   ii. Appropriate monitoring (including review of Prescription Drug Monitoring Program) with no concerns for adverse events (such as no unmonitored dose escalation, no excess sedation, no signs of developing substance use disorder)
   iii. There is a pain management agreement and/or treatment/monitoring plan between the prescriber and patient that includes monitoring plans and functional goals that has been reviewed within the previous six months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be for up to one year.

Note: To avoid abrupt discontinuation, a three-month approval may be authorized for patients established on long-acting opioid therapy to allow for submission of documentation, etc.

OTHER CRITERIA
N/A
LONG ACTING STIMULANT MEDICATIONS

MEDICATION(S)
ADDERALL XR, ADHANSIA XR, ADZENYS ER, ADZENYS XR-ODT, AMPHETAMINE, APTENSIO XR, AZSTARYS, CONCERTA, COTEMPLA XR-ODT, DAYTRAN, DEXEDRINE, DEXMETHYLPHENIDATE HCL ER, DEXTROAMPHETAMINE SULFATE ER, DEXTROAMPHETAMINE-AMPHET ER, DYANAVEL XR, FOCALIN XR, JORNAY PM, METADATE ER, METHYLPHENIDATE, METHYLPHENIDATE ER, METHYLPHENIDATE ER (LA), METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA, MYDAYIS, QUILLICHEW ER, RELEXXII, RITALIN LA, VYVANSE, XELSTRYM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For adults requesting initiation of a long-acting stimulant medication, all the following criteria must be met:
   a. Request is for a preferred agent
      i. Requests for a non-preferred agent will require one of the following:
         • Documented trial, of at least four weeks, of at least two different long-acting preferred agents with inadequate response (for example, minimal to no improvement in symptoms), or
         • Request is for Vyvanse® for binge eating disorder with a confirmed diagnosis supported by clinical documentation
   b. The requested agent will be used for one of the following diagnoses, confirmed while an adult, as follows:
      i. Attention Deficit Hyperactivity Disorder (ADHD) – diagnosis code F90.x
      ii. Narcolepsy
      iii. Binge eating disorder
2. For adult patients established on long-acting stimulant therapy, all the following criteria must be met:
   a. Patient has a confirmed current diagnosis (diagnosis must be confirmed or reconfirmed while an adult), of one of the following funded conditions:
      i. Attention Deficit Hyperactivity Disorder (ADHD)
      ii. Narcolepsy
      iii. Binge eating disorder
   b. Request is for a preferred agent
      i. Requests for a non-preferred agent will require one of the following:
         • Documented trial, of at least four weeks, of at least two different long-acting preferred agents with inadequate response (for example, minimal to no improvement in symptoms), or

• Request is for Vyvanse® for binge eating disorder with a confirmed diagnosis supported by clinical documentation
c. Documentation of positive response to therapy
3. For pediatric patients requesting a non-preferred stimulant, all the following must be met:
a. Patient has a confirmed current diagnosis of one of the following funded conditions:
   i. Attention Deficit Hyperactivity Disorder (ADHD)
   ii. Narcolepsy
   iii. Binge eating disorder
b. One of the following:
   i. Documented trial, of at least four weeks, of at least two different preferred stimulant agents with inadequate response (for example, minimal to no improvement in symptoms). Trials should be two different drug entities within the same formulation (for example, dextroamphetamine/amphetamine extended-release (ER) and methylphenidate ER tablets)
   ii. Request is for Vyvanse® for binge eating disorder with a confirmed diagnosis supported by clinical documentation
4. For all patients (pediatrics and adults):
a. The requested regimen is within Food and Drug Administration (FDA) approved age range and maximum daily dose as outlined in the Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria.
Attention Deficit Hyperactivity Disorder (ADHD) Safety Edit
i. Requests outside of these limits will require documentation that the drug regimen was developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist. Continuation of existing therapy once up to 90 days may be covered to allow time to consult with a mental health specialist.
b. Requests above the formulary quantity limit must meet one of the following:
   i. The prescribed dose cannot be achieved using a lesser quantity of a higher strength (such as utilize one 20 mg capsule instead of two 10 mg capsules), or
   ii. For more than once-daily dosing: documentation that the drug regimen was developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist. Continuation of existing therapy once up to 90 days may be covered to allow time to consult with a mental health specialist.
• Dosing regimens of long-acting stimulants that exceed two times daily are not considered medically necessary and are not covered

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For adult patients: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

For pediatric patients: Authorization will be approved until age of 18 years or until no longer eligible with the plan, whichever occurs first.

OTHER CRITERIA
N/A
MEDICATION(S)
ALOSETRON HCL, LOTRONEX

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with constipation

REQUIRED MEDICAL INFORMATION
For initiation, all the following must be met:
1. Patient is female
2. Documentation of chronic symptoms of irritable bowel syndrome (IBS) that have persisted for six months or longer
3. Documentation of severe diarrhea-predominant IBS, defined as having at least one of the following symptoms:
   a. Frequent and severe abdominal pain/discomfort
   b. Frequent bowel urgency or fecal incontinence
   c. Disability or restriction of daily activities due to IBS-D
4. Documentation of trial and inadequate response, contraindication, or intolerance to a medication from both of the following drug classes:
   a. Tricyclic antidepressants [e.g., amitriptyline (Elavil®)]
   b. Opioid mu receptor agonists [e.g., loperamide (Imodium®), diphenoxylate (Lomotil®)]

For reauthorization:
1. Documentation of response to therapy, defined as reduction in frequency and urgency of bowel movements, reduction in abdominal pain/discomfort, or improved quality of life

AGE RESTRICTION
Age 18 years or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist. Please note that prescriber should comply with the requirements of the Alosetron REMS Program.

COVERAGE DURATION
Initial authorization will be approved for three months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
OTHER CRITERIA
N/A
LUPKYNIS

MEDICATION(S)
LUPKYNIS

COVERED USES
N/A

EXCLUSION CRITERIA
1. Estimated glomerular filtration rate (eGFR) less than 45
2. History of kidney transplant
3. Use in combination with belimumab (Benlysta®), anifrolumab (Saphnelo®) or cyclophosphamide

REQUIRED MEDICAL INFORMATION
For initial authorization for active lupus nephritis, all of the following must be met:
1. Confirmed diagnosis of systemic lupus erythematosus (SLE)
2. Kidney biopsy with a histologic diagnosis of lupus nephritis classes III, IV, or V
3. Documentation of laboratory test results indicating that patient has presence of auto-antibodies for SLE, defined as one of the following:
   a. Positive Antinuclear antibody (ANA)
   b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
   c. Positive anti-Smith (Anti-Sm)
   d. Positive anti-Ro/SSA and anti-La/SSB antibodies
4. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:
   a. Mycophenolate for induction followed by mycophenolate for maintenance, OR
   b. Cyclophosphamide for induction followed by azathioprine for maintenance
5. Documentation that patient will continue to receive standard therapy (such as, corticosteroids, mycophenolate, azathioprine)

Reauthorization criteria:
1. Documentation currently receiving standard therapy for active lupus nephritis
2. Documentation of a positive response to therapy based on one of the following:
   a. Improvement in urine protein/creatinine ratio (UPCR) of less than or equal to 0.5 mg/mg and eGFR of at least 60
   b. Decrease from baseline in eGFR of less than 20%

AGE RESTRICTION
May be approved for patients aged 18 years and older.
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist or rheumatologist.

COVERAGE DURATION
Initial authorization will be approved for six months, reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
MEDICATION(S)
LUXTURNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All the following must be met:
1. Confirmed biallelic RPE65 gene mutation, and
2. Has not previously had the intended treatment eye treated with gene therapy for retinal dystrophy RPE65 mutations, and
3. Documentation by an ophthalmologist within the previous six months of BOTH of the following:
   a. Presence of sufficient viable retinal cells in the intended treatment eye as evidenced by an area of retina within the posterior pole of more than 100 micrometer thickness shown on optical coherence tomography, and
   b. The member has remaining light perception in the intended treatment eye

AGE RESTRICTION
Approved for 12 months of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an ophthalmologist from a certified Luxturna® administration site

COVERAGE DURATION
Authorization is limited to one treatment course per eye per lifetime. Approval duration will be for six months.

OTHER CRITERIA
N/A
MEDICATION(S)
MAVENCLAD

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease modifying agents for multiple sclerosis

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria must be met:
1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis (MS) or active secondary progressive disease. Note: this therapy is not indicated for use in clinically isolated syndrome (CIS)
2. ONE of the following (a, b, c or d):
   a. The patient has highly active disease defined as BOTH of the following:
      i. Greater than or equal to two relapses in the previous year
      ii. ONE of the following:
         1. The patient has greater than or equal to one gadolinium enhancing lesion on MRI
         2. The patient has significant increase in T2 lesion load compared with a previous MRI
   b. The patient has been treated with at least three multiple sclerosis agents from different drug classes
   c. Documentation of an inadequate response (after at least six months of continuous therapy) or an intolerance to either generic dimethyl fumarate or generic glatiramer
   d. FDA labeled contraindication to BOTH generic dimethyl fumarate and generic glatiramer

For patients established on therapy, both the following must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
1. Documentation of positive clinical response to therapy
2. Documentation that therapy has not exceeded two years in the patient’s lifetime

AGE RESTRICTION
Approved for patients age 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
May be approved for up to two years, ensuring the cumulative duration of therapy does not exceed two
years in a lifetime. Treatment beyond two years will not be authorized.

OTHER CRITERIA
N/A
MEDICAL NUTRITION

MEDICATION(S)
PROLEEVA

COVERED USES
N/A

EXCLUSION CRITERIA
• L-methylfolate (such as Deplin®) in the treatment of depression

REQUIRED MEDICAL INFORMATION
Oral Nutritional Supplements may be considered medically necessary for coverage when age-appropriate policy criteria have been met.

For coverage of oral or enteral nutrition must meet the following criteria:

FOR ENTERAL NUTRITION VIA FEEDING TUBE
1. Member has a feeding tube placed and nutrition will be administered via feeding tube (e.g., nasogastric [NG], nasojejunal [NJ], gastrostomy [PEG], jejunostomy [J-tube, PEG-J, PEJ])
OR
2. ALL the following criteria (a-c) must be met:
   a. Established or anticipated inadequate oral intake for adults of at least seven days. For children and infants, the length of time of inadequate oral intake will be considered on a case-by-case basis
   b. Adequate nutrition is not possible by dietary adjustment and/or oral supplementation
   c. Documentation of ONE of the following:
      i. A medical condition that prevents food from reaching the digestive tract (such as head and neck cancer with reconstructive surgery, central nervous system disease that interferes with neuromuscular mechanisms of ingestion).
      ii. Enteral nutrition comprises the sole source or is an essential source of nutrition (at least 75 percent of estimated basal caloric requirements) and is used as a therapeutic regimen to prevent serious disability in the patient.
      iii. Recent unplanned weight loss of at least 10% in the past three months or less due to: increased metabolic need resulting from severe trauma, malabsorption difficulties due to underlying medical condition, increased caloric need due to disease (such as cystic fibrosis) or severe anorexia nervosa.
   iv. Documentation of failure to thrive in patients under the age of 17.

In-line cartridge containing digestive enzymes (such as Relizorb™)
ALL of the following must be met:
1. Diagnosis of cystic fibrosis, AND
2. History of exocrine pancreatic insufficiency, AND
3. Member requires enteral tube nutrition for continuous durations of 6 hours or more

ORAL NUTRITION
For Adults and Children 6 Years of Age and Older, the following criteria (1-4) must be met:
1. A licensed prescribing practitioner has issued a written order for the formula AND
2. One of the following criteria (a or b) must be met:
   a. Documentation of a nutritional deficiency identified by one of the following:
      i. Recent low serum protein levels (albumin less than or equal to 3.2 gm/dl or low total protein), OR
      ii. Recent Registered Dietitian assessments showing that sufficient caloric/protein intake is not obtainable through regular, liquefied, or pureed foods
   OR
   b. Patient meets one of the following:
      i. Prolonged history (greater than one year) of malnutrition, and diagnosis or symptoms of cachexia OR
      ii. Member resides in a home, nursing facility, or chronic home care facility AND
3. Documentation of recent unplanned weight loss of at least 10%. Weight loss criterion may be waived if body weight is being maintained by supplements due to the patient’s medical condition (such as renal failure, AIDS) AND
4. One of the following conditions:
   a. Increased metabolic need resulting from severe trauma
   b. Malabsorption due to underlying medical conditions (such as Crohn’s disease, short gut syndrome, bowel resection, fistula, gastric bypass, cystic fibrosis, renal dialysis, dysphagia, achalasia)
   c. Diagnosis that requires additional calories and/or protein intake (such as cancer, AIDS, Pulmonary insufficiency, MS, ALS, Parkinson’s, Cerebral Palsy, Alzheimer’s)

For Pediatric Patients Less than 6 Years of Age
1. A licensed prescribing practitioner has issued a written order for the formula AND
2. One of the following criteria must be met:
   a. Documentation of failure to thrive, OR
   b. Meets criteria outlined in the Adults and Children 6 Years of Age and Older section above (criterion 2 or 4)

FOR INBORN ERRORS OF METABOLISM
ALL the following criteria (1-3) must be met:
1. Member has a confirmed in-born error of metabolism (including, but not limited to phenylketonuria [PKU], maternal phenylketonuria, maple syrup urine disease, citrullinemia, homocystinuria, histidinemia,
tyrosinemia)
AND
2. Failure to use medical food will predictably result in adverse medical outcomes
AND
3. Treatment of the condition cannot be met through normal dietary supplementation or modification

Oral thickening agents such as “Thick and easy” or “Thick-it” will be covered for patients with a diagnosis of dysphagia. Member must have a swallow evaluation completed before thickening agent will be approved. All other requests will be considered on a case-by-case basis.

Reauthorization: Continued coverage will require documentation that the requested therapeutic regimen remains medically necessary to prevent serious disability in the patient.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to one year.
For permanent or progressive conditions, authorization will be approved until no longer eligible, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
BUPHENYL, CARBAGLU, CARGLUMIC ACID, CERDELGA, DAYBUE, DICHLORPHENAMIDE, DOJOLVI, GALAFOLD, GAMIFANT, KEVEYIS, MIGLUSTAT, MYALEPT, NULIBRY, PHEBURANE, RAVICTI, SKYCLARYS, SODIUM PHENYL BUTYRATE, XURIDEN, ZAVESCA, ZOKINVY

COVERED USES
N/A

EXCLUSION CRITERIA
For Galafold® only – combination therapy with enzyme replacement therapy [such as agalsidase beta (Fabrazyme®)] for the treatment of Fabry disease

REQUIRED MEDICAL INFORMATION
Both of the following must be met:
1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted
   a. For Nulibry®: Diagnosis of molybdenum cofactor deficiency (MoCD) Type A confirmed by a mutation in
      the MOCS1 gene OR suspected molybdenum cofactor deficiency (MoCD) Type A
      AND
   2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy
      with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other
      clinical information
      AND
   3. For Pheburane Pellet (sodium phenylbutyrate): Documented trial and failure or intolerance to formulary
      generic sodium phenylbutyrate powder

REAUTHORIZATION CRITERIA:
The following must be met:
1. Documentation of successful response to therapy
   AND
2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy
   with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other
   clinical information
   AND
3. For Nulibry®: Genetic testing to confirm mutation in the MOCS1 gene (Nulibry® should be discontinued if
   the MoCD Type A diagnosis is not confirmed by genetic testing)

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a specialist in the respective disease state.

COVERAGE DURATION
For Daybue®: Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

For Nulibry®: Initial authorization will be approved for three months. Reauthorization will be approved for 12 months.

For all other medications: Initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEPRON

MEDICATION(S)
ATOVAQUONE, MEPRON

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For prevention or treatment of pneumocystis pneumonia (PCP): Documented trial and failure, intolerance or contraindication to trimethoprim/sulfamethoxazole

For Babesiosis, all of the following criteria must be met:
1. Laboratory confirmation of infection (e.g., blood smear, PCR)
2. Documentation that the patient is experiencing symptoms of disease such as hemolytic anemia, thrombocytopenia, and/or flu-like symptoms
3. Confirmation that the patient will be taking atovaquone with azithromycin

Reauthorization:
Most patients are able to be successfully treated after one 7-10-day treatment course. Subsequent treatments will require laboratory confirmation of continued infection (e.g., blood smear, PCR).

AGE RESTRICTION
Approved for 13 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an infectious disease specialist, pulmonologist, hematologist, or oncologist

COVERAGE DURATION
For PCP: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

For Babesiosis: Initial and reauthorization approved for 10-day treatment course.

OTHER CRITERIA
MEDICATION(S)
MIFEPREX, MIFEPRISTONE

COVERED USES
Mifepristone 200 mg tablet will only be covered for the termination of pregnancy in situations that are considered non-elective (such as a nonviable fetus, miscarriage, fetal demise/missed abortion, or threat to life of person carrying pregnancy).

EXCLUSION CRITERIA
Elective termination of pregnancy

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved for one month

OTHER CRITERIA
N/A
NARCOLEPSY AGENTS

MEDICATION(S)
SODIUM OXYBATE, WAKIX, XYREM, XYWAV

COVERED USES
N/A

EXCLUSION CRITERIA
Combination use of sodium oxybates, solriamfetol, and/or pitolisant
For solriamfetol (Sunosi®): idiopathic central nervous system hypersomnia

REQUIRED MEDICAL INFORMATION
1. For initial authorization, all the following indication-specific criteria must be met:
a. For treatment of narcolepsy with cataplexy (Type 1 narcolepsy) the following criteria must be met:
i. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay)
ii. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
iii. Documentation of at least three weekly cataplexy attacks
iv. For Xyrem®/Xywav™ in adults: Documentation of inadequate response (after at least three months of therapy), intolerance, or contraindication to pitolisant (Wakix®)
b. For treatment of excessive daytime sleepiness in narcolepsy without cataplexy (Type 2 narcolepsy) the following criteria must be met:
i. Diagnosis of narcolepsy as confirmed by sleep study
ii. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
iii. Other causes of sleepiness have been ruled out or treated (such as obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders)
iv. Documentation of inadequate response (after three months of therapy), intolerance, or contraindication to both of the following:
   1. Stimulant (such as amphetamine or methylphenidate)
   2. Modafinil or armodafinil
v. For Wakix®: Documentation of inadequate response (after at least three months of therapy), intolerance, or contraindication to solriamfetol (Sunosi®)
vi. For Xyrem®/Xywav™ in adults: Documentation of inadequate response (after at least three months of therapy), intolerance, or contraindication to solriamfetol (Sunosi®) AND pitolisant (Wakix®)
c. For excessive daytime sleepiness associated with obstructive sleep apnea (OSA), solriamfetol (Sunosi®)
may be covered if the following criteria are met:

i. Diagnosis of OSA as confirmed by sleep study

ii. Documented evidence of residual sleepiness and functional impairment despite compliant positive airway pressure use (compliance is defined as using positive airway pressure at least four hours each night for 70% of the nights) for at least three months

iii. The modalities to treat the underlying airway obstruction (such as continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent

iv. Failure of a three-month trial, intolerance, or contraindication to armodafinil or modafinil

d. For idiopathic hypersomnia, Xywav® may be covered if all the following criteria are met (Refer to covered uses section for additional criteria for Medicaid):

i. Diagnosis of idiopathic hypersomnia confirmed by sleep study

ii. Documentation that sleepiness is not due to another medical, behavioral, or psychiatric disorder condition, including but not limited to insufficient sleep (less than seven hours per night), depression, sedating medications, and sleep-related breathing disorders

iii. Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months

iv. Documentation of inadequate response (after three months of therapy), intolerance, or contraindication to modafinil

2. For Reauthorization, must meet indication-specific criteria below:

a. For narcolepsy: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks.

b. For OSA [solriamfetol (Sunosi®) only]:

i. Reduction in symptoms of excessive daytime sleepiness

ii. The modalities to treat the underlying airway obstruction (for example, continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent

c. For idiopathic hypersomnia: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness

AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
Must be prescribed by a sleep specialist, neurologist, pulmonologist, or psychiatrist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
NEW DRUG AWAITING ORPTC REVIEW - PRIOR AUTHORIZATION REQUEST

MEDICATION(S)
ADALIMUMAB-FKJP(CF), ADALIMUMAB-FKJP(CF) PEN, ADTHYZA, ALTUVIIIO 1,000 UNIT VIAL, ALTUVIIIO 250 UNIT VIAL, ALTUVIIIO 500 UNIT VIAL, ATORVALI Q, AUSTEDO XR, COLUMVI 2.5 MG/2.5 ML VIAL, CUVRIOR, CYLTEZO(CF), CYLTEZO(CF) PEN, CYLTEZO(CF) PEN CROHN'S-UC-HS, CYLTEZO(CF) PEN PSORIASIS, ELEVIDYS 10-10.4 KG (10ML X10), ELFABRIO, EPKINLY, FILSPARI, GOHIBIC (EUA), HULIO(CF), HULIO(CF) PEN, IDACIO(CF), IDACIO(CF) PEN, IDACIO(CF) PEN CROHN'S-UC, IDACIO(CF) PEN PSORIASIS, IHEEZO, IMJUDO 25 MG/1.25 ML VIAL, INPEFA, JOENJA, LIQREV, LUMRYZ, MIEBO, OLPRIUVA, OMISIRGE, QALSODY, REZZAYO, RYSTIGGO, SOGROYA, SYFOVRE, UZEDY, VEOZAH, VOWST, VYVGART HYTRULO, YUSIMRY(CF) PEN, ZAVZPRET, ZOLPIDEM TARTRATE 7.5 MG CAP, ZYNYZ

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
DESCRIPTION:
The Oregon Region Pharmacy & Therapeutics Committee (ORPTC) will make a reasonable effort to review a new chemical entity or new Food and Drug Administration (FDA) indication within 90 days, and will make a decision on each new chemical entity or new FDA indication within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. In some instances, the ORTPC may require an extended amount of time to allow for the availability of sufficient clinical and safety data. New medications or newly approved indications within the six Protected Classes defined by the Centers for Medicare and Medicaid Services (CMS) for Medicare Part D will be subject to an expedited ORPTC review.
The ORPTC will make a decision within 90 days, rather than the normal 180-day requirement.

