

Yamhill  
Community Care  
Pharmacy Prior Authorization Criteria  
2021



## ACNE MEDICATIONS

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### MEDICATION(S)

ACCUTANE, ACNE CONTROL CLEANSER, ACNE FOAMING WASH, ACNE MEDICATION 10% GEL, ACNE MEDICATION 5% GEL, ACNE TREATMENT, ACNECLEAR, ADAPALENE 0.1% GEL, ADAPALENE 0.3% GEL, ADVANCED EXFOLIATING CLEANSER, AMNESTEEM, ATRALIN, AVITA 0.025% CREAM, BENZACLIN, 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 ADAPALENE, 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, KLARON, MYORISAN, NEUAC GEL, PACNEX, 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. For acne: Documentation that patient has one of the following conditions (must be supported by chart notes):
  - a. Acne Fulminans
  - b. Acne Conglobata with recurrent abscesses or communicating sinuses
  - c. 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**

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## **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. 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®: For patients not established on therapy only: Documentation of trial and failure or contraindication to generic icatibant

For patients established on the requested therapy,

Documentation must be provided showing benefit of therapy with reduction of length and severity of HAE attack episodes.

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

# ADAKVEO

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## 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

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (such as dupilumab, upadacitinib, and abrocitinib)

## REQUIRED MEDICAL INFORMATION

For initial authorization, must meet all of the following criteria:

1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 and 3 below, as defined by all of the following:
  - a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot, or mucous membrane involvement)
  - b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification
  - c. Chronic condition, affecting patient for more than one year
2. Documented trial and failure of an adequate treatment course with at least one agent from all of the following conventional treatment modalities:
  - 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
  - c. For Medicaid only: Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate, mycophenolate, or oral corticosteroids) for at least two months unless contraindicated
  - d. For Medicaid only: Documentation that patient is having functional impairment due to atopic dermatitis (such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)

For reauthorization, all of the following criteria must be met:

1. Documentation of reduction or stabilization from baseline of flares, pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, lichenification or affected BSA
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



# **ADDYI**

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## **MEDICATION(S)**

ADDYI

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Sexual dysfunction without a diagnosis listed above.

## **REQUIRED MEDICAL INFORMATION**

For initial authorization, all of 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) that is causing marked distress or interpersonal difficulty
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 of 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

## **AEMCOLO**

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### **MEDICATION(S)**

AEMCOLO

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

Use for travel (when a member has not already acquired travelers' diarrhea) is a benefit exclusion for the Oregon Health Plan and is excluded from coverage.

### **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.

### **QUANTITY LIMIT:**

12 tablets per 28 days

### **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

# **ALBENZA, EMVERM**

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## **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 (i.e., guideline directed therapy or compendia supported as listed in either the American Hospital Formulary System or Drugdex).
  - ii. Must be prescribed by or in consultation with an infectious disease specialist.\*

\*Requirement that therapy is prescribed by or in consultation with an infectious disease specialist may be waived if diagnosis has been confirmed through validated laboratory testing/identification.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

See "Required Medical Information"

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for 3 months.

## **OTHER CRITERIA**

N/A

# ALINIA

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## MEDICATION(S)

ALINIA, NITAZOXANIDE 500 MG TABLET

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For diarrhea caused by *Cryptosporidium*:

1. Confirmed diagnosis of *Cryptosporidium parvum*

AND

2. For therapy greater than 3 days, up to 14 days: documentation that patient is HIV positive

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 (i.e., 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 3 to 10 days depending on appropriate treatment duration for the diagnosis.

## QUANTITY LIMIT:

Nitazoxanide (Alinia®) 500 mg tablets: 2 tablets per day

Nitazoxanide (Alinia®) 100 mg/ 5 ml suspension: 50 mL per day

## 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 3 days.

For diarrhea caused by *Cryptosporidium parvum* in patients that are HIV positive: authorization will be approved for 14 days.

For all other indications: authorization will be approved for 3 to 10 days depending on diagnosis.

**OTHER CRITERIA**

N/A

# ALPHA-1 PROTEINASE INHIBITORS

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## 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

# AMIFAMPRIDINE

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## MEDICATION(S)

FIRDAPSE, RUZURGI

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial authorization (all of 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), and
5. Documented trial (of at least one month) and failure or intolerance of pyridostigmine.
6. For Firdapse®: Documented trial and failure of Ruzurgi®

Reauthorization:

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

## AGE RESTRICTION

N/A

## 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



## ANTIFUNGAL AGENTS

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### MEDICATION(S)

CRESEMBA 186 MG CAPSULE, ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE, ITRACONAZOLE 100 MG/10 ML CUP, NOXAFIL 40 MG/ML SUSPENSION, NOXAFIL DR 100 MG TABLET, POSACONAZOLE, SPORANOX, VFEND, 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. Documented failure, intolerance, or contraindication to generic terbinafine