Medications delivered under the supervision of a covered/eligible health care provider are covered under the medical benefit and are also subject to review by the ORPTC. New medical medications and new FDA-approved indications for medical medications are reviewed within 12 months after the medication becomes available on the market, or within 12 months of the approval of a new indication by the FDA. Coverage will be limited to terms and conditions of plan medical benefit. Vaccinations administered under the medical benefit are subject to benefits and vaccine-specific policy if available.

POLICY:
Medications included under this Prior Authorization Policy may be approved subject to benefit and plan criteria listed below.

If ORPTC reviews a new medication or indication and determines that prior authorization is required, drug specific criteria will be used to evaluate reauthorization request, if applicable.

This policy applies if ORPTC reviews a new medication or indication and defers its decision for a future meeting, or if a request for a medication is received that has not been reviewed by ORPTC.

REQUIRED MEDICAL INFORMATION:
A prior authorization form and relevant chart notes documenting medical rationale are required.

CRITERIA:
To obtain a new medication or an existing medication with a new FDA indication awaiting a decision by the ORPTC, urgency must be established by meeting the following criteria:

1. The medication requested is consistent with the FDA approved indication(s) and evidence-based medicine.

AND

2. One of the following:
   a. The medication is considered a new drug entity or an existing drug with a new indication with no effective formulary alternatives available
   OR
   b. Reasonable trial and failure of suitable formulary alternatives have been documented by the provider in the chart notes.
   OR
   c. No treatment alternatives are available due to the member being at high risk for or experiencing an adverse drug event. The adverse event risk and prior therapies must be documented. An adverse event is defined as a contraindication, allergy, or sensitivity to the medication.

AND
3. The medication is being prescribed by, or in consultation with, a specialist in the treatment of the condition, or a provider with at least five years of experience treating the condition

AND

4. The prescriber indicates that the patient will experience harm (i.e., worsening clinical outcome and inability to return to baseline, loss of life or limb), if the requested medication is not covered until review by ORPTC

5. For Medicaid (OHP): coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services
NEW MEDICATIONS AND FORMULATIONS WITHOUT ESTABLISHED BENEFIT

MEDICATION(S)
ABSORICA, ABSORICA LD, ACANYA, ACTICLATE, ADAPALENE 0.1% LOTION, AMRIX, AZELASTINE-FLUTICASONE, BIDIL, BRIMONIDINE TARTRATE-TIMOLOL, BRYHALI, CALCIPOTRIENE 0.005% FOAM, CARBINOXAMINE MALEATE 6 MG TAB, CARDURA XL, CHLORZOXAZONE 375 MG TABLET, CHLORZOXAZONE 750 MG TABLET, CLARINEX-D 12 HOUR, CLINDAGEL, CLIND PH-BENZOYL PERO 1.2-2.5%, CLINDAMYCIN PHOS-TRETINOIN, CLINDAMYCIN PHOSPHATE 1% GEL, CLONIDINE HCL ER 0.17 MG TAB, COMBIGAN, CONJUPRI, CONSENSI, CONZIP, CUPRIMINE, CYCLOBENZAPRINE HCL ER, DESLORATADINE 2.5 MG ODT, DESLORATADINE 5 MG ODT, DESONIDE 0.05% GEL, DESOXIMETASONE 0.25% SPRAY, DESRX, DICLOFENAC, DICLOFENAC POT 25 MG TABLET, DICLOFENAC POTASSIUM 25 MG CAP, DICLOFENAC 2% SOLUTION PUMP, DIFFERIN 0.1% LOTION, DORYX, DORYX MPC, DOXYCYCLINE 50 MG TABLET, DOXYCYCLINE HYC DR 100 MG TAB, DOXYCYCLINE HYC DR 150 MG TAB, DOXYCYCLINE HYC DR 200 MG TAB, DOXYCYCLINE HYC DR 50 MG TAB, DOXYCYCLINE HYC DR 75 MG TAB, DOXYCYCLINE HYC DR 80 MG TAB, DOXYCYCLINE HYCLYATE 150 MG TAB, DOXYCYCLINE HYCLYATE 75 MG TAB, DOXYCYCLINE IR-DR, DOXYCYCLINE MONO 150 MG CAP, DOXYCYCLINE MONO 75 MG CAPSULE, DUEXIS, DUOBRII, DURLAZA, DYMISTA, ECOZA, EDLUAR, ELEPSIA XR, EZALLOR SPRINKLE, EZETIMIBE-ATORVASTATIN CALCIUM, FENOFIBRATE 150 MG CAPSULE, FENOFIBRATE 50 MG CAPSULE, FENTANYL 37.5 MCG/HR PATCH, FENTANYL 62.5 MCG/HR PATCH, FENTANYL 87.5 MCG/HR PATCH, FOSAMAX PLUS D, GLUMETZA, GOCOVRI, GONITRO, GRALISE, HALOBETASOL PROP 0.05% FOAM, HEMADY, HYDROCORT BUTY 0.1% LIPOP B, HYDROCORT BUTY 0.1% LIPO BLEND, HYDROCORTISONE BUTYR 0.1% LOTN, IBUPROFEN-ACETAMINE, IMPEKLO, IMPOYZ, INDOMETHACIN 20 MG CAPSULE, ISOSORBIDE DINIT-HYDRALAZINE, ISOTRETINOIN 25 MG CAPSULE, ISOTRETINOIN 35 MG CAPSULE, KENALOG, KITABIS PAK, KONVOMEP, LEVAMLODINE MALEATE, LEXETTE, LICART, LIPOFEN, LOCOID, LOCOID LIPOCREAM, LOFENA, LORZONE, LYMPEAK, LYRICA CR, MELOXICAM 10 MG CAPSULE, MELOXICAM 5 MG CAPSULE, METFORMIN ER GASTRIC, METFORMIN ER OSMOTIC, METFORMIN HCL 625 MG TABLET, METHOCARBAMOL 1,000 MG TABLET, MINOCYCLINE ER, MINOCYCLINE ER 105 MG TABLET, MINOCYCLINE ER 115 MG TABLET, MINOCYCLINE ER 55 MG TABLET, MINOCYCLINE ER 65 MG TABLET, MINOCYCLINE ER 80 MG TABLET, MINOLIRA ER, MIRAPEX ER, MONODOXYNE NL 75 MG CAPSULE, MONODOX 75 MG CAPSULE, MORPHINE SULFATE ER 10 MG CAP, MORPHINE SULFATE ER 100 MG CAP, MORPHINE SULFATE ER 120 MG CAP, MORPHINE SULFATE ER 20 MG CAP, MORPHINE SULFATE ER 30 MG CAP, MORPHINE SULFATE ER 40 MG CAP, MORPHINE SULFATE ER 45 MG CAP, MORPHINE SULFATE ER 50 MG CAP, MORPHINE SULFATE ER 60 MG CAP, MORPHINE SULFATE ER 75 MG CAP, MORPHINE SULFATE ER 80 MG CAP, MORPHINE SULFATE ER 90 MG CAP, NALOCET, NAPRELAN, NAPROXEN SODIUM CR, NAPROXEN SODIUM ER, NEO-SYNALAR 0.5%-0.025% CREAM, NEXICLON XR, NORITASE, OMEPRAZOLE-SODIUM BICARBONATE, ONEXTON, ONZETRA XSAIL, ORACEA, ORTIKOS, OXYCODONE-ACETAMINOPH 2.5-300, PENICILLAMINE 250
COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Requests are generally not approved because the requested drug is effective and available in the standard formulation. In unique circumstances, when the patient has exhausted all available formulary options for the patient's condition, not limited to the requested drug in standard formulation, coverage may be considered on a case-by-case basis given the medical rationale and the clinical evidence provided.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gimoti Nasal Spray: Authorization will be approved for three months for each episode of diabetic gastroparesis.
*Treatment with metoclopramide (all dosage forms and route of administration) longer than three months should be avoided due to risk of developing tardive dyskinesia.

For all other drugs, authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
MEDICATION(S)
NEXLETOL, NEXLIZET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial Authorization, all of the following must be met:
1. Confirmed diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or Familial Hypercholesterolemia
2. Fasting LDL-C equal to or greater than 70 mg/dL despite treatment with therapies below
3. One of the following:
   a. Current use of high-intensity statin therapy for at least three months (e.g., atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily)
   b. Provider attestation of statin intolerance, defined as one of the following:
      i. Rhabdomyolysis
      ii. Skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation
      iii. Elevated liver enzymes
   OR
   c. The patient has an FDA labeled contraindication to a statin
4. Current use of ezetimibe 10 mg daily for at least three months, or documented intolerance/contraindication to its use
5. Current use of a formulary PCSK-9 inhibitor (such as Repatha®) or intolerance/contraindication to its use

For reauthorization:
Documented response to therapy, as defined by a reduction in fasting LDL-C

AGE RESTRICTION
Approved for adults 18 years of age and older

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
NON-PREFERRED FUMARATE PRODUCTS

MEDICATION(S)
BAFIERTAM, VUMERITY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy (new starts), one of the following must be met:
1. Documented contraindication to generic dimethyl fumarate, defined as an allergy to an inactive ingredient found in all generic preparations that is not present in the non-preferred fumarate product.
2. Documented intolerable side effects (such as uncontrollable diarrhea), after attempting mitigation strategies, with use of dimethyl fumarate. Appropriate action to manage side effects must have been tried. This may include pre-dose aspirin to reduce flushing, a temporary dose reduction to reduce flushing and/or gastrointestinal issues, or administration with high fat and high protein food to reduce flushing and/or gastrointestinal issues.

For patients established, for at least three months, on the requested therapy, documentation of a positive response to therapy must be provided. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
NOURIANZ

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with a major psychotic disorder

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed diagnosis of Parkinson’s Disease
2. Documentation the patient is experiencing OFF episodes with current use of oral carbidopa/levodopa therapy
3. Documentation of attempts to adjust dosing and formulation of carbidopa/levodopa to manage OFF symptoms
4. Documentation that at least two other agents have been used as adjunctive therapy with carbidopa/levodopa [such as. dopamine agonist, catechol-O-methyltransferase (COMT) inhibitor, or monoamine oxidase B (MAO-B) inhibitor] to reduce number and frequency of OFF episodes

Reauthorization: Documentation that patient has had a positive response to therapy, such as decrease in number, duration, or severity of OFF episodes.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial authorization will be approved for six months, reauthorization will be approved for one year.

OTHER CRITERIA
N/A
OCALIVA

MEDICATION(S)
OCALIVA

COVERED USES
N/A

EXCLUSION CRITERIA
• Non-alcoholic steatohepatitis (NASH)
• Decompensated cirrhosis (such as Child-Pugh Class B or C) or a prior decompensated event
• Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)

REQUIRED MEDICAL INFORMATION
For the diagnosis of primary biliary cholangitis:
1. Confirmed diagnosis of primary biliary cholangitis as evidenced by two of the following criteria:
   a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values]
   b. Presence of antimitochondrial antibody (AMA)
   c. Histologic evidence of primary biliary cirrhosis from liver biopsy
   AND
2. Both of the following:
   a. Use of ursodiol for a minimum of 12 months and has had an inadequate response according to prescribing physician
   AND
   b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol

For reauthorization, all the following criteria must be met:
1. Maintenance of biochemical response, defined as all the following:
   a. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, and
   b. total bilirubin (tBili) less than or equal to ULN, and
   c. ALP decrease of at least 15%
   AND
2. Documentation that ursodiol will be continued, if tolerated
   AND
3. Hepatic function is assessed at least annually

AGE RESTRICTION
N/A

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.

**COVERAGE DURATION**
Initial authorization will be approved for four months. Reauthorization will be approved for one year.

**OTHER CRITERIA**
N/A
OPHTHALMIC VEGF INHIBITORS

MEDICATION(S)
BEOVU, CIMERLI, LUCENTIS, SUSVIMO, VABYSMO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy with the requested medication (new start): Must have one of the following diagnoses and meet any required criteria:
1. Neovascular (wet) age-related macular degeneration (AMD):
   a. For faricimab (Vabysmo®) and brolucizumab (Beovu®):
      Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
      i. bevacizumab
      ii. aflibercept (Eylea®)
      iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)
   b. For ranibizumab (Lucentis):
      Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
      i. bevacizumab
      ii. aflibercept (Eylea®)
      iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)
   c. For ranibizumab implant (Susvimo®):
      i. Documentation that bevacizumab and aflibercept (Eylea®) have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient AND
      ii. Documentation of previous response to at least two intravitreal injections of ranibizumab (Lucentis®), ranibizumab-eqrn (Cimerli®), or ranibizumab-nuna (Byooviz®) AND
      iii. Documentation that increased risk of endophthalmitis associated with ranibizumab (Susvimo®) has been discussed with the patient
2. Diabetic macular edema or Diabetic retinopathy:
   a. For faricimab (Vabysmo®) and brolucizumab (Beovu®):
      Documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
      i. bevacizumab
ii. aflibercept (Eylea®)
iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)

3. Macular edema following retinal vein occlusion:
   a. For ranibizumab (Lucentis®):
      Documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
      i. bevacizumab
      ii. aflibercept (Eylea®)
      iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)

4. Myopic Choroidal Neovascularization (mCNV):
   a. For ranibizumab (Lucentis®):
      Documentation that ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy with ranibizumab-nuna (Byooviz®) ranibizumab-eqrn (Cimerli®) is not appropriate for the patient

Reauthorization or continuation of therapy:
Documentation of positive response to therapy (such as stabilization or improvement in vision)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed and administered by an ophthalmologist or retinal specialist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
OPZELURA

MEDICATION(S)
OPZELURA

COVERED USES
N/A

EXCLUSION CRITERIA
• Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants
• Use for vitiligo other than nonsegmental vitiligo

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet all the following indication-specific criteria:
A. For atopic dermatitis, the following criteria must be met:
1. For Commercial only: Diagnosis of mild to moderate atopic dermatitis despite use of therapies outlined in criterion number 3 below, as defined by all the following:
   a. Patient has a body surface area (BSA) involvement of 3% to 20%
   b. Chronic condition, affecting patient for at least two years
2. For Medicaid only: Diagnosis of severe atopic dermatitis despite use of therapies outlined in criterion number 3 below, as defined by all of the following:
   a. Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on another validated tool
   AND
   b. Documentation of one of the following:
      i. Patient has a body surface area (BSA) involvement of 10% to 20%
      OR
      ii. Hand, foot, or mucous membrane involvement
   c. Chronic condition, affecting patient for at least two years
3. For both Commercial and Medicaid: Documentation of inadequate efficacy, intolerable side effects, or contraindication to ALL of the following:
   a. Moderate to high potency topical corticosteroids (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two weeks
   b. Topical calcineurin inhibitor (such as tacrolimus ointment) applied twice daily for at least one month

Reauthorization for atopic dermatitis requires documentation of reduction or stabilization from baseline of
flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification or affected BSA

B. For nonsegmental vitiligo, the following criteria must be met:
1. For Commercial and Medicaid:
   a. Diagnosis of nonsegmental vitiligo with depigmented areas affecting less than or equal to 10% total BSA
   i. Inadequate response, contraindication, or intolerance to all of the following:
      • Phototherapy or laser therapy for at least 12 weeks (such as narrowband ultraviolet B (NBUVB) or excimer laser)
      • A topical calcineurin inhibitor (such as tacrolimus)
      • A moderate to high potency topical corticosteroid (such as clobetasol 0.05% or fluocinolone 0.05%)
      AND
   b. For Medicaid only: Patient must have severe disease, as defined by both of the following:
      i. Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on another validated tool
      ii. Hand, foot, face, or mucous membrane involvement

Reauthorization for nonsegmental vitiligo requires documentation of reduction in depigmented BSA

AGE RESTRICTION
May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTION
• Atopic Dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
• Nonsegmental Vitiligo: Must be prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
ORAL ANTI-CANCER MEDICATIONS

MEDICATION(S)
ABIRATERONE ACETATE, AFINITOR, AFINITOR DISPERZ, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, AYVAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL 100 MG TABLET, ERLOTINIB HCL 150 MG TABLET, ERLOTINIB HCL 25 MG TABLET, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, EXKIVITY, FARYDAK, FOTIVDA, GAVRETO, GEFITINIB, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, JAYPIRCA, KISQALI, KISQALI FEMARA CO-PACK, KOSELUGO, KRAZATI, LAPATINIB, LENALIDOMIDE, LENVIMA, LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYSODREN, LYTGobi, MEKINIST, MEKTOVI, MELPHALAN, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, ORSERDU, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REVLIMID, REZLIDHIA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB, SPRYCEL, STIVARGA, SUNITINIB MALATE, SUTENT, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TARCEVA, TARGRETIN, TASIGNA, TAZVERIK, TEMODAR 100 MG CAPSULE, TEMODAR 140 MG CAPSULE, TEMODAR 180 MG CAPSULE, TEMODAR 250 MG CAPSULE, TEMOZOLOMIDE, TEPMETKO, TIBSOVO, TRETINOIN 10 MG CAPSULE, TRUSELTIQ, TUKYSA, TURALIO, TYKERB, UKONIQ, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VOTRIENT, WELIREG, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria must be met:
1. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
AND
2. For requests for abiraterone (Zytiga®): only generic abiraterone 250 mg tablets will be covered when criterion 1 is met
3. For requests for everolimus tablet for suspension, must meet one of the following criteria (a or b):
a. Use for adjunctive treatment of tuberous sclerosis complex-associated partial-seizures
b. Documentation of a physical or medical condition that either makes swallowing tablets a choking hazard, or requires solution for administration (such as young age, dysphagia, feeding tube)

4. For commercial members only, the following drug-specific criteria must be met:
   a. For palbociclib (Ibrance®) for advanced or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to ribociclib (Kisqali®) or abemaciclib (Verzenio®)
   b. For talazoparib (Talzenna®) for recurrent or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to olaparib (Lynparza®)

For patients established on therapy: documentation of adequate response to the medication must be provided.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation, with an oncologist unless otherwise specified below:

For avapritinib (Ayvakit®): May also be prescribed by an allergist or immunologist
For pacritinib (Vonjo®): May also be prescribed by a hematologist
For abiraterone acetate (Zytiga®): May also be prescribed by a urologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
ORAL RINSES

MEDICATION(S)
AQUORAL, BOCASAL, CAPHOSOL, EPISIL, GELCLAIR, GELX, MUGARD, NEUTRASAL

COVERED USES
N/A

EXCLUSION CRITERIA
Other indications not outlined

REQUIRED MEDICAL INFORMATION
For mucositis/stomatitis secondary to chemotherapy or radiation
1. Diagnosis of mucositis/stomatitis secondary to chemotherapy or radiation
AND
2. Documented trial of TWO of the following:
   a. Over-the-counter oral anesthetics (such as OraGel®, Anbesol®)
   b. Prescription oral anesthetics (such as viscous lidocaine 2%)
   c. Saliva substitutes (such as Biotene®, Mouth Kote®)
   d. Magic mouthwash - a compounded product often containing viscous lidocaine, Maalox®, and diphenhydramine. Multiple formulations are compounded and these may contain different ingredients. Note: premeasured kits for these solutions are not available on formulary

Reauthorization requires:
1. Documentation of continued need for therapy (such as continued chemotherapy and/or radiation)
2. Documentation of initial response to therapy (such as reduced signs and symptoms of mucositis, increased ability to tolerate food and beverages)

For xerostomia secondary to chemotherapy or radiation and Sjögren’s syndrome
1. Diagnosis of one of the following: xerostomia secondary to chemotherapy, xerostomia secondary to radiation, or Sjögren’s syndrome
AND
2. Documented trial to both of the following:
   a. TWO over the counter saliva substitutes (such as Biotene®, Mouth Kote®)
   b. Saliva stimulants (such as sugar free lozenges or chewing gum)

Reauthorization requires:
1. Documentation of continued need for therapy (e.g., continued chemotherapy and/or radiation)
2. Documentation of initial response to therapy (e.g., reduced signs and symptoms of xerostomia, increased...
ability to tolerate food and beverages)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1. For mucositis/stomatitis and xerostomia secondary to chemotherapy or radiation initial authorization and reauthorization will be approved for six months.
2. For Sjögren’s syndrome initial authorization and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A
OSTEOANABOLIC AGENTS

MEDICATION(S)
EVENITY, EVENITY (2 SYRINGES), FORTEO, TERIPARATIDE, TYMLOS

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with another osteoanabolic agent (such as Evenity®, Forteo®, and Tymlos®)

For Evenity® only: Myocardial infarction or stroke within the preceding year, hypocalcemia

REQUIRED MEDICAL INFORMATION
For the treatment or prevention of osteoporosis
1. Must meet ONE of the following criteria (a-e):
   a. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
   b. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -3.0
   c. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 to -3.0 and high risk for fracture, defined as one of the following:
      i. Age more than 80 years
      ii. Chronic glucocorticoid use
      iii. Documented increased fall risk
   d. Patient has a spine or hip BMD T-score less than or equal to -2.5 to -3.0 and one of the following:
      i. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
      ii. Documented contraindication or intolerance to therapy with all the following: 1. denosumab, 2. oral bisphosphonate (such as alendronate), and 3. IV bisphosphonate therapy (such as zoledronic acid)
   e. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:
      i. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%
      ii. One of the following:
         1. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
         2. Documented contraindication or intolerance to therapy with all the following:
            a. Denosumab
            b. Oral bisphosphonate (such as alendronate)
            c. IV bisphosphonate therapy (such as zoledronic acid).
2. For patients requesting teriparatide (Forteo®), brand or generic:
a. Documentation of trial and failure or intolerance to Tymlos® (abaloparatide). Failure is defined as a new fracture or worsening bone mineral density while adherent to Tymlos®.

AND

b. Total duration of treatment with any parathyroid analogue (teriparatide, Forteo®, Tymlos®) has not exceeded two years.

For authorization for teriparatide or brand Forteo® use exceeding two years in a lifetime, must meet both of the following criteria:
1. Documentation that previous treatment with teriparatide showed clinical improvement, defined as absence/decrease in frequency of new fragility fracture or stable/increased BMD T-score while on teriparatide
2. One of the following:
   a. Patient continues to be at very high risk for fracture, defined as one of the following while on teriparatide:
      i. BMD T-score continues to be less than or equal to -3.0
      ii. New vertebral or fragility fracture
   b. Documentation of worsening disease, defined as one of the following:
      i. A repeat BMD after discontinuation of therapy demonstrates a decline in BMD
      ii. New onset fragility fracture after discontinuation

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an endocrinologist or rheumatologist

**COVERAGE DURATION**

For Forteo®: Initial authorization may be approved for up to two years.

For use beyond two years, may be approved for up to one year provided that cumulative duration of parathyroid analogue therapy (teriparatide, Forteo®, Tymlos®) does not exceed three years in a lifetime, including both previous and planned future doses.

For Tymlos®: May be approved for up to two years, ensuring the cumulative duration of parathyroid analogue therapy (teriparatide, Forteo®, Tymlos®) does not exceed two years in a lifetime.

For Evenity®: May be approved for up to one year, ensuring the total duration of Evenity® therapy does not exceed one year of total therapy duration.

**OTHER CRITERIA**

N/A
**MEDICATION(S)**
OXBRYTA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
Used in combination with crizanlizumab (Adakveo®)

**REQUIRED MEDICAL INFORMATION**
For initial authorization, all of the following criteria (1-4) must be met:

1. Confirmed medical history or diagnosis of sickle cell disease
2. Documented hemoglobin of less than 10.5 g/dL taken within one month prior to initiating therapy
3. Documentation that patient meets one of the following:  
   a. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least six months  
   b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six months  
   c. Patient has had an intolerance or contraindication to hydroxyurea (For many patients’ myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments)
4. For tablets for oral suspension: Documentation that patient weighs less than 40 kg, is unable to swallow tablets, or requires a dose that cannot be obtained using the 500 mg tablet.
   For reauthorization: Documentation must be provided that shows the patient has had an improvement from baseline hemoglobin levels, defined as a sustained improvement of at least 1 g/dL

**AGE RESTRICTION**
May be approved for patients four years of age and older

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of sickle cell disease

**COVERAGE DURATION**
Initial authorization will be approved for six (6) months and reauthorization will be approved for 1 year

**OTHER CRITERIA**
N/A
MEDICATION(S)
OXERVATE

COVERED USES
N/A

EXCLUSION CRITERIA
Retreatment of the same eye

REQUIRED MEDICAL INFORMATION
1. Patient has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in the affected eye(s) with diagnosis supported by chart notes
2. Patient is refractory to at least two conventional treatments for neurotrophic keratitis (such as preservative-free artificial tears, topical antibiotic eye drops, therapeutic contact lenses, amniotic membrane transplant, tarsorrhaphy)
3. The request specifies the affected eye(s) intended for treatment

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an ophthalmologist

COVERAGE DURATION
Initial authorization will be approved for eight weeks, an additional eight weeks will be covered for treatment of the second eye when appropriate. Reauthorization will not be renewed for retreatment of the same eye.

OTHER CRITERIA
N/A
OXLUMO

MEDICATION(S)
OXLUMO

COVERED USES
N/A

EXCLUSION CRITERIA
1. Patients with a history of liver transplant
2. Patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m²
3. Patients with secondary hyperoxaluria or genetic test positive for another form of primary hyperoxaluria such as type 2 and type 3 primary hyperoxaluria

REQUIRED MEDICAL INFORMATION
Initial authorization for new starts:
1. Patient has a diagnosis of primary hyperoxaluria type 1 (PH1)
2. Diagnosis of PH1 has been confirmed by one of the following:
a. Genetic testing demonstrating mutation in the alanine: glyoxylate aminotransferase (AGXT) gene
b. Liver biopsy demonstrating significantly decreased or absent alanine: glyoxylate aminotransferase (AGT) enzyme activity
3. Documentation of one of the following:
a. Elevated urine oxalate (UOx) excretion as measured by body surface area-normalized daily UOx output greater than upper limit of normal (ULN)
b. Elevated UOx excretion as measured by UOx: creatinine ratio above age-specific upper limit of normal (ULN) OR
c. Elevated plasma oxalate (POx) concentration (POx concentration greater than ULN)
4. Documentation of a trial of high fluid intake of at least three liters per meter-squared of Body Surface Area (BSA) per day and that high fluid intake will continue with therapy
5. Concurrent use of pyridoxine or previous trial of at least three months with no significant improvement in urine oxalate concentration
6. Documentation of current patient weight and dosing not exceeding FDA-recommended dosing

Reauthorization or continuation of therapy:
1. Documentation of a clinically significant reduction in urine or plasma oxalate levels relative to pre-treatment baseline
2. Patient continues with concurrent high fluid intake (at least three liters per meter-squared BSA per day) and pyridoxine (unless individual is a pyridoxine non-responder)
3. Documentation of current patient weight and updated dosing not exceeding FDA-recommended dosing
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist or urologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
EXCLUSION CRITERIA
• Uncontrolled asthma
• History of eosinophilic esophagitis and other eosinophilic gastrointestinal disease
• Severe or life-threatening anaphylaxis in the last 60 days

REQUIRED MEDICAL INFORMATION
Initial Authorization requires all of the following criteria to be met:
1. Documented history of an anaphylactic allergic reaction to peanuts or peanut-containing foods that required epinephrine injection that occurred between 60 days and one year prior to treatment
2. Confirmed peanut allergy by at least one of the following:
   a. Positive skin prick test (SPT) response to peanut with a wheal diameter of 3 mm or greater when compared to the negative control
   b. Serum immunoglobulin E (IgE) to peanut of 0.35 kUA/L or greater (kUA/L = kilos of allergen specific units per liter)
3. Documentation that patient will continue to maintain a peanut-avoidant diet
4. Documentation that patient has an active prescription for auto-injectable epinephrine
5. Provider attestation that the patient is a good candidate for therapy (for example, will be able to maintain daily dosing requirements after initiation and dose titration)

Initial authorization requires all of the following criteria to be met:
1. Documented history of allergic reaction to peanuts or peanut-containing foods that required hospitalization, emergency room visit, or use of epinephrine injection
2. Confirmed peanut allergy by at least one of the following:
   a. Positive skin prick test (SPT) response to peanut with a wheal diameter of 3 mm or greater when compared to the negative control
   b. Serum immunoglobulin E (IgE) to peanut of 0.35 kUA/L or greater (kUA/L = kilos of allergen specific units per liter)
3. Documentation that patient will continue to maintain a peanut-avoidant diet
4. Documentation that patient has an active prescription for auto-injectable epinephrine
5. Provider attestation that the patient is a good candidate for therapy (for example, will be able to maintain daily dosing requirements after initiation and dose titration)
For reauthorization, all of the following criteria must be met:
1. Documentation that patient is tolerating peanut allergen immunotherapy at doses greater than 3 mg and is not exceeding 300 mg daily
2. Documentation that the patient is not experiencing adverse events on Palforzia® (for example, recurrent asthma exacerbations, persistent loss of asthma control, persistent heartburn, dysphagia, persistent abdominal pain)
3. Provider attestation that the patient continues to be compliant with daily dosing requirements
4. Documentation that patient has an active prescription for auto-injectable epinephrine

AGE RESTRICTION
• For Initiation of therapy: Aged four to 17 years
• For Continuation (up-dosing or maintenance): Aged four years or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an allergist and/or immunologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A
MEDICATION(S)
PALYNZIQ

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with sapropterin (Kuvan®).

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met:
1. Diagnosis of phenylketonuria (PKU)
   AND
2. Blood phenylalanine concentration more than 600 micromol/L (10 mg/dL) despite management with dietary phenylalanine restriction and sapropterin (Kuvan®)

For Reauthorization: One (1) of the following criteria must be met:
1. Documentation that blood phenylalanine concentration levels have decreased by at least 20% from baseline and remain at least 20% below pretreatment baseline
   OR
2. Documentation of a blood phenylalanine concentration less than or equal to 600 micromol/L (10 mg/dL)
   OR
3. For those not on maximum allowed dose of 60 mg once daily: Authorization for six (6) months may be approved those who have not met blood phenylalanine control when there is a documented plan for further dose increase up to a maximum dose of 60 mg once daily

Note: Prescribing information recommends considering dose increase in those you have been on pegvaliase 20 mg daily for at least 24 weeks or 40 mg daily for at least 16 weeks and have not met blood phenylalanine control, up to a maximum dose of 60 mg once daily.

QUANTITY LIMIT:
2.5 MG/0.5 ML: Eight (8) syringes per 28 days
10 MG/0.5 ML: One (1) syringe per day
20 MG/1 ML: Three (3) syringes per day

AGE RESTRICTION
Approved for 18 years and older.
PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic disease specialist or a provider who specializes in the
treatment of PKU.

COVERAGE DURATION
Initial authorization will be approved for six (6) months, and reauthorization will be approved for one (1)
year.

OTHER CRITERIA
N/A
**PCSK9 INHIBITORS**

**MEDICATION(S)**
LEQVIO, PRALUENT PEN, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

**COVERED USES**
N/A

**EXCLUSION CRITERIA**

- Non-familial hyperlipidemia/hypercholesterolemia
- Primary prevention of ASCVD

**REQUIRED MEDICAL INFORMATION**

1. For all indications must have documentation of:
   
a. One of the following:
      
i. Current use of high-intensity statin therapy for at least three months, defined as atorvastatin 40 mg to 80 mg daily or rosuvastatin 20 mg to 40 mg daily, OR
   
ii. Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin 5 mg daily) and any other statin at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations of creatinine kinase) that decrease or resolve after discontinuation of therapy with statin.
   
   AND

   2. Current use of ezetimibe 10 mg daily for at least three months, or documented intolerance/contraindication to its use. If patient is more than 30% above the goal low-density lipoprotein (LDL) level outlined in the hyperlipidemia criteria below, this criterion for ezetimibe may be waived.
   
   AND

   3. Must meet listed criteria below for each specific diagnosis:
      
a. For familial hypercholesterolemia (FH), both of the following:
         
i. Confirmed diagnosis by one of the following:
            
1) Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9) OR

2) Low density lipoprotein cholesterol (LDL-C) greater than 330 mg/dL OR

3) A “possible” diagnosis of FH via Simon Broome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6
   
   ii. Documentation of current (within previous three months) LDL-C greater than 100 mg/dL, taken after at least three months of continuous therapy with statin and ezetimibe outlined in criterion 1 above

b. For ASCVD, both of the following:
   
i. Documentation of current (within previous three months) LDL-C greater than 70 mg/dL, taken after at
least three months of continuous therapy with statin and ezetimibe outlined in criterion 1 above
ii. Documentation of very high-risk clinical ASCVD, defined as history of multiple ASCVD events [acute
coronary syndrome (ACS) within previous 12 months, history of myocardial infarction, history of ischemic
stroke, symptomatic peripheral artery disease] OR one ASCVD event and multiple of the following high-risk
conditions:
1) Age 65 years and older
2) Heterozygous familial hypercholesterolemia
3) History of coronary revascularization (CABG or PCI)
4) Diabetes mellitus
5) Hypertension
6) Chronic kidney disease
7) Current smoking
8) Persistently elevated LDL-C above 100 despite maximally tolerated statin therapy and ezetimibe
9) History of congestive heart failure

Initial Reauthorization:
Documentation of response to therapy, defined as a decrease in LDL-C levels of at least 40% from pre-
treatment levels.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization for one year. Reauthorization will be approved until no longer eligible with the plan,
subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
**PEDIATRIC ANALGESICS**

**MEDICATION(S)**

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
- Postoperative pain management following a tonsillectomy and/or adenoidectomy in children less than 18 years of age
- Use in children less than 12 years of age
- Use in children with history of obesity, sleep apnea, or severe lung disease
- Use for cough and cold

**REQUIRED MEDICAL INFORMATION**
1. Documented trial, failure, intolerance or contraindication to over-the-counter alternatives: acetaminophen and ibuprofen (when used for pain)
   AND
2. A statement that the risk of use of codeine or tramadol for pediatric patients has been reviewed and the benefit of these medications for the pediatric member outweighs the risk

Reauthorization Criteria:
1. Documentation that the patient is responding well to therapy without side effects
   AND
2. Documentation from the provider that continuation of therapy is medically necessary despite risks

**AGE RESTRICTION**
N/A
PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one month

OTHER CRITERIA
N/A
PITUITARY DISORDER THERAPIES

MEDICATION(S)
ISTURISA, LANREOTIDE ACETATE, MYCAPSSA, RECORLEV, SANDOSTATIN LAR DEPOT, SIGNIFOR, SIGNIFOR LAR, SOMATULINE DEPOT, SOMAVERT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, must meet indication-specific criteria below:
1. For acromegaly, Signifor® LAR, Sandostatin® LAR, Somatuline® Depot, Somavert®, or Mycapssa® may be covered if all the following are met:
   a. Confirmed diagnosis of acromegaly
   b. Documentation that the patient has persistent disease (such as biochemical or clinical) following surgical resection or is not a candidate for surgical resection
   c. For coverage of Somavert® or Signifor® LAR, documentation of trial and failure, intolerance or contraindication to octreotide injection therapy or lanreotide subcutaneous depot
   d. For coverage of Mycapssa®, patient has been maintained (for at least six months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy

2. For Cushing’s syndrome (includes Cushing’s disease), Recorlev® may be covered if all the following are met:
   a. Diagnosis of endogenous Cushing’s syndrome (E24.9)
   b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery
   c. Documentation of baseline urinary free cortisol
   d. Documentation of baseline liver enzyme function tests
   e. Documentation of trial and failure of oral ketoconazole

3. For Cushing’s disease, Signifor®, Isturisa®, or Signifor® LAR may be covered if all the following are met:
   a. Diagnosis of endogenous Cushing’s disease (E24.0)
   b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery

4. For carcinoid tumors or carcinoid syndromes, Sandostatin® LAR or Somatuline® Depot may be covered when there is documentation of severe diarrhea or flushing
5. For vasoactive intestinal peptide tumors, Sandostatin® LAR, Somatuline® Depot, may be covered when there is documentation of severe diarrhea.

6. For chemotherapy induced diarrhea, Sandostatin LAR® may be covered if all the following are met:
   a. Documentation that patient has severe diarrhea caused by chemotherapy
   b. Documentation of an inadequate response or contraindication to loperamide
   c. Documentation of good response and tolerability to short-acting octreotide

7. For AIDS-related diarrhea, Sandostatin LAR® may be covered if all the following are met:
   a. Documentation that patient has severe diarrhea
   b. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate/atropine (Lomotil®)
   c. Documentation of good response and tolerability to short-acting octreotide

8. For oncologic diagnoses, use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher.

For patients established on therapy, documentation of a positive clinical response must be provided. Appropriate documentation may include:
- For acromegaly, a reduction or normalization of IGF-1/GH level for same age and sex or reduction in tumor size
- For Cushing’s syndrome/Cushing’s disease, clinically meaningful reduction and maintenance in late-night salivary cortisol or 24-hour urinary free cortisol levels, or improvement in signs or symptoms of the disease
- For diarrhea, an improvement in the number of diarrhea episodes
- For carcinoid tumors or carcinoid syndromes, an improvement in the number of diarrhea and flushing episodes

Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for one year

**OTHER CRITERIA**
N/A
MEDICATION(S)
PROCYSBI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
All of the following:
1. Confirmed diagnosis of nephropathic cystinosis as evidenced by measuring leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene (gene that encodes cystinosin)
2. Documentation of trial and failure, contraindication or intolerance to immediate release cysteamine capsules (Cystagon®).

AGE RESTRICTION
1 year of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of the medication.

OTHER CRITERIA
N/A
PROPHYLACTIC HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)
CINRYZE, HAEGARDA, ORLADEYO, TAKHZYRO

COVERED USES
N/A

EXCLUSION CRITERIA
Combination prophylactic therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®

REQUIRED MEDICAL INFORMATION
For initiation of therapy for prophylaxis of hereditary angioedema (HAE) attacks, all the following criteria (1-5) must be met:
1. Documentation of one of the following clinical criteria:
   a. Recurrent self-limiting, non-inflammatory subcutaneous angioedema without urticaria, or
   b. Recurrent, self-remitting abdominal pain without clear organic etiology, or
   c. Recurrent laryngeal edema
2. Documentation of at least two HAE attacks per month on average for the past three months despite removal of triggers (such as estrogen containing oral contraceptives, angiotensin converting enzyme inhibitors) unless medically necessary
3. One of the following:
   a. For HAE Type I and Type II, documentation of the following (per laboratory standard):
      i. C4 is below the lower limit of normal
      ii. One of the following:
         a. C1-inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal, or
         b. C1-INH function less than 50 percent of the lower limit of normal
   b. For HAE with normal C1-INH or HAE Type III:
      i. Confirmed Factor 12 (FXII) ANGPT1, PLG, KNG1 gene mutation
      ii. Positive family history for HAE and attacks lack response to high dose antihistamines or corticosteroids.
4. Dose and frequency are in accordance with the Food and Drug Administration-approved labeling
5. For coverage of Cinryze®: Documentation of trial and failure, intolerance, or contraindication to Haegarda®.

For Patients Established on Therapy, all the following criteria (1-3) must be met:
1. Documentation of positive response to therapy, defined as reduction of frequency and severity of HAE attack episodes by at least 50% from baseline,
2. Dose and frequency are in accordance with the Food and Drug Administration-approved labeling,
3. For Takhzyro®: For patients established on Takhzyro® that are well-controlled (such as attack free) for
more than six months, the approved dose will be 300 mg every four weeks.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Must be prescribed by or in consultation with an immunologist or an allergist.

**COVERAGE DURATION**
Initial prior authorization will be approved for six months. Reauthorization will be approved for one year.

**OTHER CRITERIA**
N/A
PROVENGE - MEDICAL BENEFIT

MEDICATION(S)
PROVENGE

COVERED USES
N/A

EXCLUSION CRITERIA
• Concomitant use of chemotherapy, systemic steroid medications at greater than physiologic replacement doses and/or other systemic immunosuppressive agents to treat autoimmune disease or prevent allogeneic transplant rejection
• Presence of hepatic or other visceral metastases

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Asymptomatic or minimally symptomatic metastatic disease (e.g. no opioid use for malignant cancer pain)
2. Castrate-resistant or castration-recurrent prostate cancer, defined as both of the following:
   a. Radiographic, clinical or biochemical [i.e., prostate-specific antigen (PSA)] progression despite therapy with androgen ablation therapy (e.g. orchiectomy, GnRH agonists/antagonists) AND
   b. Testosterone level less than 50 ng/dL
3. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
4. Life expectancy more than six (6) months

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist.

COVERAGE DURATION
Authorization will be approved for 3 complete doses administered at approximately 2 week intervals (6 weeks) for one course of therapy per lifetime.

OTHER CRITERIA
N/A
MEDICATION(S)
ADEMPAS, AMBRISENTAN, BOSENTAN, EPOPROSTENOL SODIUM, FLOLAN, LETAIRIS, OPSUMIT, ORENITRAM ER, ORENITRAM MONTH 1 TITRATION KT, ORENITRAM MONTH 2 TITRATION KT, ORENITRAM MONTH 3 TITRATION KT, REMODULIN, REVATIO 10 MG/12.5 ML VIAL, REVATIO 10 MG/ML ORAL SUSP, SILDENAFIL 10 MG/12.5 MIL VIAL, SILDENAFIL 10 MG/ML ORAL SUSP, TRACLEER, TREPROSTINIL, TYVASO, TYVASO DPI, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT, UPTRAVI, VELETRI, VENTAVIS

COVERED USES
N/A

EXCLUSION CRITERIA
• Heart failure caused by reduced left ventricular ejection fraction for epoprostenol (Flolan®, Veletri®)
• Idiopathic interstitial pneumonia for riociguat (Adempas®) only

REQUIRED MEDICAL INFORMATION
For brand Tracleer® tablets, Letairis®, or Opsumit®, must meet one of the following:
1. Patient has a documented allergy to an excipient found in all generic manufacturers’ products of bosentan and ambrisentan.
2. Patient has had a therapeutic failure to a generic formulation (bosentan OR ambrisentan). This is defined as the patient taking the medication as prescribed for an adequate duration and the therapeutic failure cannot be attributed to inadequate dosing.
3. Documented medical rationale for requiring use of Opsumit®, Tracleer® tablets, or Letairis® over generic bosentan or ambrisentan.
For Tracleer® tablets for suspension: Documented medical rationale for requiring use of a suspension over generically available tablets.

For patients initiating therapy, the following criteria must be documented:
1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization as defined by:
   i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest
   AND
   ii. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg
   AND
   iii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)
   AND
2. Patient has one of the following:
i. World Health Organization (WHO) Group 1 classification PAH with WHO/New York Heart Association (NYHA) functional class as outlined below:
   a. Flolan®, Veletri®, Tyvaso®, Tyvaso® DPI and Ventavis: Class III or IV
   b. All other therapies: Class II, III, or IV

ii. For Adempas® only, WHO Group 4 classification CTEPH with WHO/New York Heart Association (NYHA) functional class II, III, or IV

iii. For Tyvaso®/Tyvaso® DPI only, WHO Group 3 classification PH-ILD

AND

3. For sildenafil citrate oral suspension or parenteral injection (Revatio®) and selexipag parenteral injection (Uptravi®): Documentation of intolerance or allergy to excipient ingredients of all available tablets or other medical rationale provided for use of oral suspension/parenteral injection over tablets.