AND

b. One of the following criteria must be met:

- i. Use is for an immunocompromised patient (e.g., current chemotherapy/radiation, HIV/AIDS)
- ii. A fungal infection of the extremity in the presence of a severe circulatory disorder
- iii. A diabetic and fungal state that poses significant risk unless treated with systemic antifungal therapy
- iv. An infected nail that cannot be removed and leads to recurrent cellulitis (more than one episode)
- v. Pain limiting normal activity

6. For dermatomycosis (itraconazole only):

- a. Documentation that the treatment area is large enough or in multiple locations such that it is not practically treated with topical agents

OR

b. Documentation of trial and failure, intolerance, or contraindication to topical therapy 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

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, an infectious disease specialist, hematologist, oncologist, or pulmonologist for all indication except onychomycosis or dermatomycosis

## **COVERAGE DURATION**

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

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: COARTEM, DARAPRIM**

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### **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 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

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## 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

# **BENLYSTA**

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## **MEDICATION(S)**

BENLYSTA

## **COVERED USES**

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 no 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 initial authorization for Systemic Lupus Erythematosus (SLE) and active lupus nephritis, all of 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
    - v. Hydroxychloroquine
    - vi. Chloroquine

vii. 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)

Reauthorization:

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**

For SLE without active lupus nephritis:

Age five years and older for IV infusion

Age 18 years and older for subcutaneous injection

For SLE with Active Lupus Nephritis:

Age 18 years and older for IV infusion or subcutaneous injection

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or nephrologist

### **COVERAGE DURATION**

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

### **OTHER CRITERIA**

N/A

# **BOTULINUM TOXIN**

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## **MEDICATION(S)**

JEUVEAU

## **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.
  - o 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 (i.e., 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

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

6. Overactive bladder in adults with:

a. Symptoms of urge urinary incontinence, urgency, and frequency

b. 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:

a. Due to detrusor over activity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis)

b. 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:

a. Prescribed by, or in consultation with, a gastroenterologist or colorectal surgeon

b. Documentation of trial and failure, intolerance, or contraindication to at least six weeks of therapy with either topical nitrates or topical calcium channel blockers

c. One of the following:

i. Documentation that the patient is not a good candidate for surgery or appropriate medical rationale is provided for avoiding surgery

ii. Botox® is to be used in conjunction with fissurotomy

d. 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)

a. The use of Botox® in combination with pneumatic dilation is considered experimental and investigational and will not be covered

AbobotulinumtoxinA (Dysport®) may 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 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 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**

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### **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

## **BRINEURA - MEDICAL BENEFIT**

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### **MEDICATION(S)**

BRINEURA

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For initial authorization all the following criteria must be met:

1. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) confirmed by both of the following:
  - a. Deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity (in a sample of leukocytes, fibroblasts, dried blood spot or saliva)
  - b. Genetic testing revealing one pathogenic mutation on each parental allele of TPP1/CLN2 gene
2. Documentation of symptomatic disease (e.g., seizures, changes in gait, falls, difficulty in ambulating, loss of language/delay in language development, visual failures)
3. Baseline Motor Domain of the CLN2 Clinical Rating Scale score of at least one (1)

Reauthorization requires documentation of response to therapy, defined as both of the following:

1. No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale
2. Motor Domain of the CLN2 Clinical Rating Scale score remains above zero

### **AGE RESTRICTION**

May be covered for ages 3-17 years

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist or medical geneticist

### **COVERAGE DURATION**

Initial approval and reauthorization will be for 1 year

### **OTHER CRITERIA**

N/A

# **BUPRENORPHINE - PROBUPHINE/SUBLOCADE - MEDICAL BENEFIT**

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## **MEDICATION(S)**

PROBUPHINE, SUBLOCADE

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Treatment of chronic pain

## **REQUIRED MEDICAL INFORMATION**

For Probuphine®:

Initial Authorization:

1. Documentation of opioid use disorder
2. Patient has been clinically stable for at least three months on 8 mg per day or less of a transmucosal buprenorphine product (i.e. Subutex® or Suboxone® sublingual tablet or generic equivalent). (The FDA indications specify that maintenance dose should not be tapered to a lower dose for the sole purpose of transitioning to Probuphine®)
3. Medical rationale of why patient cannot be continued on maintenance therapy with a transmucosal buprenorphine product.
4. Documentation that Probuphine® will be used along with counseling and/or psychosocial support

Reauthorization:

1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that Probuphine® will be continue to be used along with counseling and/or psychosocial support
3. Documentation that this is the second course of therapy to be inserted into the contralateral arm. (Treatment beyond two courses has not been studied in clinical trials and is not considered medically necessary).