For patients established on therapy, documentation of response to therapy such as lack of disease progression, improvement in WHO functional class must be provided.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or cardiologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
REQUIRED MEDICAL INFORMATION
For initiation of therapy, the following criteria must be met:
1. Diagnosis of pyruvate kinase deficiency (PKD) (ICD-10 d55.21). Must include evidence supporting diagnosis, such as:
   a. Documentation of markers of chronic hemolytic anemia (such as low hemoglobin, low haptoglobin, elevated bilirubin, and elevated reticulocytes) and evidence of family history of PKD OR
   b. Documentation of pyruvate kinase enzyme activity below the lower limit of normal per the laboratory standard (actual laboratory results must be included) OR
   c. Documentation of at least two mutant alleles in the PKLR gene
2. Hemoglobin less than or equal to 10 mg/dL taken within the previous three months

For patients established on therapy, one of the following criteria must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
1. Sustained increase in hemoglobin (Hb) of at least 1.5 mg/dL from pre-treatment level. Note: initial hemoglobin level prior to treatment plus a recent level (within the last three months) must be provided OR
2. Documentation of a reduction in transfusion burden in the previous 6 months, compared with prior to treatment

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.
N/A
QUDEXY XR/TROKENDI XR

MEDICATION(S)
QUDEXY XR, TOPIRAMATE ER, TROKENDI XR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following criteria must be met:
1. Confirmed diagnosis of one of the following conditions:
   a. Seizure disorder
   b. Migraine Headaches
   OR
2. For the diagnosis of bipolar affective disorder or schizoaffective disorder, documented trial and failure of at least two of the following drugs or contraindication/intolerance to all:
   a. Lithium
   b. Valproate and derivatives
   c. Lamotrigine
   d. Carbamazepine
   e. Atypical antipsychotic

Reauthorization for migraine headaches requires documented positive response to therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For Migraine Headaches: Initial authorization will be approved for three months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

For seizure disorders, bipolar affective disorder or schizoaffective disorder: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
OTHER CRITERIA
N/A
**MEDICATION(S)**
RADICAVA, RADICAVA ORS

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
1. For initiation of therapy, all the following criteria (a-d) must be met:
   a. Documentation of definite or probable amyotrophic lateral sclerosis (ALS) within the previous two years per the El Escorial (Airlie House) Criteria
   b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with at least two points in each individual item
   c. Forced vital capacity (FVC) of at least 80% (taken within the past three months)
   d. Dosing is in accordance with the FDA approved labeling
2. For patients established on therapy:
   a. Documentation of a clinical benefit from therapy such as stabilization of disease or slowing of disease progression from pre-treatment baseline ALSFRS-R scores. Edaravone may not be covered for patients experiencing rapid deterioration while on therapy due to lack of clinical benefit in this patient population.
   b. Documentation that patient is not dependent on invasive ventilation or tracheostomy
   c. Dosing is in accordance with the FDA approved labeling

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by, or in consultation with, a neurologist with expertise in ALS.

**COVERAGE DURATION**
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

**OTHER CRITERIA**
N/A
REBLOZYL

MEDICATION(S)
REBLOZYL

COVERED USES
N/A

EXCLUSION CRITERIA
1. Evidence of active pregnancy
2. History of thrombosis

REQUIRED MEDICAL INFORMATION
For initial authorization for beta-thalassemia, all of the following must be met:
1. Diagnosis of beta-thalassemia, which can be confirmed by one of the following:
   a. Hemoglobin analysis or genetic testing
   b. Complete blood count that showed reduced Hgb level (less than 7 g/dL), mean corpuscular volume (MCV) between 50 and 70 fl, and mean corpuscular hemoglobin (MCH) between 12 and 20 pg
   c. Peripheral blood smear results that show red blood cell (RBC) morphologic changes including microcytosis, hypochromia, anisocytosis, poikilocytosis and nucleated RBC
2. Documentation of symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
3. Documentation that patient is transfusion-dependent, defined as receiving at least 6-20 units RBC transfusions every 24 weeks

For continuation of therapy for beta-thalassemia beyond nine weeks, ongoing documentation of patient response to therapy must include maintenance of reduced transfusion levels

For initial authorization for myelodysplastic syndrome (MDS), all of the following must be met:
1. Documentation of symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
2. Diagnosis of MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
3. Documentation of ring sideroblasts greater than or equal to 15% or ring sideroblasts greater than or equal to 5% and less than 15% with a SF3B1 mutation
4. Documentation of a score of very low to intermediate risk based on the Revised International Prognostic Scoring System
5. Documentation that patient requires RBC transfusions of at least two units every eight weeks
6. One of the following:
a. Documented trial and failure [of at least two months], intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin) with or without a granulocyte-colony stimulating factor (such as filgrastim)
b. Documentation of endogenous erythropoietin level greater than 500 mU/mL

For reauthorization for MDS: Documentation that patient was able to achieve transfusion independence for at least eight weeks during previous treatment period

AGE RESTRICTION
At least 18 years of age

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a hematologist

COVERAGE DURATION
Beta-thalassemia: Initial authorization will be for nine weeks. Reauthorization will be for one year.

MDS-RS: Initial authorization will be for six months. Reauthorization will be for one year.

OTHER CRITERIA
N/A
REBYOTA

MEDICATION(S)
REBYOTA

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Authorization for the prevention of recurrence of Clostridioides difficile infection (CDI) requires all the following criteria be met:
1. Confirmed diagnosis of recurrent CDI, defined as two or more recurrences after a primary episode. Episodes must have occurred less than eight weeks after completion of treatment for a previous episode.
2. Positive stool test for C. difficile within 30 days before prior authorization request
3. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days)

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist

COVERAGE DURATION
Authorization will be approved for one treatment course per primary episode. Subsequent requests must meet initial authorization criteria.

OTHER CRITERIA
N/A
REGRANEX

MEDICATION(S)
REGRANEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented ulcer(s) due to diabetes mellitus

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved for six months. There is no medical evidence to support ongoing treatment after six months of becaplermin treatment.

OTHER CRITERIA
N/A
RELYVRIOS

**MEDICATION(S)**
RELYVRIOS

**COVERED USES**
All Food and Drug Administration (FDA)-Approved Indications

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
1. For initiation of therapy, all the following criteria (a-d) must be met:
   a. Documentation of diagnosis of amyotrophic lateral sclerosis (ALS)
   b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R)
   c. Forced vital capacity (FVC) greater than 60% of predicted (taken within the past three months)
   d. Documentation that patient is not dependent on invasive ventilation or tracheostomy

2. For patients established on therapy, all the following criteria (a-b) must be met:
   a. Documentation of a clinical benefit from therapy such as stabilization of disease or slowing of disease progression from pre-treatment baseline ALSFRS-R scores
   b. Documentation that patient is not dependent on invasive ventilation or tracheostomy

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation with, a neurologist with expertise in ALS

**COVERAGE DURATION**
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

**OTHER CRITERIA**
N/A
RESCUE MEDICATIONS FOR EPILEPSY

MEDICATION(S)
NAYZILAM, VALTOCO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
RETHYMISC

MEDICATION(S)
RETHYMIC

COVERED USES
N/A

EXCLUSION CRITERIA
• Patients with severe combined immunodeficiency (SCID)
• Patients with heart surgery anticipated within four weeks prior to, or three months after, treatment
• Patients with pre-existing cytomegalovirus (CMV) infection or human immunodeficiency virus (HIV) infection
• Repeat administration of allogenic processed thymus tissue implant or previous history of thymus transplant
• Patients over 18 years of age

REQUIRED MEDICAL INFORMATION
For authorization of a one-time implant, all the following must be met:
1. Diagnosis of congenital athymia confirmed by all the following criteria:
   a. Absence of genetic markers of severe combined immunodeficiency (SCID)
   b. Flow cytometry, defined as one of the following:
      i. Less than 50 naïve T cells/mm3 in the peripheral blood
      ii. Less than 5% of total T cells being naïve in phenotype
   c. One of the following:
      i. Genetic defect associated with congenital athymia [such as 22q11.2 deletion syndrome, forkhead box protein N1 (FOXN1) deficiency]
      ii. CHARGE syndrome
2. Documentation that infection control measures, including immunoprophylaxis, will be maintained until thymic function is established (immune reconstitution sufficient to protect from infection is unlikely to develop until 6-12 months after treatment)
3. Attestation from provider of absence of comorbidities, in the opinion of the treating clinician, that are reasonably likely to result in severe complications, including death, from administration of allogeneic processed thymus tissue
4. Dose will not exceed 42 slices

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a pediatric immunologist.

**COVERAGE DURATION**
Authorization will be for one dose per lifetime. Repeat administration will not be covered.

**OTHER CRITERIA**
N/A
MEDICATION(S)
REVCOVI

COVERED USES
N/A

EXCLUSION CRITERIA
Other forms of autosomal recessive severe combined immune deficiencies

REQUIRED MEDICAL INFORMATION
1. Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following:
   a. Documentation of a mutation in the ADA gene by molecular genetic testing
   b. Deficient ADA catalytic activity (less than 1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (such as, blood mononuclear cells, fibroblasts)
   AND
   2. A marked increase in the metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides [the sum of deoxyadenosine monophosphate (dAMP), deoxyadenosine diphosphate (dADP), and dATP] in erythrocytes
   AND
   3. Documentation showing that patient is not a candidate for or has failed a hematopoietic stem cell transplantation (HSCT)
      a. May be approved as a “bridge” therapy before undergoing HSCT or an HSC-Gene Therapy clinical trial if a donor/clinical trial has been identified (subject to policy coverage durations)
      AND
   4. Documentation that patient does not have severe thrombocytopenia (platelet count less than 50,000 cells/microliter)
      AND
   5. Documentation of patient’s recent weight and that dosing is within FDA labeled dosing

Reauthorization criteria:
1. Documentation of plasma target trough ADA activity of at least 30 mmol/hr/L in the past two months
   AND
2. Documentation of a trough erythrocyte dAXP level maintained below 0.02 mmol/L in the past six months
   AND
3. Documentation of immune function improvement (such as decrease in number of infections)
   AND
4. Documentation of patient’s recent weight and that dosing is within FDA labeled dosing

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an expert in the treatment of immune deficiencies such as an immunologist or hematologist

COVERAGE DURATION
Initial authorization will be approved for four months
Reauthorization will be approved for six months

OTHER CRITERIA
N/A
REYVOW

MEDICATION(S)
REYVOW

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For initial authorization, the following criteria must be met (a and b):
   a. Diagnosis of migraine headaches
   b. One of the following:
      i. For Commercial: Inadequate response to two oral triptans (such as sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) and one additional triptan formulation (such as oral disintegrating tablet, nasal spray, injection)
      ii. For Medicaid: Inadequate response to two triptan products (such as sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan)
      iii. Documented intolerance to at least two triptan drug entities
      iv. Documented contraindication to the use of triptans, such as:
         • Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal’s angina)
         • History of stroke or transient ischemic attack (TIA)
         • Peripheral vascular disease
         • Ischemic bowel disease
         • Uncontrolled hypertension
         • History of hemiplegic or basilar migraine

2. For Reauthorization: Documentation of treatment success as demonstrated by a reduction of migraine pain or freedom from migraine symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial Authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and or benefit changes.

OTHER CRITERIA
N/A
REZUROCK

MEDICATION(S)
REZUROCK

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial authorization for chronic graft-versus-host disease:
1. Use must be supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

For patients established on therapy:
1. Documentation of adequate response to the medication must be provided

For coverage of twice daily dosing, all of the following must be met:
1. Patient is on an interacting drug and dosing is recommended per labeling
2. The interacting drug cannot be substituted with an alternative agent treating the same condition
3. The interacting drug is medically necessary to continue

AGE RESTRICTION
May be approved for patients 12 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist or transplant specialist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
RIABNI, RITUXAN, RITUXAN HYCELA, RUXIENCE, TRUXIMA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For all requests for non-preferred rituximab products: Documented trial and failure, intolerance, or contraindication to the use of both preferred biosimilar medications: Ruxience® (rituximab-pvvr) and Truxima® (rituximab-abbs)

For initiation of therapy: Requests for rituximab may be approved for the following indications when the criteria below are met:
1. For Oncologic Diagnoses: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For Rheumatoid Arthritis:
   a. Documentation of trial, failure, intolerance, or contraindication to at least one of the following targeted immune modulators: etanercept (Enbrel®), adalimumab (Humira®), or a preferred infliximab product AND
   b. Documentation that rituximab will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.
3. For Vasculitis, including antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)] and refractory polyarteritis nodosa (resistant to cyclophosphamide):
   a. Documentation that rituximab will be given in combination with glucocorticoids AND
   b. Documentation of severe disease (for example, critical organ system involvement)
4. For Immune Thrombocytopenia (ITP):
   a. Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy AND
   b. Documentation of active bleeding, or high-risk of bleeding, or a platelet count less than 30,000 cells per microliter
5. For Relapsing and Remitting Multiple Sclerosis (RRMS): One of the following:
   a. Documentation of trial, failure, or intolerance to at least two disease modifying therapies indicated for RRMS
   OR
   b. Documentation that patient has highly active or aggressive disease

6. For Refractory Myasthenia Gravis:
   a. Documentation that patient has severely impaired function due to myasthenia gravis
   AND
   b. Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies:
      i. Acetylcholinesterase inhibitors (for example, pyridostigmine)
      ii. Corticosteroids (for example, prednisone, methylprednisolone)
      iii. Immunosuppressive agents (for example, azathioprine, cyclosporine, mycophenolate)
      iv. Plasma exchange

7. For Autoimmune Hemolytic Anemia (AIHA):
   a. Diagnosis of warm AIHA and documentation of trial, failure, intolerance, or contraindication to glucocorticoids
   OR
   b. Diagnosis of cold AIHA or cold agglutinin disease

8. Confirmed diagnosis of Neuromyelitis Optica

9. Confirmed diagnosis of Moderate to Severe Pemphigus Vulgaris

For patients established on therapy: Documentation of adequate response to the medication must be provided.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a specialist for the respective indication, such as: an oncologist, hematologist, rheumatologist, neurologist (in the case of RRMS, NMO), dermatologist (in the case of PV), or nephrologist (in the case of renal disease).

COVERAGE DURATION
For oncologic diagnoses: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

For non-oncologic diagnoses: Initial authorization will be approved for six months and reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes
OTHER CRITERIA
N/A
MEDICATION(S)
RYPLAZIM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following criteria must be met:
1. Diagnosis of plasminogen deficiency type 1 confirmed by one of the following:
   a. Genetic testing (biallelic pathogenic variants in PLG gene), or
   b. Confirmed hypoplasminogenemia (reduced plasminogen protein levels and functional activity)
2. Documentation of plasminogen activity level of 45% or lower of laboratory standard within the previous six months
3. Documentation of clinical signs and symptoms of the disease (such as ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing)
For initial reauthorization, the following criteria must be met:
1. Documented positive response to therapy, defined as improvement in lesion number/size or improved function from baseline
For subsequent reauthorization, the following criteria must be met:
1. Documentation of no new or recurring lesions
2. Documentation that trough plasminogen activity levels are maintained at least 10% above baseline trough levels (indicating absence of anti-plasminogen antibodies)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a geneticist, hematologist, pulmonologist, ophthalmologist, and/or pediatric subspecialist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for six months.

OTHER CRITERIA
SABRIL

MEDICATION(S)
SABRIL, VIGABATRIN, VIGADROME

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For New Starts:
For refractory complex partial seizures:
1. Must be at least two years of age
AND
2. Documentation of trial and failure, contraindication, or intolerance to two alternative formulary generic antiepileptic medications

For infantile spasms:
1. Must be between one month and two years of age

For patients established on therapy: documentation of positive clinical response and continued periodic vision assessment.

AGE RESTRICTION
For complex partial seizures: approved for ages two years and older.

For infantile spasms: approved for ages one month to two years old.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist.

COVERAGE DURATION
For infantile spasms, initial authorization and reauthorization will be approved for one year.
For complex partial seizures, authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A
MEDICATION(S)
SAPHNELO

COVERED USES
N/A

EXCLUSION CRITERIA
Anifrolumab will not be approved if any of the following are present:
1. Severe active lupus nephritis
2. Severe active central nervous system lupus
3. Current use of other biologic immunomodulators
4. Concurrent use of voclosporin (Lupkynis®) or belimumab (Benlysta®)

REQUIRED MEDICAL INFORMATION
All of the following must be met:
Initial authorization:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist
   AND
2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined
   as one of the following:
   a. Positive Antinuclear antibody (ANA)
   b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an
      antibody level above laboratory reference range
   c. Positive anti-Smith (Anti-Sm)
   d. Positive anti-Ro/SSA and anti-La/SSB antibodies
   AND
3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or
   frequent flares), contraindication, or intolerance to at least one of the following:
   a. Oral corticosteroid(s)
   b. Azathioprine
   c. Methotrexate
   d. Mycophenolate mofetil
   e. Hydroxychloroquine
   f. Chloroquine
   g. Cyclophosphamide
   AND
4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids,
hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

Reauthorization:
1. Documentation of positive clinical response to anifrolumab (e.g., improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of anifrolumab)
2. Patient currently receiving standard therapy for SLE

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
SCENESSE

MEDICATION(S)
SCENESSE

COVERED USES
N/A

EXCLUSION CRITERIA
1. Current Bowen’s disease, basal cell carcinoma, or squamous cell carcinoma
2. Personal history of melanoma or dysplastic nevus syndrome
3. Erythropoietic protoporphryia (EPP) or X-linked protoporphryia (XLP) with significant hepatic involvement

REQUIRED MEDICAL INFORMATION
1. For initial authorization, all the following criteria must be met:
   a. Confirmed diagnosis of erythropoietic protoporphryia (EPP) or X-linked protoporphryia (XLP) by one of the following:
      i. Gene sequencing showing an FECH, CLPX, or ALAS2 mutation
      ii. Elevated total erythrocyte protoporphryin greater than 80 mcg/dL AND erythrocyte fractionation shows more than 50% metal-free vs. zinc protoporphryin
   b. Documentation of characteristic symptoms of EPP/XLP phototoxicity (such as intolerance to light with symptoms including itching, burning, pain, erythema, or scarring of the skin on contact with sunlight)
   c. Documentation that sun avoidance and use of sunscreen and protective clothing have proven inadequate in controlling EPP/XLP-associated painful skin reactions
   d. Documentation that the condition is having a significant impact on quality of life (QOL)
2. For reauthorization: documentation of a positive response to therapy by of one of the following:
   a. Decreased severity and number of phototoxic reactions
   b. Increased duration of sun exposure
   c. Increased quality of life
3. For request of more than three implants per year: medical justification must be provided addressing why member needs coverage for more than six months out of the year (afamelanotide is typically given during periods of high sunlight exposure, such as from spring to autumn)

AGE RESTRICTION
Approved for 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a dermatologist or porphyria specialist
COVERAGE DURATION
Initial and reauthorization will be approved for six months for three implants (Medical justification is required for requests beyond three implants for seasonal coverage)

OTHER CRITERIA
N/A
SECOND AND THIRD GENERATION ANTIHISTAMINES

**MEDICATION(S)**

12 HOUR ALLERGY-D, 24HR ALLERGY RELIEF, 24HR ALLERGY-CONGESTION RELIEF, ALAVERT, ALAVERT D-12, KRO ALL DAY ALLERGY 10 MG SFGL, GNP ALL DAY ALLERGY 10 MG SFGL, ALL DAY ALLERGY-D, ALLEGRA ALLERGY, ALLEGRA HIVES, ALLEGRA-D 12 HOUR, ALLEGRA-D 24 HOUR, ALLER-EASE, ALLER-FEX, ALLER-TEC D, ALLERCLEAR D-12HR, ALLERCLEAR D-24HR, ALLERGY COMPLETE-D, ALLERGY RELIEF 180 MG TABLET, ALLERGY RELIEF 60 MG TABLET, ALLERGY RLF (FEXO) 60 MG TAB, ALLERGY RLF(CETRZN) 10 MG SFGL, CVS ALLERGY (FEXO) 60 MG TAB, CVS ALLERGY (LORAT) 10 MG ODT, CVS ALLERGY (LORAT) 5 MG ODT, CVS ALLERGY RELIEF 180 MG TAB, CVS ALLERGY RELIEF 5 MG TABLET, CVS ALLERGY(CETRZN) 10 MG SFGL, EQ ALLERGY RELIEF 180 MG TAB, EQL ALLERGY RELIEF 180 MG TAB, FT ALLERGY (FEXO) 180 MG TAB, FT ALLERGY (FEXO) 60 MG TABLET, GNP ALLERGY RELIEF 180 MG TAB, GNP ALLERGY RELIEF 5 MG TABLET, HM ALLERGY RELIEF 180 MG TAB, HM ALLERGY RELIEF 60 MG TABLET, KRO ALLERGY RELIEF 180 MG TAB, KRO ALLERGY RELIEF 60 MG TAB, PUB ALLERGY RELIEF 180 MG TAB, QC ALLERGY RELIEF 180 MG TAB, RA ALLERGY RELIEF 180 MG TAB, SM ALLERGY RELIEF 60 MG TABLET, ALLERGY RELIEF D, ALLERGY RELIEF D-12, ALLERGY RELIEF D-24HR, ALLERGY RELIEF D24, ALLERGY RELIEF NASAL DECONGEST, ALLERGY RELIEF-D, ALLERGY RELIEF-D12, ALLERGY RELIEF-NASAL DECONGEST, ALLERGY-CONGESTION 12HR, ALLERGY-CONGESTION ER, ALLERGY-CONGESTION RELIEF, ALLERGY-CONGESTION RELIEF 12HR, ALLERGY-CONGESTION RELIEF-D, CETIRI-D, CETIRIZINE HCL 10 MG CHEW TAB, CETIRIZINE HCL 5 MG CHEW TAB, CETIRIZINE HCL 5 MG/5 ML SOLN, CETIRIZINE-PSEUDOEPHEDRINE ER, CHILDREN'S ALLEGRA ALLERGY, CHILD ALLERGY (FEXO) 30 MG/5ML, CVS CHILD ALLERGY RLF 5 MG CHW, CVS CHILD ALLERGY(FEX) 30 MG/5, EQL CHILD ALLERGY RLF 5 MG CHW, HM CHILD ALLERGY RLF 5 MG CHEW, RA CHILD ALLERGY RLF 5 MG CHEW, CHILD CETIRIZINE 10 MG CHEW TB, CHILD CETIRIZINE 5 MG CHEW TAB, CHILD'S CLARITIN 5 MG TAB CHEW, CHILD LORATADINE 5 MG TAB CHEW, CHILDEN'S WAL-FEX, CHILD'S WAL-ZYR 10 MG CHEW TAB, CHILDREN'S WAL-ZYR 10 MG ODT, CHILD ZYRTEC 10 MG CHEW TABLET, CHILD ZYRTEC 2.5 MG CHEW TAB, CHILDREN'S ZYRTEC ALLERGY, CLARINEX, CLARITIN 10 MG CHEWABLE TABLET, CLARITIN 10 MG LIQUI-GEL CAP, CLARITIN 10 MG REDITABS, CLARITIN 5 MG REDITABS, CLARITIN-D 24 HOUR, DESLORATADINE 5 MG TABLET, FEXOFENADINE HCL 180 MG TABLET, FEXOFENADINE HCL 60 MG TABLET, HM FEXOFENADINE HCL 180 MG TAB, HM FEXOFENADINE HCL 60 MG TAB, SM FEXOFENADINE HCL 180 MG TAB, SM FEXOFENADINE HCL 60 MG TAB, FEXOFENADINE-PSE ER, LEVOCETIRIZINE 2.5 MG/5 ML SOL, LEVOCETIRIZINE 5 MG TABLET, LORATA-D, LORATA-DINE D, EQ LORATADINE 10 MG ODT, GNP LORATADINE 10 MG ODT, LORATADINE 10 MG ODT, LORATADINE-D, WAL-FEX ALLERGY, WAL-FEX D 12 HOUR, WAL-FEX D 24 HOUR, WAL-ITIN D, WAL-ITIN D 12 HOUR, WAL-ZYR 10 MG SOFTGEL, WAL-ZYR D, XYZAL, ZYRTEC 10 MG CHEWABLE TABLET, ZYRTEC 10 MG LIQUID GELS, ZYRTEC 10 MG ODT, ZYRTEC-D
REQUIRED MEDICAL INFORMATION
For initial authorization, one of the following criteria (1 or 2) must be met:

1. For children less than 21 years of age: Documentation that all the following criteria (a, b, and c) are met:
   a. Confirmed medically appropriate diagnosis for use of antihistamines (such as allergic rhinitis, urticaria)
   b. Documentation that condition is impacting the patient’s health (such as quality of life, function, growth,
      development, ability to participate in school, perform activities of daily living, etc.)
   c. Documented trial and failure, intolerance, or contraindication to both preferred products (cetirizine
      tablets/solution AND loratadine tablet/syrup)

2. For adults 21 years of age and older: Documentation that all the following criteria (a, b, and c) are met:
   a. Confirmed diagnosis of allergic rhinitis, allergic conjunctivitis, or chronic
      rhinitis/pharyngitis/nasopharyngitis
   b. Confirmed diagnosis of one of the following comorbid conditions:
      i. Asthma or reactive airway disease exacerbated by chronic/allergic rhinitis or allergies
         a) Patient must be using an asthma controller medication (such as an inhaled corticosteroid, leukotriene
            antagonist, and/or inhaled rescue beta-agonist) within the previous six months
      ii. Acute or chronic inflammation of the orbit
      iii. Chronic sinusitis
      iv. Acute sinusitis
      v. Sleep apnea
      vi. Wegener’s Granulomatosis
   c. Documented trial and failure (defined as inadequate response to at least one month of therapy),
      intolerance, or contraindication to both preferred products (cetirizine tablets/solution AND loratadine
      tablet/syrup)

AGE RESTRICTION
See specific product information for age restrictions.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
SELF-ADMINISTERED DRUG (SAD) EXCLUSION

MEDICATION(S)
ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, ACTIMMUNE, ADBRY, AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, AJOVY SYRINGE, AMJEVITA(CF), AMJEVITA(CF) AUTOINJECTOR, ARIXTRA, AVONEX, AVONEX PEN, BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE, BESREMI, BETASERON, BYDUREON BCISE, BYETTA, CABLIVI, CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT, COPAXONE, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, DUPIXENT PEN, DUPIXENT SYRINGE, EGRIFTA SV, EMGALITY PEN, EMGALITY SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, ENOXAPARIN SODIUM, ENSPRYNG, EXTAVIA, FASENRA PEN, FIRAZYR, FONDAPARINUX SODIUM, FORTEO, FRAGMIN, FUROSCIX, FUZEON, GATTEX, GENOTROPIN, GLATIRAMER ACETATE, GLATOPA, HADLIMA, HADLIMA PUISHTOUCH, HADLIMA(CF), HADLIMA(CF) PUSHTOUCH, HAEGARDA, HUMATROPE, HUMIRA, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS, ICATIBANT, IMITREX 4 MG/0.5 ML CARTRIDGES, IMITREX 4 MG/0.5 ML PEN INJECT, IMITREX 6 MG/0.5 ML CARTRIDGES, IMITREX 6 MG/0.5 ML PEN INJECT, IMITREX 6 MG/0.5 ML VIAL, INCRELEX, KESIMPTA PEN, KEVZARA, KINERET, LOVENOX, MYALEPT, NORDITROPIN FLEXPRO, NUCALA, NUTROPIN AQ NUSPIN, OMNITROPE, ORENCIA CLICKJECT, OZEMPIC, PEGASYS, PLEGIRIDY, PLEGIRIDY PEN, PRALUENT PEN, REBIF, REBIF REBIDOSE, RELISTOR 12 MG/0.6 ML SYRINGE, RELISTOR 12 MG/0.6 ML VIAL, RELISTOR 8 MG/0.4 ML SYRINGE, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE, SAIZEN, SAIZEN-SAIZENPREP, SAJAZIR, SEROSTIM, SIGNIFOR, SILIQ, SIMPONI, SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI ON-BODY, SKYRIZI PEN, SKYTROFA, SOMAVERTR, STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE, STRENSIQ, SUMATRIPTAN 4 MG/0.5 ML CART, SUMATRIPTAN 4 MG/0.5 ML INJECT, SUMATRIPTAN 6 MG/0.5 ML CART, SUMATRIPTAN 6 MG/0.5 ML VIAL, SUMATRIPTAN 6 MG/0.5 ML AUTOINJ, TAKHZYRO, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TERIPARATIDE, TEZSPIRE, TREMFYA, TRULICITY, TYMLOS, VICTOZA 2-PACK, VICTOZA 3-PACK, VOXZOGO, XOLAIR 150 MG/ML SYRINGE, XOLAIR 75 MG/0.5 ML SYRINGE, ZOMACTON, ZORBTIVE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A
REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Refer to applicable clinical policy and/or formulary documents

PRESCRIBER RESTRICTION
Relevant chart notes are required and must document medical rationale for requiring administration by a healthcare professional.

Healthcare provider administration may be considered medically necessary if one of the following criteria is met:
1. History of anaphylaxis in the past five years, from any cause, that either required the use of epinephrine or resulted in hospitalization
2. History of allergic reaction to the requested medication
3. Documentation that the patient has one of the following that prevents self-administration:
   a. Mental health or cognitive changes that require increased level of care for the safe administration of medications
   b. Physical conditions or dexterity issues that impede clean handling of medication and safe administration technique
   c. Inability to recognize symptoms of anaphylaxis and/or act to treat anaphylaxis reactions appropriately
   d. Needle-phobia diagnosed by a mental health provider that is congruent with the most current DSM criteria for phobia. Please note that this does not include general fear of needles

COVERAGE DURATION
Authorization and reauthorization for coverage under the medical benefit will be approved for one year

OTHER CRITERIA
N/A
**SGLT-2 INHIBITORS**

**MEDICATION(S)**
FARXIGA, INVOKAMET, INVOKAMET XR, INVOKANA, JARDIANE, SEGLUROMET, STEGLATRO, SYNJARDY, SYNJARDY XR, XIGDUO XR

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Empagliflozin (Jardiance/Synjardy/Synjardy XR®), canagliflozin (Invokana/Invokamet®), and dapagliflozin (Farxiga/Xigduo XR®) may be covered if the following criteria are met:
1. One of the following:
   a. History of paid claim for metformin
   b. For type 2 diabetes, documentation of trial, intolerance, or contraindication to metformin
   c. For patient without type 2 diabetes, documentation of FDA-labeled indication for use for the requested medication
2. Documentation of estimated glomerular filtration rate (eGFR), measured within the last 12 months, showing the product is not contraindicated

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

**OTHER CRITERIA**
N/A
SKYSONA

MEDICATION(S)
SKYSONA

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For authorization, ALL of the following must be met:

1. Patient has early active cerebral adrenoleukodystrophy (CALD) defined by ALL of the following:
   a. Elevated very-long-chain fatty acid (VLCFA) values
   b. Confirmed Adenosine Triphosphate (ATP)-binding cassette, subfamily D, member 1 (ABCD1) mutation
   c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating:
      i. Loes score between 0.5 and 9 (inclusive) on the 34-point scale
      ii. Gadolinium enhancement on MRI of demyelinating lesions
   d. Neurologic Function Score (NFS) of 1 or less

2. Documentation is provided indicating that patient has NONE of the following:
   a. History of hematopoietic stem cell transplant (HSCT)
   b. History of elivaldogene autotemcel treatment
   c. HLA-matched willing sibling donor

AGE RESTRICTION
May be approved for patients aged 4-17 years

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a pediatric metabolic geneticist, neurologist, endocrinologist, hematologist, or oncologist

COVERAGE DURATION
Authorization is limited to one treatment course per lifetime. Approval duration will be for 12 weeks.

OTHER CRITERIA
N/A
SOLIRIS - MEDICAL BENEFIT

MEDICATION(S)
SOLIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent therapy with another FDA-approved product for PNH, meaning Ultomiris® or Empaveli®, unless in a four-week period of cross-titration between Soliris® and Empaveli®.

REQUIRED MEDICAL INFORMATION
For Paroxysmal Nocturnal Hemoglobinuria (PNH), all of the following must be met:
1. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (such as RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycophasphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
AND
2. Severe disease as indicated by at least one of the following (a or b):
a. Documented history of thrombosis, OR
b. Documentation of at least 10% PNH type III red cells AND at least one of the following:
i. Transfusion dependence (such as hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
ii. Disabling fatigue
iii. End-organ complications
iv. Frequent pain paroxysms (such as dysphagia or abdominal pain)
v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
AND
3. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
AND
4. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for PNH:
1. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms
2. Dose and frequency is in accordance with FDA-approved labeling
For Complement-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:
1. Diagnosis of non-infectious HUS, meaning HUS is not due to infection with Shiga toxin-producing
   Escherichia coli
   AND
2. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL),
   thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
   AND
3. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
   AND
4. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for HUS:
1. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
   a. Maintenance of platelet counts, meaning improvements or reductions less than 25%
   b. Reductions in LDH
   c. Reduction in number of needed plasmapheresis or plasma infusion events
   d. Improvement in kidney function and reduction of dialysis
2. Dose and frequency is in accordance with FDA-approved labeling

For Generalized Myasthenia Gravis (gMG), all of the following must be met:
1. Anti-acetylcholine receptor (anti-AChR) antibody positive
   AND
2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
   AND
3. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
   AND
4. Failed treatment for at least one year with the following:
   a. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil,
      cyclosporine and tacrolimus, corticosteroids)
      OR
   b. ONE immunosuppressive therapy and required at least four infusions/ year of either intravenous
      immunoglobulin (IVIg) OR plasma exchange (PE)
      AND
5. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
      AND
6. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Myasthenia Gravis (MG):
1. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:

1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following:
   a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions)
   AND
   b. Anti-AQP4 antibody positive
   AND
   2. Documentation that other alternative diagnoses have been excluded, such as multiple sclerosis
   AND
   3. Trial and failure, intolerance (such as neutropenia, LFT elevation, hypogammaglobulinemia) or contraindication to rituximab AND satralizumab (Enspryng®)
   AND
   4. Medication will not be used in combination with complement inhibitor (e.g., ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)
   AND
   5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD):

1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement inhibitor (e.g., ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)
3. Dose and frequency is in accordance with FDA-approved labeling

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
- PNH or aHUS: Prescribed by an hematologist/oncologist or nephrologist
- MG or NMOSD: Prescribed by a neurologist

**COVERAGE DURATION**
Initial authorization for up to three months and reauthorization will be approved for up to one year.
MEDICATION(S)
SPEVIGO

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met:
1. Diagnosis of generalized pustular psoriasis (GPP), confirmed by both of the following:
   a. Primary, sterile, macroscopically visible pustules on non-acral skin AND
   b. Pustulation is not restricted to psoriatic plaques
2. Presence of an acute flare of generalized pustular psoriasis of moderate to severe intensity, as defined by:
   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 3 or greater AND
   b. The presence of new or worsening pustules AND
   c. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or greater AND
   d. At least 5% of body surface area (BSA) with erythema and the presence of pustules
3. Dosing must be in accordance with FDA-approved labeling
Requests for one additional dose may be approved one week after initial dose for treatment of the same flare if the following criteria are met:
1. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 2 or higher AND
2. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or higher
3. Dosing must be in accordance with FDA-approved labeling

For reauthorization, all of the following criteria must be met:
1. All criteria for initial authorization must be met AND
2. Documentation of a clinical response to prior treatment with spesolimab, defined as achieving a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1

AGE RESTRICTION
May be approved for patients aged 18 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a dermatologist.

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for two weeks, limited to one 900 mg (2 vials) infusion.

**OTHER CRITERIA**
N/A
SPINRAZA - MEDICAL BENEFIT

MEDICATION(S)
SPINRAZA

COVERED USES
N/A

EXCLUSION CRITERIA
1. Concomitant use with, or following, gene therapy for SMA (such as onasemnogene abeparvovec)
2. Use in combination with risdiplam (Evrysdi®)
3. Advanced symptoms of SMA (such as complete paralysis of limbs, tracheostomy or ongoing invasive ventilator support in the absence of an acute reversible illness)

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following criteria must be met:
1. Confirmed genetic diagnosis of spinal muscular atrophy (SMA) with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to three copies of SMN2, AND
2. Documentation that patient is presymptomatic or has symptoms with an onset at age less than 30 years, AND
3. Documentation of baseline motor function, with one of the following standardized test appropriate based on the patient’s age and level of function:
   a. CHOP-INTEND: Children’s hospital of Philadelphia Infant Test of Neuromuscular Disorders
   b. HINE: Hammersmith Infant Neurological Examination
   c. HFSME: Hammersmith Functional Motor Scale Expanded
   d. 6MWT: six-minute walk test
   e. RULM: Revised Upper Limb Module

NOTE the following guidance on selecting an appropriate test:
• Non-sitters (infants and kids): CHOP-INTEND, HINE (may need HFSME as they transition to sitting).
• Sitters: HFSME, RULM
• Walkers (kids): 6WWT, HFSME
• Walkers (adults): 6MWT, RULM
• Non-walkers (adults): RULM

For reauthorization: Improvement or maintenance of motor function, evidenced by stabilization or improvement in motor function test scores performed at baseline.

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A
SPRAVATO

MEDICATION(S)
SPRAVATO

COVERED USES
N/A

EXCLUSION CRITERIA
• Concomitant use with another dissociative agent
• Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation
• History of intracerebral hemorrhage
• Current or prior DSM-5 diagnosis of a psychotic disorder or MDD with psychosis, bipolar or related disorders, comorbid obsessive compulsive disorder, intellectual disability, autism spectrum disorder, borderline personality disorder, antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder
• Current or recent history (i.e. within the last six months) of moderate or severe substance or alcohol use disorder

REQUIRED MEDICAL INFORMATION
For initial authorization for treatment-resistant depression (TRD), all of the following criteria must be met:
1. Individual has been diagnosed with treatment-resistant depression (TRD) by a psychiatrist within the previous three months. Clinical documentation must be provided that outlines the patient evaluation, plan for on-going management, and treatment options reviewed.
2. Baseline score from one of the following standardized depression rating scales confirming severe depression:
   a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20
   b. Hamilton Depression Scale (HAMD17) score of at least 24
   c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16
   d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28
3. Individual has tried and failed three oral antidepressants in at least two different therapeutic classes for at least eight weeks of treatment at the highest tolerable dose or the FDA-approved maximum dose for the medication. Trials should have occurred within the previous two years
4. Individual has tried and failed augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly). Trial should have occurred within the previous two years
5. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy
6. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For reauthorization, all of the following criteria must be met:
1. Documentation of clinical improvement in depression symptoms as measured by a clinically significant decrease in baseline depression rating scores
2. Documentation of on-going management with a psychiatrist at minimum of every three months
3. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For initial authorization for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior all of the following criteria must be met:
1. Individual has been diagnosed with depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior by a psychiatrist
2. Baseline score from one of the following standardized depression rating scales confirming severe depression:
   a. PHQ-9 score of at least 20
   b. MADRS total score of at least 28
   c. HAMD 17 score of at least 24
   d. QIDS-C 16 score of at least 16
3. Individual received standard of care treatment including one of the following:
   a. Initiation of an antidepressant, or
   b. Optimized oral antidepressant, or
   c. Added augmentation therapy to current antidepressant
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For continuation of care post initiation in inpatient setting all of the following criteria must be met:
1. Documentation of the number of doses provided in the inpatient setting
2. Documentation of clinical improvement in depression symptoms as measured by a clinically significant decrease in baseline depression rating scores
3. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a psychiatrist. The administration/monitoring of this product may be completed by any mental health provider.
COVERAGE DURATION
For treatment resistant depression: Initial authorization will be approved for three months. Reauthorization will be approved for six months.

For Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior: Initial authorization will be approved for one month or the remainder of weeks to one month of treatment post inpatient initiation. Reauthorization will only be approved for treatment resistant depression criteria.

OTHER CRITERIA
N/A
STRENSIQ

MEDICATION(S)
STRENSIQ

COVERED USES
N/A

EXCLUSION CRITERIA
Adult-onset hypophosphatasia or odonto-hypophosphatasia

REQUIRED MEDICAL INFORMATION
Initial authorization requires all the following criteria to be met:
1. Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP) confirmed by both criteria a and b below.
   a. Documentation of one of the following:
      i. Confirmation of at least one pathogenic variant in tissue-nonspecific alkaline phosphatase (TNALPL or ALPL) gene mutation
      OR
      ii. Total serum alkaline phosphatase (ALP) below the lower limit of normal for age AND Plasma pyridoxal-5'-phosphate (PLP) above the upper limit. Note: Plasma PLP should not be measured while the member is receiving pyridoxine treatment
   b. Documentation of at least one of the following prior to the age of 18 years:
      i. Presence of HPP related clinical signs and symptoms OR
      ii. Radiographic features supporting diagnosis of HPP
2. For members 18 years of age or older at the time of request, in addition to criterion 1 above, documentation is required of medical history consistent with progressive, untreated disease, demonstrating all the following:
   a. Limited mobility or functional capacity
   b. Long term chronic musculoskeletal pain
3. Current radiographic evidence of widespread skeletal demineralization, pseudofractures, and skeletal deformities due to recurrent fractures and/or widened metaphyseal Dosing is within the Food and Drug Administration approved label dose

Reauthorization:
1. Pediatric patients: Documentation of response to therapy with improvements in at least one of the following: respiratory status, bone mineralization, or mobility
2. Adult patients:
   a. Initial reauthorization requires documentation of response to therapy with all the following:
i. Increased mobility, and
ii. Decreased pain, and
iii. Evidence of improved bone mineralization (such as radiographic findings, decrease in number of fractures, improvement in fracture healing, decrease in pseudofractures)
b. Subsequent reauthorization requires documentation of stabilization or improvement in all the above criteria (i-iii).
3. Dosing is within the Food and Drug Administration approved label dose

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
MEDICATION(S)
SUCRAID

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of secondary (acquired) disaccharide deficiencies

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Diagnosis of congenital sucrase-isomaltase deficiency has been confirmed by one of the following:
   a. A small bowel biopsy with disaccharidase enzyme assay that is positive for sucrase deficiency, defined
      as a sucrase level below the laboratory’s reference level, typically less than 25 mcM/min/g
   b. A positive genetic test for a pathogenetic mutation in the sucrase-isomaltase (SI) gene
   c. If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, then the patient must
      meet all the following:
         i. Stool pH less than six
         ii. A negative lactose breath test
         iii. Breath hydrogen increase greater than 10 ppm following fasting sucrose challenge
2. Documentation that patient is having significant symptoms due to congenital sucrase-isomaltase
   deficiency such as diarrhea, bloating, abdominal cramping, failure to thrive, dehydration and malnutrition
3. Documentation that patient has tried and failed a low sucrose and starch diet
4. Documentation that sacrosidase therapy will be used in conjunction with dietary limitation of sucrose and
   starch intake

Reauthorization criteria:
1. Documentation of a positive improvement in gastrointestinal symptoms
2. Documentation that sacrosidase therapy will continue to be given in conjunction with dietary limitation of
   sucrose and starch intake

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
Initial authorization will be approved for six months and reauthorization will be approved for one year

OTHER CRITERIA

N/A
SUNLENCA

MEDICATION(S)
SUNLENCA 4- 300 MG TABLET, SUNLENCA 5- 300 MG TABLET

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy (new starts) all the following must be met:
1. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance, intolerance or contraindication to at least two (2) antiretroviral medications in each of at least three (3) following classes:
   a. Non-nucleoside reverse transcriptase inhibitor
   b. Nucleoside reverse transcriptase inhibitor
   c. Protease inhibitor
   d. Integrase strand-transfer inhibitor
2. Documentation current antiretroviral regimen has been stable for at least two months and current viral load is greater than or equal to 400 copies/mL
3. Confirmation that patient will take an optimized background regimen of antiretroviral therapy along with lenacapavir
4. Dose and frequency are in accordance with FDA-approved labeling

For patients established on therapy, all the following must be met:
1. Patient is currently receiving treatment with lenacapavir
2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy) of at least 0.5 log10 copies/mL. Note: A decrease in viral load less than 0.5 log10 copies/mL may be considered if there is documentation that a M66I mutation has not occurred
3. Confirmation that patient will continue to take an optimized background regimen of antiretroviral therapy
4. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged eighteen (18) years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist
COVERAGE DURATION
Initial authorization will be approved for six (6) months.
Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
SYFOVRE

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
• History of or active choroidal neovascularization (CNV), associated with AMD or any other cause
• History of ocular or periocular infections
• History of endophthalmitis, retinal detachments, or increased intraocular pressure

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met:
1. Documentation of diagnosis of geographic atrophy (GA) confirmed by clinical exam or diagnostic imaging (such as Color Fundus Photography, Fundus Autofluorescence, Near Infrared Reflectance Imaging, Optical Coherence Tomography)
2. Documentation that GA is secondary to age-related macular degeneration (AMD)

For reauthorization, the following must be met: Documentation of response to therapy defined as one of the following:
1. Reduction in GA growth lesion
2. Documentation of improvement in visual function through visual function assessment test (such as normal luminance best-correct visual acuity [BCVA], maximum reading speed, Functional Reading Independence Index, microperimetry)

AGE RESTRICTION
May be approved for patients age equal to 60 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an ophthalmologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A
MEDICATION(S)
SYLVANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Confirmed diagnosis of Multicentric Castleman Disease (MCD)
   AND
2. Documentation of negative human immunodeficiency virus (HIV) status
   AND
3. Documentation of negative human herpes-virus 8 (HHV-8) status
   AND
4. Documentation that siltuximab (Sylvant®) will be used as a single agent

Reauthorization will require positive response to therapy as well as documentation that patient remains HIV and HHV-8 negative.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist, hematologist, or rheumatologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
T-CELL THERAPY

MEDICATION(S)
ABECMA, BREYANZI, CARVYKTI, KYMRIAH, TECARTUS, TECVAYLI, YESCARTA

COVERED USES
N/A

EXCLUSION CRITERIA
Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy. Repeat administration of T-cell therapy is considered experimental and investigational because the effectiveness of this approach has not been established.