For Sublocade®:

Initial authorization:

1. Documentation of opioid use disorder
2. Patient is currently maintained or will be maintained on an 8 mg to 24 mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least seven days prior to initiation of extended-release buprenorphine injection
3. Medical rationale of why therapy with a transmucosal buprenorphine product is not appropriate for this patient
4. Documentation that Sublocade® will be used along with counseling and/or psychosocial support

Reauthorization:

1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that patient continues to receive Sublocade® along with counseling and/or psychosocial support

QUANTITY LIMIT:

For Probuphine®: one kit (4 implants) per six months, lifetime limit of one insertion in each arm (two kits)

For Sublocade®: one injection per 28 days

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

For Probuphine®: Initial authorization and reauthorization will be approved for six months. Coverage will be limited to two courses of treatment (one insertion into each arm). Treatment for longer than 12-months (two treatment courses) has not been studied in clinical trials and is not considered medically necessary.

For Sublocade®: Initial authorization and reauthorization will be approved for six months.

**OTHER CRITERIA**

N/A

# **CABENUVA**

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## **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 (6) 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 18 years and older

## **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

Initial authorization for 1 year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

## **OTHER CRITERIA**

N/A

# CABLIVI

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## 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**

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## **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 of the following criteria are met:

i. Diagnosis of migraine headaches with at least four migraine headache days per month, AND

ii. Documentation of trial and failure, defined as minimal to no improvement after at least six weeks of therapy, of at least one prophylactic medication from all of the following categories, or intolerance/contraindication to the drugs outlined below from each of the following classes:

1. Anticonvulsants (specifically divalproex, valproate, or topiramate)
2. Beta-blockers (specifically metoprolol, propranolol, or timolol)
3. 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 (Aimovig®, Vyepti®, Nurtec ODT®, Qulipta®): Documentation of inadequate response, intolerance, or contraindication to the preferred products Emgality® and Ajovy®

b. For episodic cluster headaches, Emgality® may be covered if ALL of 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 trial and failure, defined as minimal to no improvement after at least six weeks of therapy, to two of the following prophylactic medications:

1. Verapamil
2. Melatonin
3. Lithium
4. Frovatriptan
5. Prednisone

6. Sub occipital steroid injection

7. Topiramate

8. Valproate

c. For the acute treatment of migraine headaches, Nurtec ODT® or Ubrovelvy® may be covered if the following criteria are met:

i. Failure of three different triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) or documented contraindication to the use of triptans, such as:

1. Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)

2. History of stroke or transient ischemic attack (TIA)

3. Peripheral vascular disease

4. Ischemic bowel disease

5. Uncontrolled hypertension

6. History of hemiplegic or basilar migraine

ii. If the patient also has chronic migraines, the following additional criteria must be met:

1. Patient has a history of at least four migraines per month, AND

2. 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

# **CAMBIA**

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## **MEDICATION(S)**

CAMBIA

## **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**

## CAR-T - MEDICAL BENEFIT

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### MEDICATION(S)

ABECMA, BREYANZI, KYMRIA<sup>®</sup>, TECARTUS, YESCARTA

### COVERED USES

N/A

### EXCLUSION CRITERIA

Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy. Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established.

### REQUIRED MEDICAL INFORMATION

For all indications, the following criteria must be met:

1. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver)

For B-cell precursor acute lymphoblastic leukemia (ALL), Kymriah<sup>®</sup>, Tecartus<sup>™</sup> may be approved when all the following criteria are met:

1. Documentation of cluster of differentiation 19 (CD19) positive, B-cell precursor acute lymphoblastic leukemia (ALL), and
2. Documentation of relapsed or refractory disease, as defined by one of the following scenarios:
  - a. For Kymriah<sup>®</sup>:
    - i. Second or later bone marrow relapse, or
    - ii. Bone marrow relapse after allogeneic stem cell transplant, or
    - iii. Primary refractory (not achieving a complete response after two cycles of standard chemotherapy), or
    - iv. Chemorefractory (not achieving a complete response after one cycle of standard chemotherapy for relapsed disease)
  - b. For Tecartus<sup>®</sup>:
    - i. First relapse if first remission is less than or equal to 12 months, or
    - ii. Bone marrow relapse after allogeneic stem cell transplant, or
    - iii. Primary refractory disease, or
    - iv. Chemo-refractory after two or more lines of systemic therapy
3. For Philadelphia chromosome (Ph)-positive disease only: Have failed adequate trials of, contraindication, or intolerance to two prior lines of tyrosine kinase inhibitor (TKI) therapy (for example, imatinib, dasatinib, nilotinib, ponatinib)
4. Performance score:
  - a. Kymriah<sup>®</sup>: Karnofsky or Lansky Scale greater than or equal to 50%
  - b. Tecartus<sup>™</sup>: Eastern Cooperative Oncology Group (ECOG) performance status 0-1

5. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For relapsed or refractory B-cell lymphoma, Breyanzi®, Yescarta® or Kymriah® may be approved when all the following criteria are met:

1. Confirmed diagnosis of relapsed or refractory FDA approved B-cell lymphomas
2. Refractory or relapsed disease to two or more prior treatment regimens. Prior therapy must have included the following unless otherwise not indicated/tolerated:
  - a. An anthracycline containing chemotherapy regimen (such as doxorubicin), and
  - b. Anti-CD20 monoclonal antibody (such as rituximab)
3. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
4. Member does not have any of the following:
  - a. Primary central nervous system (CNS) lymphoma
  - b. Evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For relapsed or refractory mantle cell lymphoma (MCL), Tecartus™ may be approved when all the following criteria are met:

1. Histologically confirmed mantle-cell lymphoma [cyclin D1 overexpression or chromosomal translocation]
2. Disease is considered relapsed or refractory
3. Previous use to the following therapy: anthracycline or bendamustine containing chemotherapy, an anti-CD20 monoclonal antibody, and BTK inhibitor therapy
4. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
5. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For multiple myeloma, Abecma® may be approved when all the following criteria are met:

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 infection (including hepatitis B or C)

## **AGE RESTRICTION**

Abecma®: Approved for 18 years of age and older

Breyanzi®: 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 large B-cell lymphoma

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**

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



# **CFTR MODULATORS - KALYDECO/ORKAMBI/SYMDEKO/TRIKAFTA**

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## **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)

Reauthorization:

Documented response to therapy as defined as one of the following:

- a. A lack of decline in lung function as measured by the FEV1 when the patient is clinically stable
- b. A reduction in the incidence of pulmonary exacerbations
- c. Reduced respiratory symptoms (e.g., persistent productive cough, wheezing, shortness of breath)
- d. A significant improvement in BMI by 10% from baseline

## **AGE RESTRICTION**

For elexacaftor- tezacaftor-ivacaftor (Trikafta™): six 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**

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## **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 6-month duration, contraindication, or intolerance to ursodiol

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 (2) years.

## **OTHER CRITERIA**

N/A

# CHOLBAM

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## 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

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## 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 indicated 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

# **CIBINQO**

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## **MEDICATION(S)**

CIBINQO

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (e.g., dupilumab, upadacitinib, and tralokinumab)

## **REQUIRED MEDICAL INFORMATION**

For initial authorization, must meet all of the following criteria:

1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of the following:
  - a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot, or mucous membrane involvement)
  - b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification
  - c. Chronic condition, affecting patient for more than one year
  - d. For Medicaid only: Documentation that patient is having functional impairment due to atopic dermatitis (such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)
2. Documented trial and failure of an adequate treatment course with at least one agent from all of the following conventional treatment modalities:
  - 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
  - c. For Medicaid only: Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate, mycophenolate, or oral corticosteroids) for at least two months unless contraindicated

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

## **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



# CONSTIPATION AGENTS

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## MEDICATION(S)

AMITIZA, LINZESS, LUBIPROSTONE, MOTEGRITY, MOVANTIK, RELISTOR, SYMPROIC, TRULANCE, ZELNORM

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For all requests, the patient must have an FDA labeled indication for the requested agent.
2. For all requests, medication will not be used concomitantly with other intestinal secretagogues, selective 5-HT agonists or peripherally acting mu-opioid receptor antagonists covered by this policy
3. For patients already established on the requested product (starting on samples will not be considered as established on therapy):
  - i. Documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools)
4. For patients not established on the requested product must meet ALL of the following indication-specific criteria:
  - i. For chronic idiopathic constipation (CIC):
    - a. Documentation of weekly constipation (less than three (3) spontaneous bowel movements) for at least three (3) months
    - b. Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
    - c. Inadequate response or contraindication to a reasonable trial (at least two (2) weeks treatment) to ALL of the following:
      - 1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids),
      - 2) A stimulant laxative (e.g. senna, bisacodyl)
      - 3) Routine laxative therapy, with a different mechanism of action than the laxative(s) listed above (e.g., lactulose, Miralax®)
      - 4) Lubiprostone (Amitiza®)

ii. For irritable bowel syndrome with constipation (IBS-C):

a. Documentation of recurrent abdominal pain occurring, on average, at least one (1) day per week during the previous three (3) months with two (2) or more of the following criteria:

- 1) Related to defecation (either increased or improved pain)
- 2) Associated with a change in stool frequency
- 3) Associated with a change in stool form (appearance)

b. Inadequate response or contraindication to a reasonable trial (at least two (2) weeks treatment) to ALL of the following:

- 1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids)
- 2) Routine laxative therapy with polyethylene glycol (Miralax®)

c. For Zelnorm®: patient is a woman aged 65 years or younger without contraindication to therapy.