REQUIRED MEDICAL INFORMATION
For all chimeric antigen receptor therapy (CAR-T) therapy requests, the following criteria must be met:
1. Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher
2. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver)
3. One of the following regarding functional status must be met:
   a. For Kymriah® for B-cell precursor acute lymphoblastic leukemia (ALL) only: Karnofsky or Lansky Scale greater than or equal to 50%
   b. Provider attestation/documentation that the patient’s functional status is sufficient to undergo treatment. This may include but is not limited to a documented Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 or a written statement acknowledging that the patient is fit to tolerate therapy.
4. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)
5. For B-cell lymphomas, patient does not have primary central nervous system lymphoma

For Tecvayli®:
1. Confirmed diagnosis of multiple myeloma
2. Refractory or relapsed disease to four or more prior lines of therapy. Prior therapy must have included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
3. Asymptomatic or minimally symptomatic with Eastern Cooperative Oncology Group (ECOG) performance status 0-1
4. No evidence of active systemic infection

AGE RESTRICTION
Abecma®: Approved for 18 years of age and older
Breyanzi®: Approved for 18 years of age and older
Carvykti®: Approved for 18 years of age and older
Kymriah®:
• Approved for 25 years of age or younger for acute lymphoblastic leukemia (ALL)
• Approved for 18 years of age and older for relapsed or refractory B-cell lymphomas

Tecartus®: Approved for 18 years of age and older

Yescarta®: Approved for 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist

COVERAGE DURATION
For Tecvayli®: Initial authorization and reauthorization will be approved for one year and with up to four doses of tocilizumab (Actemra®) at up to 800 mg per dose.

For all other immunotherapies: Two months (limited to one treatment course per lifetime, with four doses of tocilizumab [Actemra®] at up to 800 mg per dose).

OTHER CRITERIA
N/A
MEDICATION(S)
VYNDAMAX, VYNDAQEL

COVERED USES
N/A

EXCLUSION CRITERIA
1. A New York Heart Association (NYHA) Heart Failure classification of IV
2. Prior liver transplantation
3. Implanted cardiac mechanical assist device such as left ventricular assist device (LVAD)
4. Used in combination with patisiran (Onpattro®) or inotersen (Tegsedi®)

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmation of amyloid deposits showing cardiac involvement by ONE of the following:
   a. A positive radionuclide imaging scan, defined as showing Grade 2 or 3 cardiac uptake using one of the following radiotracers:
      i. 99m technetium-Pyrophosphate (99mTc-PYP)
      ii. 99m technetium (Tc)-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid ((99mTc-DPD)
      iii. 99mTc-labeled hydroxymethylene diphosphonate (HMDP)
   b. A positive cardiac biopsy for ATTR amyloid
   c. A positive non-cardiac biopsy for ATTR amyloid and evidence of cardiac involvement by evidence of cardiac involvement by end-diastolic interventricular septal wall thickness greater than 12 mm (by echocardiogram or MRI) or suggestive cardiac MRI findings
2. Documentation of patient’s NYHA functional class (functional class IV is excluded from coverage)
3. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure such as dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels.

Reauthorization requires documentation of a positive clinical response. Appropriate documentation may include evidence of slowing of clinical decline, reduced number of cardiovascular hospitalizations, or improvement or stabilization of the 6-minute walk test.

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be written by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A
MEDICATION(S)
TARPEYO

COVERED USES
N/A

EXCLUSION CRITERIA
Patient is on dialysis or has undergone kidney transplant

REQUIRED MEDICAL INFORMATION
For the diagnosis of primary immunoglobulin A nephropathy (IgAN), ALL of the following criteria must be met:
1. Documentation of biopsy-proven IgAN
   AND
2. Patient is receiving a stable dose of an ACE inhibitor or ARB at a maximally tolerated dose
   AND
3. Urine protein/creatinine ratio (UPCR) greater than or equal to 1.5 g/g
   AND
4. eGFR greater than or equal to 35 mL/min/1.73 m2

AGE RESTRICTION
Approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist

COVERAGE DURATION
One nine month treatment course. No reauthorization will be approved.

OTHER CRITERIA
N/A
**TAVNEOS**

**MEDICATION(S)**
TAVNEOS

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For initial authorization, all of the following criteria (1-3) must be met:
1. Confirmed diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis or microscopic polyangiitis)
2. Documentation that avacopan (Tavneos®) will be used in combination with standard therapy (cyclophosphamide or rituximab) including glucocorticoids for induction of remission, unless therapy is contraindicated or clinically significant adverse effects have occurred
3. Documentation of organ-threatening or life-threatening disease (such as active glomerulonephritis, pulmonary hemorrhage, cerebral vasculitis, progressive peripheral or cranial neuropathy, orbital pseudotumor, scleritis, gastrointestinal bleeding due to vasculitis, cardiac disease due to vasculitis [pericarditis, myocarditis]) despite standard therapy outlined above

For reauthorization, all of the following must be met:
1. Documentation of clinical benefit of therapy defined as one of the following:
   a. Improved or sustained renal function
   b. Documentation of decreased glucocorticoid dose

**AGE RESTRICTION**
May be approved for patients aged 18 years and older

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation with, a rheumatologist or nephrologist

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for six months. Reauthorization will be approved for six months.

**OTHER CRITERIA**
N/A
MEDICATION(S)
TEPEZZA

COVERED USES
N/A

EXCLUSION CRITERIA
Sight-threatening thyroid eye disease (defined as presence of direct optic neuropathy or corneal breakdown)

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Confirmed diagnosis of moderate-to-severe thyroid eye disease/Grave’s Orbitopathy, as defined as eye disease that significantly impacts quality of life and at least one of the following:
   a. Lid retraction of at least 2 mm, marginal reflex distance-1 (MRD1) greater than four, or presence of lagophthalmos
   b. Moderate or severe soft-tissue involvement (such as swelling or redness of the eyes)
   c. Inconstant diplopia (diplopia at extremes of gaze) or constant diplopia (continuous diplopia in primary or reading position)
2. Documentation of active disease, defined as a Clinical Activity Score (CAS) of at least four
3. Laboratory evidence of euthyroid state
4. Inadequate response to at least two weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) unless there is a contraindication, intolerance, or presence of proptosis or diplopia.
5. Dosing is within the Food and Drug Administration approved label dose

Reauthorization is not considered medically necessary and will not be covered.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an ophthalmologist.

COVERAGE DURATION
Authorization will be approved for six months for a total of up to eight infusions

OTHER CRITERIA
TEZSPIRE

MEDICATION(S)
TEZSPIRE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with another therapeutic immunomodulator agent utilized for the same indication

REQUIRED MEDICAL INFORMATION
1. For patients initiating therapy, all the following criteria must be met:
   a. Documentation of treatment with maximally tolerated high-dose inhaled corticosteroid plus an inhaled long-acting beta-2 agonist and has been adherent to therapy in the past three months (this may be verified by pharmacy claims information),
   b. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following
      i. Asthma Control Questionnaire (ACQ) score greater than equal to 1.5,
      ii. At least two asthma exacerbations require oral corticosteroids for at least three days in last 12 months,
      iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit
   c. For patients with eosinophilic asthma or steroid-dependent asthma: Documented trial and failure, intolerance, or contraindication to therapy with dupilumab (Dupixent®)

AGE RESTRICTION
May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
THERAPEUTIC IMMUNOMODULATORS (TIMS)

MEDICATION(S)
ACTEMRA, ACTEMRA ACTPEN, AMJEVITA(CF), AMJEVITA(CF) AUTOINJECTOR, AVSOLA, CIMZIA, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, ENTYVIO, HADLIMA, HADLIMA PUSHTOUCH, HADLIMA(CF), HADLIMA(CF) PUSHTOUCH, HUMIRA, HUMIRA PEN, HUMIRA PEN CROHN’S-UC-HS, HUMIRA PEN PSOR-UV-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN’S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN’S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS, ILUMYA, INFLECTRA, INFLIXIMAB, KEVZARA, KINERET, OLUMIANT, ORENCIA, ORENCIA CLICKJECT, OTEZLA, REMICADE, RENFLEXIS, RINVOQ, SILIQ, SIMPONI, SIMPONI ARIA, SKYRIZI, SKYRIZI (2 SYRINGES) KIT, SKYRIZI ON-BODY, SKYRIZI PEN, SOTYKTU, STELARA, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TREMFYA, XELJANZ, XELJANZ XR

COVERED USES
N/A

EXCLUSION CRITERIA
1. Below the line diagnoses (such as alopecia areata)
2. Combination therapy with another therapeutic immunomodulator (TIM) agent or apremilast (Otezla®)

REQUIRED MEDICAL INFORMATION
1. For all requests, the patient must have an FDA labeled indication for the requested agent and is a covered indication according to the Prioritized List of Health Care Services.
AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®)
AND
3. One of the following:
a. For patients established on the requested therapeutic immunomodulator, the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
i. For Hidradenitis Suppurativa, continuation of adalimumab therapy may be covered with clear evidence of response, defined as BOTH of the following:
1) A reduction of 25% or more in the total abscess and inflammatory nodule count, AND
2) No increase in abscesses and draining fistulas
ii. For Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Psoriatic Arthritis:
1) Documentation that patient is adherent to both TIMs agent and DMARD (if DMARD therapy has been
prescribed in conjunction with the biologic therapy)

2) Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

iii. Requests for non-preferred infliximab product (Remicade® or Avsola®) or non-preferred adalimumab product (Amjevita®) will require failure, intolerance, or contraindication to the preferred infliximab biosimilar products (Inflectra® AND Renflexis®) or preferred adalimumab product (Humira®), respectively. Accepted contraindications include: contraindications listed in the package insert or a documented allergic reaction to an ingredient found only in the preferred biosimilar product(s).

iv. For all other indications: Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

b. Patients not established on the requested therapeutic immunomodulator must meet the following indication-specific criteria:

i. Requests for non-preferred infliximab product (Remicade® or Avsola®) or non-preferred adalimumab product (Amjevita®) will require failure, intolerance, or contraindication to the preferred infliximab biosimilar products (Inflectra® AND Renflexis®) or preferred adalimumab product (Humira®), respectively, in addition to the indication-specific criteria below. Accepted contraindications include: contraindications listed in the package insert or a documented allergic reaction to an ingredient found only in the preferred biosimilar product(s).

ii. For Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Psoriatic Arthritis, all the following criteria (1-3) must be met:

1) Use of disease-modifying anti-rheumatic drugs (DMARDs):
   a) Documented inadequate response to at least one of the following disease-modifying antirheumatic drugs (DMARDs) after at least six months of therapy: methotrexate, leflunomide, sulfasalazine or hydroxychloroquine
   OR
   b) Documented intolerance or contraindication to all of the above DMARDs (such as methotrexate, leflunomide, sulfasalazine and hydroxychloroquine)

2) Documentation that the patient is currently using a DMARD and will continue concomitant use (unless contraindicated).

3) Preferred products (adalimumab, etanercept, infliximab biosimilars Inflectra® and Renflexis®) may be covered. For non-preferred TIMs agent:
   a) Documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to at least one of the following preferred TIMs agents: adalimumab (Humira®), etanercept (Enbrel®), or preferred infliximab biosimilar (Inflectra® or Renflexis®)

iii. For inflammatory bowel diseases (e.g., Crohn’s disease, ulcerative colitis), all the following criteria (1 and 2) must be met:

1) Use of conventional immunosuppressive therapies:
   a) Documented inadequate response to at least one of the following conventional immunosuppressive therapies for at least six months: mercaptopurine, azathioprine, or budesonide
   OR
b) Documented intolerance or contraindication to these therapies
OR
c) Medical rationale is provided for escalating to biologic therapy without previous trial of conventional therapies (for example, patient is having severe symptoms of the disease, such as significant weight loss, evidence of obstruction, high fever, persistent vomiting)

2) Preferred products [(adalimumab, infliximab biosimilars (Inflectra® and Renflexis®), or vedolizumab] may be covered. For non-preferred TIMs agent: documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to at least two of the following TIMs agents:
   a) Adalimumab (Humira®)
   b) Preferred infliximab biosimilar (Inflectra® or Renflexis®)
   c) Vedolizumab (Entyvio®)

iv. For psoriasis, all the following criteria (1-3) must be met:
1) Patient must have severe disease, as defined by both of the following:
   a) Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on other validated tool
   b) At least one of the following:
      • At least 10% of body surface area involved
      • Hand, foot, face, or mucous membrane involvement
2) Documentation of inadequate efficacy, intolerable side effects, or contraindications to at least one of the following:
   a) Four-week trial of a combination of moderate to high potency topical corticosteroid and a topical non-steroidal agent.
   b) Oral immunomodulator (such as methotrexate, cyclosporine)
3) Preferred products (adalimumab, etanercept, infliximab biosimilars Inflectra® and Renflexis®, or secukinumab) may be covered. For non-preferred TIMs agent: Documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to the following preferred agents:
   a) One of the following TNF inhibitor agents: adalimumab (Humira®) or preferred infliximab biosimilar (Inflectra® or Renflexis®)
   AND
   b) Secukinumab (Cosentyx®)

v. For atopic dermatitis, upadacitinib (Rinvoq®) may be covered if all the following criteria (1-2) are met:
1) Patient must have severe disease, as defined by both of the following:
   a) Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on other validated tool
   b) At least one of the following:
      • At least 10% of body surface area involvement
      • Hand, foot, face, or mucous membrane involvement
2) Documentation of inadequate efficacy, intolerable side effects, or contraindication to at least one of the
a) Four-week trial of a combination of moderate to high potency topical corticosteroid and a topical non-steroidal agent.

b) Oral immunomodulator (such as cyclosporine, methotrexate, oral corticosteroid)

vi. For ankylosing spondylitis, preferred agents (adalimumab, infliximab biosimilars Inflectra® and Renflexis®, or etanercept) may be covered:

1) For non-preferred TIMs agent: Documented trial and failure (after at least three months of therapy), intolerance or contraindication to at least one of the following preferred agents: adalimumab (Humira®), etanercept (Enbrel®) or preferred infliximab biosimilar (Inflectra® or Renflexis®)

vii. For Hidradenitis Suppurativa, adalimumab (Humira®) may be covered if the following criteria are met:

1) Documentation of moderate to severe disease (e.g., Hurley Stage II or Hurley Stage III)

2) Documented inadequate response to at least one conventional therapy after 90 days of therapy (e.g., oral antibiotics) unless contraindicated or not tolerated

viii. For immune checkpoint inhibitor related diarrhea/colitis, a preferred infliximab product (Inflectra® or Renflexis®) may be covered if the following criteria are met:

1) Documentation of severe diarrhea/colitis (G3-4)

2) Documentation of inadequate response to a 1–2-day trial of intravenous prednisone or methylprednisolone

ix. For polymyalgia rheumatica (PMR), sarilumab (Kevzara®) may be covered if the following criteria are met:

1) Diagnosis of PMR and documentation of the following:

a) Age 50 years or older at disease onset AND

b) One of the following:

- Bilateral shoulder or pelvic aching or stiffness lasting longer than 45 minutes and persisting for at least two weeks OR
- If younger than 50 years of age and having asymmetric shoulder or pelvic pain, documentation of PMR with atypical features
- Documentation that similar disorders have been ruled out (such as giant cell arteritis rheumatoid arthritis, drug-induced myalgias, fibromyalgia, other musculoskeletal disease, or other bone disease).

- One of the following:
  - Inadequate response to full dose systemic systemic corticosteroid
  - Documented PMR flare while attempting to taper systemic corticosteroid
  - Intolerance or contraindication to systemic corticosteroids

x. For all other indications, the requested agent may be covered if FDA approved for the indication and age of the patient.

Note:

- Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent
- Conventional therapy and preferred agent requirements may be waived with clinically appropriate medical
rationale

For quantity limit exception requests

1. For patients already established on the requested dose and frequency, the following criteria must be met:
   Documentation of response to therapy with increased dosing. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.

2. For patients not established on requested dose and frequency (e.g., requesting dose escalation, previous dose escalation sponsored by manufacturer not previously approved by a health plan), one of the following must be met:
   a. Requested dose is FDA-labeled for the indication. For example:
      i. For Crohn’s disease: Stelara® and Skyrizi® will be approved for FDA-labeled dosing for this condition (Stelara: 90 mg every eight weeks, Skyrizi: 360 mg every eight weeks)
      ii. For Hidradenitis Suppurativa: Humira® will be approved for FDA-labeled dosing for this condition (40 mg once weekly)
      iii. For psoriasis: Cimzia® will be approved for FDA-labeled dosing for this condition (800 mg every four weeks)
      iv. For ulcerative colitis: Simponi® will be approved for FDA-labeled dosing for this condition (100 mg every 28 days)
   b. For requests for dose escalation in inflammatory bowel disease (such as Crohn’s disease or ulcerative colitis), adalimumab 40 mg once weekly or ustekinumab 90 mg every six weeks may be covered if all of the following criteria are met:
      i. Documentation that patient initially responded to the medication, but has experienced an inadequate response, or waning of response, to the medication. Patient must have used the medication at the FDA-labeled dosing for at least six months.
      ii. Documentation of current and active inflammation on endoscopy or imaging [such as computed tomography enterography (CTE) or magnetic resonance enterography (MRE)] obtained after at least six months of treatment on the FDA-approved dosing outlined above. Results must have been obtained within the last six months prior to this request.
   c. For other disease states: requests for dose escalation are considered experimental/investigational and are not covered

AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
• Prior Authorization: Authorization will be approved until no longer eligible with the plan, subject to
formulary or benefit changes
• Quantity Limitation: Initial authorization will be approved for six months. Reauthorization will be approved for one year.
  o Exception: Authorization for FDA-approved dosing above the quantity limit will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
THROMBOCYTOPENIA MEDICATIONS

MEDICATION(S)
DOPTELET, MULPLETA, NPLATE, PROMACTA, TAVALISSE

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with other thrombopoietin receptor agonists (e.g., Mulpleta®, Promacta®, Nplate®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

REQUIRED MEDICAL INFORMATION
For initiation of therapy, must meet indication-specific criteria below:

1. For Oncologic Diagnoses: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher.

2. For Immune Thrombocytopenia (ITP), Doptelet®, Nplate®, Promacta®, or Tavalisse®, may be covered if all the following criteria (a-c) are met:
   a. Diagnosis of chronic immune thrombocytopenia (ITP)
   b. Platelet count of less than 30,000 cells per microliter
   c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated:
      i. Systemic corticosteroids
      ii. Immune globulin
      iii. Splenectomy
      iv. Rituximab

3. For Chronic Hepatitis C-associated Thrombocytopenia, Promacta® may be covered if all the following criteria (a-b) are met:
   a. Platelet count of less than 75,000 cells per microliter
   b. Patient will be initiating and maintaining interferon-based therapy or is currently receiving interferon-based therapy

4. For Severe Aplastic Anemia, Promacta® may be covered if there is documentation that the patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter

5. For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD), all the following criteria (a-d) must be met:
   a. Request is for Doptelet® or Mulpleta®
i. For Mulpleta®: Documented trial, failure, intolerance, or contraindication to Doptelet®
b. Diagnosis of chronic liver disease
c. Platelet count of less than 50,000 cells per microliter,
d. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started prior to the procedure as follows:
i. For Doptelet: 10-13 days prior to the procedure
ii. For Mulpleta: 8-14 days prior to the procedure

6. For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], Nplate® may be covered if patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

For patients established on therapy, must meet indication-specific criteria below:
1. For oncologic diagnoses: Documentation of improved platelet levels from baseline

2. For ITP or severe aplastic anemia:
a. Documentation of improved platelet levels from baseline
b. Documentation the continued therapy is medically necessary to maintain a platelet count of at least 50,000 cells per microliter

3. For Chronic Hepatitis C-associated Thrombocytopenia:
a. Documentation of improved platelet levels from baseline
b. Patient continues to receive interferon-based therapy

4. For CLD or HSARS: Patient must meet the initial approval criteria above for each request

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist, hematologist, gastroenterologist or hepatologist.

COVERAGE DURATION
• For ITP, chronic hepatitis C-associated thrombocytopenia, severe aplastic anemia and oncologic diagnoses: Initial authorization will be approved for six months. Reauthorization will be approved for one year
• For CLD: Authorization will be approved for one month for one treatment course
• For HSARS: Authorization will be approved for three months

OTHER CRITERIA
TOLVAPTAN

MEDICATION(S)
JYNARQUE, SAMSCA, TOLVAPTAN

COVERED USES
N/A

EXCLUSION CRITERIA
• Hepatic Impairment
• Anuria
• Hypovolemia
• For Jynarque®: Patients with eGFR of less than 25 mL/min

REQUIRED MEDICAL INFORMATION
For autosomal dominant polycystic kidney disease (ADPKD), Jynarque® may be approved when all the following criteria are met:
1. Diagnosis of ADPKD confirmed by ultrasound, magnetic resonance imaging (MRI) or computed tomography (CT) scan
   Note: genetic testing may also be used to help confirm the diagnosis
2. The patient must have a confirmed diagnosis of rapidly progressing ADPKD by at least one of the following criteria:
   a. eGFR decline of at least 5 mL/min/1.73 m2 per year over one year
   b. eGFR decline of at least 2.5 mL/min/1.73 m2 per year over a period of five years
   c. Total kidney volume increase of at least 5% per year confirmed by at least three repeated ultrasound or MRI measurements taken at least six months apart
   d. Height-adjusted total kidney volume (htTKV) compatible with Mayo class 1D or 1E disease
   e. htTKV compatible with Mayo class 1C disease AND additional evidence of rapid disease progression such as a predicting renal outcomes in ADPKD (PROPKD) score greater than six, early hypertension or urological manifestations, truncating PKD1 mutation or family history of early onset dialysis related to ADPKD
3. Patient does not have significant renal disease other than ADPKD (such as renal cancer, acute kidney injury)

Reauthorization for ADPKD requires documentation of a positive response to therapy (such as a slowing in patient’s decline in kidney function)

For hypervolemic and euvolemic hyponatremia, Samsca® may be covered when all of the following criteria are met:
1. One of the following:
   a. Serum sodium of less than 125 mEq/L
   b. Less marked hyponatremia (less than 135 mEq/L), but symptomatic
2. Patient will be initiated or re-initiated on therapy in a hospital setting where serum sodium can be monitored closely
3. Patient does not have an urgent need to raise serum sodium acutely (such as acute/transient hyponatremia associated with head trauma)

AGE RESTRICTION
May be covered for patients aged 18 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist, cardiologist, or endocrinologist.