Contraindications include:

- 1) History of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina
- 2) History of ischemic colitis or other forms of intestinal ischemia, bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesion
- 3) Moderate or severe hepatic impairment
- 4) Severe renal disease or end-stage renal disease

iii. For opioid-induced constipation (OIC):

a. Patient is on chronic opioid therapy

b. Documentation of less than three (3) spontaneous bowel movements per week

c. Inadequate response or contraindication to a reasonable trial (at least two (2) weeks treatment) of ALL of the following:

- 1) A stimulant laxative (e.g. senna, bisacodyl)
- 2) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g. lactulose, Miralax®)

3) For Relistor®: Failure, contraindication, or intolerance to one (1) of the following medications:

i. Naloxegol (Movantik®)

ii. Lubiprostone (Amitiza®)

iii. Naldemedine (Symproic®)

#### QUANTITY LIMIT:

Relistor:

- 8-mg syringe: one (1) single use syringe per day (12 ml per 30 days)
- 12-mg syringe or vial: one (1) single use syringe or vial per day (18 ml per 30 days)
- 150-mg tablet: three (3) tablets per day

#### AGE RESTRICTION

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

For OIC: Initial authorization will be approved for six (6) months. Reauthorization will be approved for one (1) year

For CIC or IBS: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

**OTHER CRITERIA**

N/A

## **CONTINUOUS GLUCOSE MONITORS FOR PERSONAL USE**

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### **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 RECEIVER, FREESTYLE LIBRE 10 DAY READER, FREESTYLE LIBRE 10 DAY SENSOR, FREESTYLE LIBRE 14 DAY READER, FREESTYLE LIBRE 14 DAY SENSOR, FREESTYLE LIBRE 2 READER, FREESTYLE LIBRE 2 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 treatment of insulin-dependent diabetes when all of 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 treated a rapid-acting insulin (such as Humalog®) or regular insulin (such as Humulin R®). This may be verified by pharmacy claim for rapid-acting or regular insulin within the previous 120 days

#### Replacement of Continuous Glucose Monitors

II. 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.

III. 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/Freestyle Libre/Libre 2: 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

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## MEDICATION(S)

CORLANOR

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For chronic heart failure in adults, all of 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 a maximally tolerated dose of an ACE inhibitor (e.g., lisinopril, enalapril) or ARB (e.g., losartan, valsartan), unless contraindicated or did not tolerate
5. On a maximally tolerated dose of one of the three beta-blockers proven to reduce mortality in all stable patients of heart failure with reduced left ventricular ejection fraction (carvedilol, metoprolol succinate, bisoprolol), unless contraindicated or did not tolerate
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 sinus rhythm and resting heart rate (HR) greater than 100 bpm (with a mean HR greater than 90 bpm over 24 hours) or 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
2. Documentation that other causes of sinus tachycardia have been ruled out (e.g. thyroid disease, drug-induced)
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), all of 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
  - a. Documentation that patient is currently in normal sinus rhythm with a resting heart rate (HR) as follows:

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

# CRYSVITA - MEDICAL BENEFIT

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## MEDICATION(S)

CRYSVITA

## COVERED USES

N/A

## EXCLUSION CRITERIA

Pediatric patients with an estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73m<sup>2</sup> or adult patients with creatinine clearance (CLcr) less than 30 mL/min.

## REQUIRED MEDICAL INFORMATION

Initial authorization for new starts:

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), 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**

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## **MEDICATION(S)**

DALIRESP

## **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**

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### **MEDICATION(S)**

ACYCLOVIR 5% CREAM, ACYCLOVIR 5% OINTMENT, DENAVIR, 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

# DESCOVY

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## 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

# DIACOMIT

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## 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

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 3,000mg) per day

## AGE RESTRICTION

Approved for two years of age and older

## PRESCRIBER RESTRICTION

Prescribed by, or in consultation with a neurologist

## COVERAGE DURATION

Initial authorization will be approved for six months.

Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

## OTHER CRITERIA

N/A

# DIHYDROERGOTAMINE

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## MEDICATION(S)

D.H.E.45, DIHYDROERGOTAMINE 1 MG/ML AMP, DIHYDROERGOTAMINE 4 MG/ML SPRY, MIGRANAL

## COVERED USES

N/A

## EXCLUSION CRITERIA

- Use during pregnancy
- History of ischemic heart disease
- Hemiplegic or basilar migraine

## REQUIRED MEDICAL INFORMATION

1. Documented trial, failure, intolerance or contraindication to, at least two formulary, generic triptan medications (e.g. sumatriptan, rizatriptan)
2. Documented trial, failure, intolerance, or contraindication to ergotamine/cafeine tablets (Cafergot®). If unable to use oral formulations, then a documented trial, failure, intolerance or contraindication ergotamine/cafeine rectal suppositories (Migergot®) will be required.

## QUANTITY LIMIT:

Dihydroergotamine nasal spray: eight units per 30 days

- Each unit consists of one vial and one nasal spray applicator. Each vial contains 4 mg dihydroergotamine in 3.5 mL.
- Each vial must be discarded eight hours after preparation
- Dosing: 0.5 mg (one spray) every 15 minutes to maximum dose of 3 mg per 24 hours or 4 mg per seven days

Dihydroergotamine injection: 24 mL per 28 days

- Each vial contains 1 mg dihydroergotamine in 1 mL
- Dosing: 1 mL every hour to maximum dose of 3 mL per 24 hours or 6 mL per seven days

## AGE RESTRICTION

18 years of age and older

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

**OTHER CRITERIA**

N/A



# DISPOSABLE INSULIN PUMPS

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## MEDICATION(S)

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.

## 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**

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### **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**

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## **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

# DUPIXENT

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## MEDICATION(S)

DUPIXENT PEN, DUPIXENT SYRINGE

## COVERED USES

N/A

## EXCLUSION CRITERIA

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (e.g., omalizumab, mepolizumab, benralizumab, reslizumab)

## REQUIRED MEDICAL INFORMATION

For initial authorization, must meet all of the following criteria:

For moderate-severe atopic dermatitis:

1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of the following:

- a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot, or mucous membrane involvement)
- b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification
- c. Chronic condition, affecting patient for more than one year
- d. For Medicaid (OHP) only: Documentation that patient is having functional impairment due to atopic dermatitis (e.g., inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)

2. Documented trial and failure of an adequate treatment course with at least one agent from all each of the following treatment modalities:

- 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 two weeks
- b. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least one month
- c. For Medicaid only: Systemic immunomodulatory agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate, or oral corticosteroids) for at least two months unless contraindicated

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

For eosinophilic asthma:

1. Documentation of eosinophilic asthma by one of the following:
  - a. A blood eosinophil count of 150 cells/microliter or higher in the past 12 months
  - b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. Documentation of treatment with maximally tolerated dose of medium to high-dose inhaled corticosteroid plus a long-acting inhaled beta 2-agonist and has been compliant to therapy in the past three months (this may be verified by pharmacy claims information)
3. Documentation of severe asthma with 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 more than 1.5
  - b. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
  - c. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

For corticosteroid dependent asthma:

1. Documentation of 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).
2. Documentation that in the past three months patient is adherent to a combination of a high-dose inhaled corticosteroid and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)
3. Documentation of severe asthma with 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 more than 1.5
  - b. Documentation, within the last 12 months, of one or more asthma exacerbations defined as any of the following:
    - i. Increase in dose of systemic corticosteroid treatment
    - ii. Urgent care visit or hospital admission
    - iii. Intubation

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all of the following must be met:

1. Evidence of nasal polyposis by direct examination, endoscopy, or sinus CT scan
2. Documentation of one of the following:
  - a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery



- b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
- 3. Patient has tried and had an inadequate response to a 3-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
- 4. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with dupilumab

Reauthorization for CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement

### **AGE RESTRICTION**

- Moderate-to-severe atopic dermatitis: Age six years and older
- Eosinophilic and corticosteroid dependent asthma: Age six years and older
- Chronic rhinosinusitis with nasal polyposis: Age eighteen years and older

### **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

### **COVERAGE DURATION**

For atopic dermatitis and chronic rhinosinusitis with nasal polyposis: 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

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## 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

## 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

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## MEDICATION(S)

EGRIFTA, 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

## **ELIDEL/PROTOPIC**

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### **MEDICATION(S)**

ELIDEL, PIMECROLIMUS, PROTOPIC, TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

Requests for coverage for vitiligo or 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 and Oral Lichen Planus

1. Documentation of severe disease (e.g., causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)

AND

2. Documentation of one of the following

a. At least 10% of body surface area involved

OR

b. Hand, foot or mucous membrane involvement

AND

3. Documentation of trial and failure of an adequate treatment course (two weeks or longer) of two formulary topical corticosteroids, unless member has a contraindication to corticosteroid therapy or use would be on a part of the body where steroid application is not recommended (face, groin, axillae).

For Elidel® only:

1. Documented trial, failure, intolerance or contraindication to tacrolimus 0.1% ointment or tacrolimus 0.03% ointment

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial authorization for three months. Reauthorization for 12 months.

**OTHER CRITERIA**

N/A

# EMFLAZA

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## 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

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## 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):

For initial authorization, 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 (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosphosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
2. Severe disease as defined 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 (e.g., 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 (e.g., dysphagia or abdominal pain)
    - v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

Reauthorization:

1. Documentation of reduced LDH levels, reduced transfusion requirements, 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

# ENSPRYNG

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## 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

# **ENSTILAR/TACLONEX/TACLONEX SCALP/WYNZORA**

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## **MEDICATION(S)**

CALCIPOTRIENE-BETAMETHASONE, CALCIPOTRIENE-BETAMETHASONE DP, ENSTILAR, TACLONEX, WYNZORA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For calcipotriene/betamethasone ointment (Taclonex®) and calcipotriene/betamethasone topical suspension (Taclonex® Scalp):