COVERAGE DURATION
Jynarque®: Initial approval and reauthorization will be approved for one year
Samsca®: Authorization will be approved for 30 days per treatment course

OTHER CRITERIA
N/A
TOTAL PARENTERAL NUTRITION (TPN)

MEDICATION(S)
AMINOSYN, AMINOSYN II, AMINOSYN II WITH ELECTROLYTES, AMINOSYN M, AMINOSYN WITH ELECTROLYTES, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E 2.75%-5% SOLUTION, CLINIMIX E 4.25%-10% SOLUTION, CLINIMIX E 5%-15% SOLUTION, CLINIMIX E 5%-20% SOLUTION, CLINIMIX E 8%-10% SOLUTION, CLINIMIX E 8%-14% SOLUTION, CLINISOL, CLINOLIPID, FREAMINE III, INTRALIPID, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, TRAVASOL, TROPHAMINE

COVERED USES
N/A

EXCLUSION CRITERIA
Coverage for intradialytic parenteral nutrition (IDPN) when offered in addition to regularly scheduled TPN infusions

REQUIRED MEDICAL INFORMATION
One of the following criteria must be met:
1. Member has a central or peripheral line and nutrition will be administered via this line.
   OR
2. Documentation of a failure to enteral nutrition (either oral or via tube), defined as either a or b:
   a. A documented loss of at least 10% of body weight over a three-month period
   b. Member is unable to reach nutritional needs from combined oral and enteral intake (less than 75 percent of estimated basal caloric requirements)
   OR
3. Evidence of structural or functional bowel disease (e.g., massive small bowel resection, short bowel syndrome) that makes oral and tube feedings not possible
   OR
4. A condition in which it is necessary for the gastrointestinal tract to be totally non-functioning for a period of time (such as bowel rest)

Medically necessary intradialytic parenteral nutrition (IDPN) may be covered for members on chronic dialysis who meet criteria 2, 3 or 4 AND cannot tolerate daily TPN.

For continued coverage, annual assessment that documents the ongoing medical necessity of PN as per the above criteria will be required

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for three months and reauthorization will be approved for up to one year.

OTHER CRITERIA
N/A
TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)
AMVUTTRA, ONPATTRO, TEGSEDI

COVERED USES
N/A

EXCLUSION CRITERIA
• New York Heart Association (NYHA) Heart Functional class III or IV
• History of liver transplantation
• Peripheral neuropathy attributed to causes other than hATTR
• Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis [such as Amvuttra® (vutrisiran), inotersen (Tegsedi®), patisiran (Onpattro®), or tafamidis (Vyndaqel®, Vyndamax®)]

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met:
1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
   AND
2. Documentation of a pathogenic TTR mutation
   AND
3. Patient has a baseline polyneuropathy disability (PND) score of less than or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II
   AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130
   AND
5. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
   a. Peripheral sensorimotor polyneuropathy (such as tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
   b. Autonomic neuropathy symptoms (such as orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])
6. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization:
1. Documentation that patient is tolerating applicable therapy (vutrisiran (Amvutra®), inotersen (Tegsedi®))
or patisiran (Onpattro®))

AND

2. Documented improvement or stabilization in polyneuropathy symptoms from baseline, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures:
   a. Baseline polyneuropathy disability (PND) score
   b. Familial amyloid polyneuropathy (FAP) stage

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of amyloidosis

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
TRIENTINE

MEDICATION(S)
CLOVIQUE, SYPRINE, TRIENTINE HCL

COVERED USES
N/A

EXCLUSION CRITERIA
Cystinuria or rheumatoid arthritis

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of Wilson’s Disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or genetic specialist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)

TYSABRI

COVERED USES

N/A

EXCLUSION CRITERIA

1. Use of natalizumab in combination with other disease modifying therapy (DMT) to treat patients with multiple sclerosis (e.g., dimethyl fumarate, glatiramer)
2. Use of natalizumab in combination with immunosuppressants or TNF inhibitors (e.g., adalimumab).

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy for Multiple Sclerosis, all of the following criteria (a-c) must be met:
   a. Must have one of the following confirmed diagnoses:
      i. Relapsing-remitting disease (RRMS)
      ii. Secondary progressive multiple sclerosis (SPMS)
      iii. Clinically isolated syndrome (CIS)
   b. One of the following:
      i. Documentation of trial, failure, or intolerance to at least one of the following disease modifying therapies:
         1. Interferon therapy (Avonex®, Rebif®, Plegridy®, or Betaseron®)
         2. Generic dimethyl fumarate
         3. glatiramer acetate (Copaxone®)
         4. teriflunomide (Aubagio®)
         5. fingolimod (Gilenya®)
         6. ocrelizumab (Ocrevus®)
         7. ozanimod hydrochloride (Zeposia®)
         8. siponimod (Mayzent®)
      OR
      ii. Documentation that patient has highly active or aggressive disease defined as one of the following:
         1. Relapse leading to deterioration in physical functioning or disabilities
         2. Magnetic resonance imaging (MRI) findings of new or worsening lesions
         3. Manifestations of multiple sclerosis-related cognitive impairment
   AND
   c. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
      i. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil
ii. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

2. For initiation of therapy for Crohn’s disease, all of the following criteria (a-c) must be met:
   a. Diagnosis of moderate to severe Crohn’s disease, AND
   b. Documentation of trial, failure, intolerance, or lack of response to a formulary TNF inhibitor (Remicade® and/or Humira®) indicated for Crohn’s, AND
   c. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
      i. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, and mycophenolate mofetil, AND
      ii. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

3. For patients established on therapy: Documentation of positive clinical response to therapy must be provided

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, either a neurologist (for multiple sclerosis) or gastroenterologist (for Crohn’s disease)

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
MEDICATION(S)
TZIELD

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
Stage 3 (symptomatic) type 1 diabetes

REQUIRED MEDICAL INFORMATION
Initial authorization requires all the following be met:
1. Diagnosis of stage 2 type 1 diabetes (meaning that the patient is at risk of developing symptomatic type 1 diabetes) as evidenced by both the following (a and b):
   a. Documentation of the presence of two or more of the following autoantibodies:
      • Glutamic acid decarboxylase 65 (GAD) autoantibody
      • Insulin autoantibody (IAA)
      • Insulinoma-associated antigen 2 autoantibody (IA-2A)
      • Zinc transporter 8 autoantibody (ZnT8A)
      • Islet cell autoantibody (ICA)
   b. Evidence of dysglycemia without overt hyperglycemia confirmed by an oral glucose tolerance test (meaning a 2-hour post prandial blood glucose of 140-199 mg/dL)
   Note: If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be considered such as fasting plasma glucose 100–125 mg/dL
2. Dosing is within FDA-labeled guidelines

AGE RESTRICTION
May be approved for patients aged eight years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an endocrinologist

COVERAGE DURATION
Authorization will be approved for one 14-day treatment course per lifetime

OTHER CRITERIA
N/A
UCERIS

MEDICATION(S)
BUDESONIDE 2 MG RECTAL FOAM, BUDESONIDE ER, UCERIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For budesonide extended release tablets (Uceris®)
For mild to moderate, active ulcerative colitis:
1. Confirmed diagnosis of mild to moderate, active ulcerative colitis
   AND
2. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g.,
   sulfasalazine, mesalamine)
   AND
3. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids:
   dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule

For microscopic colitis:
1. Confirmed diagnosis of active, microscopic colitis

For budesonide foam (Uceris®):
For mild to moderate, active ulcerative colitis:
1. Documented trial, failure, intolerance or contraindication to a rectal mesalamine product
   AND
2. Documented trial, failure, intolerance or contraindication to a rectal steroid product, specifically
   hydrocortisone rectal enema

The initial approval will allow for an eight week treatment course. Further approval for Uceris® requires
medical rationale why additional treatment is warranted for ulcerative colitis and microscopic colitis and if
patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.

AGE RESTRICTION
Approved for patients 18 years and older.

PRESCRIBER RESTRICTION
COVERAGE DURATION
Initial authorization and reauthorization will be approved for eight weeks.

OTHER CRITERIA
N/A
ULTOMIRIS

MEDICATION(S)
ULTOMIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent therapy with Soliris® or Empaveli®

REQUIRED MEDICAL INFORMATION
For Paroxysmal Nocturnal Hemoglobinuria (PNH):
1. For initiation of therapy (new starts) all the following criteria (a-c) must be met:
a. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64), and
b. Severe disease as indicated by at least one of the following (i or ii):
i. Documented history of thrombosis, OR
ii. Documentation of at least 10% PNH type III red cells AND at least one of the following:
   1) Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
   2) Disabling fatigue
   3) End-organ complications
   4) Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
   5) Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
c. Dose and frequency is in accordance with FDA-approved labeling
2. For patients currently on eculizumab (Soliris®) or pegcetacoplan (Empaveli®) switching to ravulizumab (Ultomiris®) for PNH:
a. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1a above) and severe disease (criteria 1b above). However, this can be based on patient’s history prior to starting eculizumab or pegcetacoplan.
b. Dose and frequency are in accordance with FDA-approved labeling
3. For patients established on the requested agent for PNH, both of the following criteria must be met for continuation of therapy:
a. Documentation of reduced LDH levels, reduced transfusion requirements, increase or stabilization of hemoglobin levels or improvement in PNH related symptoms
b. Dose and frequency are in accordance with FDA-approved labeling

For Complement-Mediated Hemolytic Uremic Syndrome (HUS)
1. For initiation of therapy (new starts) all the following criteria (a-c) must be met:
   a. Diagnosis of non-infectious HUS, meaning HUS is not due to infection with Shiga toxin-producing
      Escherichia coli, and
   b. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL),
      thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
   c. Dose and frequency are in accordance with FDA-approved labeling
2. For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for HUS, both of the
   following criteria must be met:
   a. Confirmed documentation of Complement-Mediated Hemolytic Uremic Syndrome (criteria 1a and 1b
      above). However, this can be based on patient’s history prior to starting eculizumab, and
   b. Dose and frequency are in accordance with FDA-approved labeling
3. For patients established on the requested agent for HUS, both of the following criteria must be met:
   a. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
      i. Maintenance of platelet counts, defined as an improvement or reduction less than 25%
      ii. Reductions in LDH
      iii. Reduction in number of needed plasmapheresis or plasma infusion events
      iv. Improvement in kidney function and reduction of dialysis
   b. Dose and frequency are in accordance with FDA-approved labeling

For Generalized Myasthenia Gravis (gMG),
1. For initial authorization, all the following must be met:
   a. Anti-acetylcholine receptor (anti-AChR) antibody positive
   b. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
   c. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
   d. Failed treatment for at least one year with ONE of the following:
      i. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil,
         cyclosporine and tacrolimus, corticosteroids)
      ii. ONE immunosuppressive therapy and required at least four infusions/ year of either intravenous
         immunoglobulin (IVIg) OR plasma exchange (PE)
   e. Dose and frequency are in accordance with FDA-approved labeling
2. For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for gMG, both the
   following must be met:
   a. Confirmed documentation of gMG (criteria 1a-c above). However, this can be based on patient’s history
      prior to starting eculizumab.
   b. Dose and frequency are in accordance with FDA-approved labeling
3. Reauthorization for Myasthenia Gravis (MG):
1. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from baseline.
2. Dose and frequency are in accordance with FDA-approved labeling

**AGE RESTRICTION**
The patient’s age must be within FDA labeling for the requested indication

**PRESCRIBER RESTRICTION**
• PNH or HUS: Prescribed by a hematologist/oncologist or nephrologist
• MG or NMOSD: Prescribed by a neurologist

**COVERAGE DURATION**
Initial authorization for up to three months and reauthorization will be approved for up to one year.

**OTHER CRITERIA**
N/A
**UPLIZNA**

**MEDICATION(S)**
UPLIZNA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as both of the following:
   a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions)
   AND
   b. Anti-AQP4 antibody positive
2. Documentation that other alternative diagnoses have been excluded (such as Multiple Sclerosis)
3. For Commercial members: Trial and failure, intolerance, or contraindication to rituximab
4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
5. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
3. Dose and frequency are in accordance with FDA-approved labeling

**AGE RESTRICTION**
May be approved for patients aged 18 years and older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization will be approved for six months. Reauthorization will be approved for one year.
OTHER CRITERIA
N/A
UPNEEQ

MEDICATION(S)
UPNEEQ

COVERED USES
N/A

EXCLUSION CRITERIA
• Congenital ptosis
• Horner syndrome
• Myasthenia gravis
• Mechanical ptosis
• Visual field loss from any cause other than ptosis

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Documentation of acquired blepharoptosis,
2. Documentation of a superior visual field deficit [e.g., inability to detect at least 8 of 17 points in the top two rows on the Leicester Peripheral Field Test (LPFT)],
3. Marginal reflex distance 1 (MRD-1) of less than or equal to two (2) mm.

Reauthorization requires documentation of improvement in visual field deficit

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an ophthalmologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A
VAGINAL PROGESTERONE FORMULATIONS

MEDICATION(S)
CRINONE, ENDOMETRIN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For Prevention of Preterm birth or Pregnancy Support:
   a. One of the following:
      i. Documentation of current pregnancy, or
      ii. Documentation of a history of prior pregnancy loss or spontaneous preterm birth, or
      iii. Documentation of short cervix.
   b. For Crinone® gel: Documented medical rationale for use of the requested agent over Endometrin®.
2. For use for luteal support: Endometrin® will be approved if the member’s benefit covers infertility treatments.
   a. Crinone® gel may be approved for infertility due to secondary amenorrhea if the member’s benefit covers infertility treatments and there is a documented trial and failure, intolerance or contraindication to Endometrin®

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gynecologist, urologist, or endocrinologist

COVERAGE DURATION
Authorization will be approved for one year

OTHER CRITERIA
N/A
MEDICATION(S)
ICOSAPENT ETHYL, VASCEPA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Hypertriglyceridemia all the following must be met:
1. Trial and failure (defined as at least two months of therapy), intolerance, or contraindication to one of the following formulary agents to treat very high triglycerides: fenofibrate or gemfibrozil.
2. A triglyceride level within the past six months that is greater than 500 mg/dL.

For ASCVD Risk Prevention all of the following must be met:
1. One of the following:
a. Established atherosclerotic heart disease as defined as one or more of the following:
i. Documented multivessel coronary artery disease (equal or greater than 50% stenosis in at least two major epicardial coronary arteries), prior myocardial infarction (MI), or hospitalization for non-ST elevation acute coronary syndrome.
ii. Documented cerebrovascular or carotid artery disease
iii. Documented peripheral arterial disease OR
b. Diabetes mellitus and two or more of the following additional risk factors for cardiovascular disease:
i. Age 50 years or older
ii. Hypertension
iii. High-density lipoprotein cholesterol (HDL-C) equal to or less than 40 mg/dL for men or equal to or less than 50 mg/dL for women
iv. High-sensitivity C-reactive protein (hs-CRP) greater than 3.0 mg/dL
v. Reduced kidney function (eGFR less than 60 mL/min per 1.73m2)
vi. Current cigarette smoker or recently quit smoking cigarettes within the past three months
vii. Retinopathy
viii. Micro- or macro-albuminuria
ix. Ankle-brachial index less than 0.9 without symptoms of intermittent claudication
2. Current use of a high-intensity statin therapy for at least four weeks or documentation of statin intolerance, defined as one of the following:
a. Rhabdomyolysis
b. Skeletal muscle related symptoms while receiving separate trials of at least two different statins with resolution of symptoms after discontinuation

c. Elevated liver enzymes while on separate trials of at least two different statins with resolution after discontinuation

3. A triglyceride level within the past six months that is equal to or greater than 150 mg/dL.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

**OTHER CRITERIA**
N/A
VEREGEN

MEDICATION(S)
VEREGEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented trial, failure, intolerance, or contraindication to imiquimod 5% cream packets (Aldara®).

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for four months. Reauthorization will not be approved, since safety and effectiveness beyond 16-weeks, or for multiple treatment courses has not been established.

OTHER CRITERIA
N/A
VERKAZIA

MEDICATION(S)
VERKAZIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization requires documentation of all the following:
1. Clinical diagnosis of vernal keratoconjunctivitis (H16.26)
2. Documentation of inadequate response to a trial (defined as at least three weeks of consistent use) of two of the following topical mast cell stabilizer eye drops: olopatadine, azelastine, epinastine, ketotifen fumarate, cromolyn, nedocromil (Alocril®), or lodoxamide (Alomide®). Note that olopatadine and ketotifen are available over-the-counter (OTC).
3. Documentation of inadequate response to a trial (defined as at least three weeks of consistent use) one of the following second- or third-generation oral antihistamines: fexofenadine, loratadine, desloratadine, cetirizine, and levocetirizine. Note that all are available OTC, except for desloratadine)

Reauthorization requires documentation of positive clinical response to therapy.

AGE RESTRICTION
May be covered for patients aged four years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for six (6) months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
MEDICATION(S)
VERQUVO

COVERED USES
N/A

EXCLUSION CRITERIA
Current pregnancy or plan to become pregnant while on therapy

REQUIRED MEDICAL INFORMATION
For chronic heart failure, all the following criteria must be met:
1. Documentation of symptomatic heart failure (NYHA Class II-IV) with a left ventricular ejection fraction (LVEF) less than 45%
2. On maximally tolerated guideline-directed therapy for at least six months including all the following, unless contraindicated or intolerant:
   a. Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol)
   b. SGLT-2 (specifically empagliflozin or dapagliflozin)
   c. One of the following:
      i. Angiotensin-converting enzyme (ACE) inhibitor, such as lisinopril,
      ii. Angiotensin II receptor blocker (ARB), such as losartan,
      iii. Angiotensin receptor-neprilysin inhibitor (ARNI), such as sacubitril/valsartan (Entresto®)
3. On maximally tolerated therapy with the following, as clinically appropriate:
   a. Aldosterone antagonists for patients with symptoms despite maximally tolerated therapy above
   b. Diuretic therapy for symptomatic patients with persistent volume overload
4. Documentation of clinical worsening of heart failure, defined as one of the following, despite maximal therapy as outlined above:
   a. Hospitalization for heart failure within the previous six months
   b. Need for outpatient intravenous diuretic therapy within the previous three months

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a cardiologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
OTHER CRITERIA
N/A
VIBERZI

MEDICATION(S)
VIBERZI

COVERED USES
N/A

EXCLUSION CRITERIA
Patients without a gallbladder

REQUIRED MEDICAL INFORMATION
1. Diagnosis of Irritable Bowel Syndrome with Diarrhea (IBS-D) 
AND
2. Documentation of trial and failure, contraindication, or intolerance to medication from each of the following drug classes:
   a. Tricyclic antidepressants [e.g., amitriptyline (Elavil®)]
   b. Opioid mu receptor agonists [e.g., loperamide (Imodium®), diphenoxylate (Lomotil®)]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
 REQUIRED MEDICAL INFORMATION
Initial authorization requires criteria 1-3 to be met:
1. Confirmed diagnosis of PIK3CA-related overgrowth spectrum (PROS) as defined by meeting criteria A-D:
   a. Presence of somatic PIK3CA mutation
   b. Congenital or early childhood onset
   c. Overgrowth sporadic or mosaic (other terms: patchy, irregular)
   d. Clinical features as described in either a or b:
      i. Spectrum (require two or more of the following):
         • Overgrowth (adipose, muscle, nerve, skeletal)
         • Vascular malformations (capillary, venous, arteriovenous malformations, lymphatic)
         • Epidermal nevus
      OR
      ii. Isolated features (one of the following):
         • Large isolated lymphatic malformation
         • Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs
         • Truncal adipose overgrowth
         • Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia
         • Epidermal nevus
         • Seborrheic keratoses vii. Benign lichenoid keratoses large,
   AND
2. Patient has at least one target lesion identified on imaging,
   AND
3. Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician.

Reauthorization requires criteria 1 and 2 to be met:
1. At least a 20% reduction from baseline in the sum of measurable target lesion volume (1 to 3 lesions)
confirmed by at least one subsequent imaging assessment, AND
2. Absence of a 20% or greater increase from baseline in any target lesion, progression of non-target lesions, or appearance of a new lesion.

AGE RESTRICTION
Approved for patients two years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a specialist in treating PROS

COVERAGE DURATION
Initial authorization and reauthorization will be approved for six months

OTHER CRITERIA
N/A
VMAT2 INHIBITORS

MEDICATION(S)
AUSTEDO, INGREZZA, INGREZZA INITIATION PACK, TETRABENAZINE, XENAZINE

COVERED USES
N/A

EXCLUSION CRITERIA
• Active suicidality
• Untreated or inadequately treated depression
• Hepatic Impairment
• Use in combination with monoamine oxidase inhibitors, other VMAT2 inhibitors or reserpine

REQUIRED MEDICAL INFORMATION
1. For chorea associated with Huntington disease [tetrabenazine (Xenazine®) or deutetrabenazine (Austedo®) only]
   a. Initiation of therapy requires all of the following must be met:
      i. Diagnosis of Huntington Disease confirmed by all of the following:
         1. DNA testing showing CAG expansion of more than 36, AND
         2. Family history (if known), AND
         3. Classic presentation (choreiform movements, psychiatric problems, and dementia), AND
      ii. Documentation that chorea is causing functional impairment, AND
      iii. For deutetrabenazine (Austedo®): Documented trial (of at least eight weeks) and failure or intolerance to tetrabenazine.
   b. For reauthorization: Documented benefit of therapy, as evidence by improved function through reduction in choreiform movements.