1. Documentation of trial and failure of calcipotriene (cream, ointment or solution) and a topical high-potency steroid (e.g., betamethasone dipropionate cream/ointment, clobetasol propionate cream/solution/shampoo) as separate products used simultaneously OR inability (other than convenience or non-compliance) to use two separate medications

For calcipotriene & betamethasone aerosol foam (Enstilar®) and calcipotriene & betamethasone cream (Wynzora®):

1. Documentation of trial and failure of calcipotriene (cream, ointment, or solution) and a topical high-potency steroid (e.g., betamethasone dipropionate cream/ointment, clobetasol propionate cream/solution/shampoo) as separate products used simultaneously OR inability (other than convenience or non-compliance) to use two separate medications

AND

2. Documentation of trial and failure of calcipotriene & betamethasone ointment (Taclonex®) or calcipotriene & betamethasone topical suspension (Taclonex® Scalp)

For Medicaid ONLY for all products:

1. Documentation that condition is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction

AND

2. Documentation of one of the following:

- a. At least 10% of body surface area involved

OR

- b. Hand, foot or mucous membrane involvement

## **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

# ENZYME REPLACEMENT THERAPY

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## MEDICATION(S)

ALDURAZYME, CEREZYME, ELAPRASE, ELELYSO, FABRAZYME, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, NEXVIAZYME, VIMIZIM, VPRIV

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For initial authorization both of the following must be met:

1. Documentation of FDA-labeled indication for the requested product

AND

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®)

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.

## REAUTHORIZATION:

Both of the following must be met:

1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms).
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

- Aldurazyme®: N/A
- Cerezyme®: The safety and efficacy have not been established in patients less than two years of age
- Elaprase®: The safety and efficacy have not been established in patients less than 16 months of age
- Elelyso®: The safety and efficacy have not been established in patients less than four years of age

- Fabrazyme®: The safety and efficacy not established in patients under two years of age
- Kanuma®: N/A
- Lumizyme®: N/A
- Mepsevii®: N/A
- Naglazyme®: N/A
- Nexviazyme®: The safety and efficacy have not been established in patients less than one year of age
- Vimizim®: The safety and effectiveness have not been established in patients less than five years of age
- Vpriv®: The safety and efficacy have not been established in patients less than four years of age

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a Hepatologist, Endocrinologist, Medical Geneticist, Cardiologist, Pulmonologist, 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



# **EPIDIOLEX**

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## **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. 25mg/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)**

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### **MEDICATION(S)**

ARANESP, EPOGEN, PROCRIT, RETACRIT

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

- Patients with uncontrolled hypertension
- Anemia induced from hepatitis C therapy

### **REQUIRED MEDICAL INFORMATION**

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 3 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 3 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

3. Patient is currently on myelosuppressive chemotherapy and anemia is not able to be managed by transfusion therapy

c. Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis

i. Adequate iron stores as indicated by current (within the last 3 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 3 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 3 months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml

ii. Zidovudine dose is less than or equal to 4200mg/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 (e.g., expected to lose more than 2 units of blood)
  - iii. Patient is unwilling to donate autologous blood pre-operatively

Reauthorization:

- 1. Documentation of continued medical necessity (e.g., 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 (1) 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

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 (e.g., FVC, DLCO) and improved or stable respiratory symptoms (e.g., cough, 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**

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## **MEDICATION(S)**

EUCRISA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Documentation of trial and failure of an adequate treatment course (two weeks or longer) of two topical corticosteroids, including one high potency corticosteroid (such as betamethasone dipropionate augmented ointment, clobetasol propionate cream or ointment, or halobetasol cream/ointment), unless member has a contraindication (such as an affected area that is not amenable to topical corticosteroid)

AND

2. Documentation of trial, failure, intolerance or contraindication to topical tacrolimus

AND

3. For Medicaid only:

a. Documentation that conditions is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction

AND

b. Documentation of one of the following

i. At least 10% of body surface area involved

OR

ii. Hand, foot or mucous membrane involvement

## **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**

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## **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 (e.g., onasemnogene abeparvovec)

## **REQUIRED MEDICAL INFORMATION**

For initial authorization, all of the following criteria must be met:

1. Confirmed genetic diagnosis of Spinal Muscular Atrophy (SMA) type 1, 2, or 3
2. Patient does not require invasive ventilation or tracheostomy
3. Baseline assessment with an age appropriate tool that establishes baseline motor ability must be submitted (e.g., HINE-2, HFSME, CHOP-INTEND, MFM-32)
4. Requested dose is within FDA labeling

Reauthorization:

1. Documentation of response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (e.g., stabilization or improvement in motor function test scores performed at baseline)
2. Requested dose is within FDA labeling

## **AGE RESTRICTION**

May be approved for patients aged two months and older

## **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**

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### **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.