2. For Tardive Dyskinesia
   a. For initiation of therapy, all of the following criteria must be met:
      i. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent (e.g. first or second generation antipsychotics, metoclopramide), AND
      ii. Documentation of moderate to severe tardive dyskinesia that is causing functional impairment, defined as an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of items 1 through 9 (see supplemental information) OR tardive dyskinesia that is interfering with activities of daily living (ADLs), AND
      iii. For deutetrabenazine (Austedo®) and valbenazine (Ingrezza®): Documented trial (of at least eight weeks) and failure or intolerance of tetrabenazine.
   b. For reauthorization: Documentation of positive clinical response to therapy, as demonstrated by improved function or activities of daily living (ADLs), or a decrease in AIMS score
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist or psychiatrist.

COVERAGE DURATION
Initial prior authorization will be approved for three months. Reauthorization may be approved for one year.

OTHER CRITERIA
N/A
**VOXZOGO**

**MEDICATION(S)**
VOXZOGO

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
- History of bone-related surgery or fracture of long bone or spine within the previous six months
- Planned bone surgery

**REQUIRED MEDICAL INFORMATION**
Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services

For initial authorization, ALL the following criteria must be met:
1. Documentation of confirmed diagnosis of achondroplasia (Q77.4) through genetic testing  
   AND
2. Documentation of a baseline annual growth velocity (AGV)  
   AND
3. Current annual growth velocity greater than or equal to 1.5 cm/year (0.6 in/year)  
   AND
4. Evidence of open epiphyses, defined as follows:
   a. Tanner stage less than 4  
   OR
   b. Bone age less than 16 years in male or less than 14 years in female. Bone age must be obtained annually when chronologic age reaches 15 years in male or 13 years in female  
   AND
5. Person is ambulatory and able to stand without assistance

For reauthorization, ALL of the following criteria must be met:
1. Documentation of an improvement in annual growth velocity of greater than or equal to 1.0 cm/year from baseline (for example, if baseline AGV is 2.0 cm/year, 3.0 cm/year is required for reauthorization)  
   AND
2. Current growth velocity greater than or equal to 1.5 cm/year (0.6 in/year)  
   AND
3. One of the following:
a. Tanner stage less than 4

OR

b. Bone age less than 16 years in male or less than 14 years in female. Bone age must be obtained annually when chronologic age reaches 15 years in male or 13 years in female

AND

4. Person is ambulatory and able to stand without assistance

AGE RESTRICTION
Approved for children ages five years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a pediatric endocrinologist or other prescriber specialized in the care of patients with achondroplasia or skeletal dysplasia.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year. Shorter reauthorization period may be approved based on slowing of growth velocity or bone age approaching epiphyseal closure.

OTHER CRITERIA
N/A
VTAMA/ZORYVE

MEDICATION(S)
VTAMA, ZORYVE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following must be met:
1. Diagnosis of severe psoriasis (for adults 21 years of age and older) as defined by all the following:
   a. Documentation that patient is having functional impairment as indicated by one of the following:
      i. Dermatology Life Quality Index (DLQI) of at least 11
      ii. Children’s Dermatology Life Quality Index (CDLQI) of at least 13
      iii. Severe score on other validated tool
   b. Documentation of one of the following:
      i. At least 10% of body surface area involved
      ii. Hand, foot, face, or mucous membrane involvement
2. Documentation of inadequate efficacy, intolerable side effects, or contraindication to the following:
   a. For mild to moderate psoriasis (children less than 21 years of age only), two of the following:
      i. Four-week trial of moderate to high potency topical corticosteroid
      ii. Four-week trial of topical vitamin D analogues (calcitriol, calcipotriene)
      iii. Eight-week trial of tazarotene
      iv. Eight-week trial of calcineurin inhibitor (tacrolimus, pimecrolimus)
   b. For severe psoriasis: Four-week trial of at least two different high to super-high potency topical corticosteroids

For reauthorization, must have documentation of response to therapy indicating improvement or stabilization of condition

AGE RESTRICTION
Vtama® - Approved for patients 18 years and older
Zoryve® - Approved for patients 12 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
Vuity

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pilocarpine 1.25% ophthalmic solution (Vuity®) is not considered medically necessary and will not be covered as corrective lenses (reading glasses) are available over-the-counter (OTC) or covered through vision benefit, if available.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
N/A
MEDICATION(S)
VYLEESI

COVERED USES
N/A

EXCLUSION CRITERIA
• Uncontrolled hypertension
• Known cardiovascular disease

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet ALL of the following criteria:
1. Patient is female and premenopausal
AND
2. Diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) or Female Sexual Interest/Arousal Disorder (FSIAD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty for at least six months and is NOT due to:
   a. A co-existing medical condition (such as sexual pain, bladder dysfunction, endocrine disorders, and central nervous system disease)
   b. A co-existing psychiatric condition (such as depression, anxiety, history of physical or sexual abuse, and alcohol use)
   c. A co-existing psychological condition (such as loss of income and bereavement)
   d. Problems within the relationship
   e. The effects of a medication or drug substance

Reauthorization requires documentation that the patient continues to be pre-menopausal and has had a positive response to the medication

AGE RESTRICTION
Approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for eight weeks and reauthorization will be approved for one year

OTHER CRITERIA
VYVGART

MEDICATION(S)
VYVGART

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Generalized Myasthenia Gravis (gMG), all the following must be met (1-5):
1. Anti-acetylcholine receptor (anti-AChR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
3. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of five or greater
4. History of failure of at least two immunosuppressive agents over the course of at least 12 months (such as azathioprine, methotrexate, cyclosporine, mycophenolate, corticosteroids) or has an intolerance or contraindication to these therapies
5. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization for Generalized Myasthenia Gravis (gMG), all the following must be met (1-2):

1. Documentation of improvement in MG-ADL by at least two points from baseline

2. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist or rheumatologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
WEIGHT MANAGEMENT MEDICATIONS

MEDICATION(S)
ADIPEX-P, CONTRAVE, PHENTERMINE 15 MG CAPSULE, PHENTERMINE 30 MG CAPSULE, PHENTERMINE 37.5 MG CAPSULE, PHENTERMINE 37.5 MG TABLET, QSYMIA, SAXENDA, WEGOVY

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
For liraglutide (Saxenda®) and semaglutide (Wegovy®): Concurrent use with another GLP-1 receptor agonist for any indication

REQUIRED MEDICAL INFORMATION
1. For initiation of therapy, all the following criteria must be met:
   a. Patient is less than 21 years of age,
   b. Documentation of current height and weight (measured within the previous month) indicating one of the following:
      i. Body mass index (BMI) in the 95th percentile or greater, standardized for age and sex
      Note: Lower BMI thresholds (usually reduced by 2.5) should be considered for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds,
   c. Documentation that the condition is of sufficient severity that it impacts the patient’s health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc).
2. For continuation of therapy, all the following criteria must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.):
   a. Patient is less than 21 years of age,
   b. Patient achieved and maintained at least a 5% weight loss from baseline body weight while on the requested medication.

AGE RESTRICTION
Per FDA label for the requested medication

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
XERMELO

MEDICATION(S)
XERMELO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All the following criteria must be met:
1. Diagnosis of carcinoid syndrome diarrhea
2. Inadequately controlled diarrhea despite use, for at least three months, of a long-acting somatostatin analog therapy such as octreotide LAR (Sandostatin LAR®) or lanreotide (Somatuline®)
3. Documentation that long-acting somatostatin analog therapy will be used in combination with the requested medication

Reauthorization will require documentation of positive clinical response to therapy

AGE RESTRICTION
Age 18 years or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A
MEDICATION(S)
XHANCE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Diagnosis of nasal polyps
2. ONE of the following:
   a. Patient has tried and had an inadequate response to a three month trial of a formulary generic or over-the-counter (OTC) intranasal corticosteroid (for example, fluticasone, mometasone, flunisolide), or
   b. Patient has a documented intolerance or hypersensitivity to therapy with generic or OTC intranasal corticosteroids that are not expected to occur with the requested agent, or
   c. Patient has a contraindication to ALL generic or OTC intranasal corticosteroids that is not expected to occur with the requested agent

Reauthorization: Documentation of clinical benefit with the requested agent (such as a decrease in nasal congestion, decrease in pain, decrease in pressure, decrease in rhinorrhea, increased sense of smell, or decrease in nasal polyps)

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an allergist, pulmonologist or head and neck surgeon (Ear Nose and Throat [ENT] specialist)

COVERAGE DURATION
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
XIAFLEX

COVERED USES
N/A

EXCLUSION CRITERIA
• PD involving the urethra.
• More than three total injections per affected cord for DC
• More than eight total injections per lifetime for PD.

REQUIRED MEDICAL INFORMATION
Initial Authorization Criteria:

For Dupuytren’s contracture (DC):
1. Both of the following diagnostic criteria:
   a. Finger flexion contracture of at least 20° with a palpable cord in a metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint
   b. Documentation of a positive “table top test,” defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top
2. Documentation that affected joint has not had surgical intervention within the previous 90 days

For Peyronie’s disease (PD):
1. Patient’s disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a curvature of the penis that is between 30 and 90 degrees with a palpable cord, or a cord that is documented through ultrasound
3. Patient has intact erectile function, with or without the use of medications
4. Documentation of a functional impairment that is expected to improve with treatment (e.g., inability to have intercourse despite intact erectile function, due to curvature)
5. Documentation showing the patient does not have any of the following:
   a. Significant pain with palpation of the plaque
   b. Lack of full erectile response to prostaglandin E1 during curvature measurement
   c. Ventral curvature
   d. Calcified plaque
   e. Plaque located proximal to the base of the penis
6. Documentation that the patient has been counseled on expectations of treatment (e.g., expected average curvature reduction is 17 degrees without reduction in pain or erectile dysfunction, potential for adverse
Reauthorization Criteria:
For DC:
1. Documentation of fewer than three total injections in affected cord.

For PD
1. Documentation that the curvature of the penis remains greater than 15 degrees. Limited to eight total injections per lifetime.

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For DC:
Initial authorization will be approved for three months for a maximum of three treatment courses. Reauthorization will be approved for three months, not to exceed three injections per affected cord.

For PD:
Initial authorization will be approved for three months, not to exceed four injections. Reauthorization will be approved for six months, not to exceed eight injections per lifetime.

OTHER CRITERIA
N/A
MEDICATION(S)
XIFAXAN

COVERED USES
N/A

EXCLUSION CRITERIA
More than three treatment courses in a rolling 6-month period for IBS-D.

REQUIRED MEDICAL INFORMATION
Traveler’s diarrhea (200 mg tablets):
1. Diagnosis of traveler’s diarrhea caused by noninvasive strains of Escherichia coli. Xifaxan® is not covered if documentation shows diarrhea that is complicated by fever or blood in stool.

Hepatic Encephalopathy (550 mg tablets):
1. Documentation of trial and failure, contraindication, or intolerance to lactulose

Irritable Bowel Syndrome with Diarrhea (IBS-D) with or without small intestinal bacterial growth (SIBO) for 550 mg tablets):
1. Documentation of trial and failure, contraindication, or intolerance to a tricyclic antidepressant [such as amitriptyline (Elavil®)]

Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms. Limited to three total 14-day course treatments per rolling 6-month period (initial treatment and two reauthorizations).
• A response is defined as a 50% or more decrease from baseline in number of days per week with loose and watery stool AND improvement in abdominal pain for at least 2 out of 4 weeks after treatment
• A recurrence is defined as a loss of treatment response for either weekly abdominal pain or stool consistency for at least 3 weeks of a consecutive, rolling 4-week period

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For irritable bowel syndrome with diarrhea (IBS-D): Must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION
IBS-D (550 mg tablets):
Initial authorization: One-time 14-day treatment course per three months
Reauthorization: Will be approved for up to two additional 14-day treatment courses (total of three treatment courses within six months)

Traveler’s diarrhea (200 mg tablets): One-time three-day treatment course (Quantity of nine tablets)

Hepatic Encephalopathy (550 mg tablets): Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

OTHER CRITERIA
N/A
MEDICATION(S)
XOLAIR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with anti-IL5 (such as mepolizumab, reslizumab, benralizumab), anti-IgE, anti-TSLP (such as tezepelumab), or anti-IL4 (such as dupilumab) monoclonal antibodies

REQUIRED MEDICAL INFORMATION
For asthma, must meet all of the following criteria:
1. Diagnosis of moderate to severe persistent allergic asthma
2. IgE baseline levels greater than 30 IU/ml
3. Positive skin test to a common perennial aeroallergens
4. Documentation that in the past three months patient is adherent to a combination of a medium/high-dose inhaled corticosteroids and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)
5. Documentation of inadequate asthma control despite above therapy, defined as one of the following:
   a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
   b. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months
   c. At least one exacerbation requiring hospitalization
Reauthorization for asthma requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

A. Asthma
1. For patients initiating therapy, all the following criteria must be met:
   a. Diagnosis of moderate to severe persistent allergic asthma
   b. IgE baseline levels greater than 30 IU/ml
   c. Positive skin test to a common perennial aeroallergens
   d. Documentation that, in the past three months, patient is adherent to treatment with maximally tolerated doses of both of the following, taken concurrently, unless patient has an intolerance to an inhaled steroid and a LABA, LTRA, or LAMA or has a contraindication to ALL therapies (This may be verified by pharmacy claims information):
      i. Inhaled corticosteroid
      ii. One of the following:
1) A long-acting inhaled beta 2-agonist (LABA)
2) A leukotriene receptor antagonist (LTRA)
3) A long-acting muscarinic antagonist (LAMA)

e. Documentation of inadequate asthma control despite above therapy, defined as one of the following:
   i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
   ii. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months
   iii. At least one exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months
   iv. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
   v. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted

2. For patients established on therapy for asthma: Documentation of response to therapy indicating improvement or stabilization of condition

B. Chronic Spontaneous (Idiopathic) Urticaria
1. For initial authorization, one of the following criteria (a or b) must be met:
   a. All of the following criteria must be met:
      i. Patient has had over 6 weeks of hives and itching
      ii. Documentation that the condition is idiopathic and that secondary causes of urticaria (such as offending allergens, physical contact, etc.) have been ruled out
      iii. Trial and failure of a second-generation non-sedating H1 antihistamine (such as levocetirizine, loratadine, cetirizine, fexofenadine)
      iv. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (such as montelukast), first generation H1 antihistamine (such as diphenhydramine), or histamine H2-receptor antagonist (such as famotidine, ranitidine)
   b. For Medicaid members under the age of 21, all of the following criteria must be met:
      i. Documentation that the urticaria is of sufficient severity that it impacts the patient’s health (such as quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)
      ii. Trial and failure of a second-generation non-sedating H1 antihistamine (such as loratadine, cetirizine)
      iii. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (such as montelukast), first generation H1 antihistamine (such as diphenhydramine), or histamine H2-receptor antagonist (such as famotidine)

2. For reauthorization for chronic spontaneous urticaria: Documentation of response to therapy indicating improvement or stabilization of condition

C. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
1. For initial authorization, all of the following criteria must be met:
a. Evidence of bilateral nasal polyposis by direct examination, endoscopy or sinus CT scan
b. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (such as fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
c. Documentation that patient will continue standard maintenance therapy (such as intranasal corticosteroids, nasal saline irrigation) in combination with omalizumab

2. For reauthorization for CRWsNP: Documentation of response to therapy indicating improvement or stabilization of condition

AGE RESTRICTION
• Asthma: May be approved for patients six years of age or older
• Urticaria: May be approved for patients 12 years of age or older
• Chronic rhinosinusitis with nasal polyps: May be approved for patients 18 years of age or older

PRESCRIBER RESTRICTION
Asthma: Must be prescribed by, or in consultation with, an asthma specialist (such as a pulmonologist, immunologist, or allergist)

Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist

Chronic rhinosinusitis with nasal polyps: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist or immunologist

COVERAGE DURATION
Asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

Urticaria: Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
• For Medicaid members under the age of 21: Initial authorization and reauthorization will be approved for one year or until the member reaches the age of 21, whichever is the shortest duration.

Chronic rhinosinusitis with nasal polyps: Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEDICATION(S)
ZEPOSIA

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with another TIM agent (such as apremilast, adalimumab)

REQUIRED MEDICAL INFORMATION
For initial authorization for multiple sclerosis (MS), all the following criteria must be met:
1. Must have one of the following confirmed diagnoses:
   a. Relapsing-remitting disease (RRMS)
   b. Secondary progressive multiple sclerosis (SPMS)
   c. Clinically isolated syndrome (CIS)
2. One of the following (a or b):
   a. Highly active disease, defined as both of the following:
      i. Two or more relapses in the previous year, and
      ii. One of the following:
         1) The patient has at least one gadolinium enhancing lesion of MRI, OR
         2) The patient has significant increase in T2 lesion load compared with a previous MRI, OR
         3) The patient has been treated with at least three MS agents from different drug classes
   b. Documented inadequate response or intolerance to generic dimethyl fumarate or generic glatiramer, or contraindication to BOTH dimethyl fumarate and glatiramer
3. The prescriber has performed an electrocardiogram within six months prior to initiating treatment

Initial Authorization for ulcerative colitis (UC), all the following criteria must be met:
1. Documentation of moderately to severely active disease
2. Documentation of one of the following:
   a. Trial and failure, or intolerance to one of the following conventional therapies for UC: 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, or sulfasalazine, OR
   b. Documented FDA labeled contraindication to ALL the therapies outlined above, OR
   c. Documentation of history of use of another therapeutic immunomodulatory (TIM) agent for the treatment of UC, TIM must be FDA labeled or compendia supported for the treatment of UC
3. Documentation of one of the following:
   a. Inadequate response or intolerance to two of the following preferred TIM agents: Humira® (adalimumab), infliximab biosimilars (Renflexis® and Inflectra®), or vedolizumab (Entyvio®)
b. FDA Labeled contraindication to ALL the therapies outlined above (3.a.)
4. The prescriber has performed an electrocardiogram within six months prior to initiating treatment

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist (for MS) or gastroenterologist (for UC)

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
ZINPLAVA - MEDICAL BENEFIT

MEDICATION(S)
ZINPLAVA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All the following criteria must be met for Clostridioides difficile infection (CDI):
1. Previous trial of standard-of-care antibiotic regimen for recurrent CDI (such as oral vancomycin, fidaxomicin)
2. Bezlotoxumab (Zinplava®) must be used in combination with standard-of-care antibiotics for treatment (such as oral vancomycin, fidaxomicin)
3. Dosing is within Food and Drug Administration’s approved labeling
4. For Commercial/Medicare Part B only: Patient has at least one risk factor for higher likelihood of recurrent CDI [for example, age of 65 years or older, history of CDI in the previous six months, compromised immunity, clinically severe CDI (defined as a Zar score greater than or equal to 2, scores range from 1 to 8, with higher scores indicating more severe infection)]

Reauthorization requires all the following criteria to be met:
1. Previous dose was at least 12 months prior
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline
3. Bezlotoxumab (Zinplava®) is used in combination with standard-of-care antibiotics for treatment (such as oral vancomycin, fidaxomicin)
4. Dosing is within Food and Drug Administration’s approved labeling

AGE RESTRICTION
Approved for 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for a one-time intravenous
OTHER CRITERIA
N/A
ZOLGENSMA

MEDICATION(S)
ZOLGENSMA

COVERED USES
N/A

EXCLUSION CRITERIA
- Use in combination with nusinersen (Spinraza®) or risdiplam (Evrysdi®) therapy
- Repeat infusion of onasemnogene abeparvovec
- Advanced symptoms of SMA (such as, complete paralysis of limbs, tracheostomy or ongoing invasive ventilator support in the absence of an acute reversible illness)

REQUIRED MEDICAL INFORMATION
1. Confirmed genetic diagnosis of spinal muscular atrophy (SMA) with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to three copies of SMN2
2. Documentation that premedication with prednisolone 1 mg/kg/day (or equivalent) will be started 24 hours prior to infusion and continue for at least 30 days
3. Documentation of baseline anti-AAV9 antibody titers of less than or equal to 1:50
4. Documentation of baseline tests for liver function, platelet count, and troponin-I

AGE RESTRICTION
May be covered for patients two years of age and under

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
Authorization will be approved for a one-time infusion

OTHER CRITERIA
N/A
ZTALMY

MEDICATION(S)
ZTALMY

COVERED USES
All Food and Drug Administration (FDA) approved indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria must be met:
1. Diagnosis of CDKL5 deficiency disorder (CDD) confirmed with genetic testing
2. Documented trial and failure with three or more antiepileptic drugs
3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
4. The dose requested is within FDA labeled dosing based on the patient’s weight (patient’s weight must be provided)

For patients established on therapy, the following criteria must be met:
1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
2. The dose requested is within FDA labeled dosing based on the patient’s weight (updated weight must be provided)

AGE RESTRICTION
The patient’s age must be within FDA labeling for the requested indication

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
ZYNTEGLO

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For beta-thalassemia, Zynteglo® may be approved when all the following criteria are met:
1. Documented diagnosis of beta-thalassemia confirmed by genetic testing
2. Patient has transfusion-dependent disease defined as one of the following:
   a. History of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs)
   b. Eight or more transfusions of pRBCs per year in the two years preceding therapy
3. Patient is clinically stable and eligible to undergo the pre-conditioning regimen and infusion regimen
4. Patient does not have any of the following:
   a. Prior history of receiving a hematopoietic stem-cell transplant
   b. Prior history of receiving gene therapy for the requested indication
   c. Advanced liver disease (such as evidence of cirrhosis and/or persistent alanine aminotransferase, aspartate transferase or direct bilirubin values greater than three times the upper limit of normal)
   d. Evidence of severe iron overload (such as T2* less than 10 ms by magnetic resonance imaging (MRI) or other evidence of severe iron overload in the opinion of treating physician)

AGE RESTRICTION
May be approved for patients aged four years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist

COVERAGE DURATION
Authorization will be limited to one treatment course per lifetime

OTHER CRITERIA
N/A