# EXTAVIA

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## MEDICATION(S)

EXTAVIA

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial Authorization for multiple sclerosis (MS), all of 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. Documented inadequate response or intolerance to generic dimethyl fumarate or glatiramer, or contraindication to BOTH dimethyl fumarate and glatiramer
3. Documentation of trial and failure, contraindication, or intolerance to one additional of the following preferred agents OR medical rationale why therapies cannot be tried:
  - 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®)

## 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

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## 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 Abstral®, 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

## QUANTITY LIMIT:

Fentanyl citrate lozenge/troche: 120 lozenge/troche per 30 days

Fentora® and Abstral®: Limited to 120 tablets per 30 days

Lazanda®: Limited to 30 bottles per 60 days. (Each bottle contains 8 sprays)

Subsys®: Limited to 120 units (sprays) per 30 days

**AGE RESTRICTION**

Fentanyl citrate lozenge/troche: Approved for 16 years or older

Abstral®, 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**

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### **MEDICATION(S)**

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 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**

### **COVERAGE DURATION**

Authorization will be approved for one year

**OTHER CRITERIA**

N/A

# **FINTEPLA**

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## **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 the patient has seizures associated with Dravet syndrome (DS)
2. Documented trial, failure, intolerance, or contraindication to two of the following:
  - a. Valproate/Valproic acid
  - b. Clobazam
  - c. Topiramate

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**

N/A

## **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

Initial authorization will be approved for six month. Reauthorization will be approved for one year.

## **OTHER CRITERIA**

N/A



# **GALAFOLD**

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## **MEDICATION(S)**

GALAFOLD

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

- Given concurrently with Enzyme Replacement Therapy [agalsidase beta (Fabrazyme®)]
- Severe renal impairment or end-stage renal disease

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of Fabry Disease
2. Documentation that patient has an amenable galactosidase alpha gene (GLA) variant based on an in vitro assay

Reauthorization requires documentation of response to therapy.

## **QUANTITY LIMIT:**

Galafold® 123 mg capsule: 14 capsules per 28 days (0.5 capsules per day)\*

\*Note Galafold® is dosed every other day

## **AGE RESTRICTION**

Approved for 18 years and older.

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a metabolic specialist, geneticist, nephrologist or prescriber with experience treating lysosomal storage disorders.

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one (1) year.

## **OTHER CRITERIA**

N/A

# **GAMIFANT**

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## **MEDICATION(S)**

GAMIFANT

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initiation Criteria:

1. One of the following (a, b, or c):
  - a. Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) based on genetic mutation known to cause HLH (e.g., PRF1, UNC13D, STX11 and STXP2)
  - b. Family history consistent with primary HLH
  - c. Five out of the following eight criteria fulfilled:
    - i. Fever
    - ii. Splenomegaly
    - iii. Cytopenias affecting two of three lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100,000 cells per microliter, neutrophils less than 1,000 cells per microliter
    - iv. Hypertriglyceridemia (fasting triglycerides greater than 3 mmol/L or equal or greater than 265 mg/dL) and/or hypofibrinogenemia (equal or less than 1.5 g/L)
    - v. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
    - vi. Low or absent NK-cell activity
    - vii. Ferritin equal or greater than 500 mcg/L
    - viii. Soluble CD25 equal or greater than 2400 U/mL
2. Documentation that patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin)
3. Documentation that patient is a candidate for stem cell transplant and emapalumab is being used as part of the induction or maintenance phase for stem cell transplant and will be discontinued at the initiation of conditioning for stem cell transplant
4. Dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling
5. Documentation that patient currently has no active infection (e.g., mycobacteria and Histoplasma Capsulatum)

Reauthorization Criteria:

1. Patient continues to be a candidate for stem cell transplant
2. Documentation of positive clinical response such as improvement in the following clinical and laboratory parameters: fever, splenomegaly, central nervous system symptoms, complete blood count, fibrinogen and/or D-dimer, ferritin, and soluble CD25 (also referred to as soluble interleukin-2 receptor) levels
3. Documentation that patient is being monitored for serious infections (such as tuberculosis, adenovirus, EBV, and CMV)
4. Documentation that dose does not exceed max FDA approved dosing of 10 mg/kg per dose for two doses per week

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist or oncologist

**COVERAGE DURATION**

Initial authorization approved for three months, reauthorization for one month.

**OTHER CRITERIA**

N/A

# **GATTEX**

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## **MEDICATION(S)**

GATTEX

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

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

Reauthorization: Documentation that parenteral nutrition support requirement has decreased since initiation of teduglutide

## **QUANTITY LIMITS:**

Round quantity to the nearest number of 5-mg kits, within 10% of calculated dose, based on weight-based dosing of 0.05 mg/kg once daily

## **AGE RESTRICTION**

Approved for 1 year and older

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist

## **COVERAGE DURATION**

Initial authorization will be approved for 6 months, and reauthorization will be approved for 12 months.

## **OTHER CRITERIA**

N/A

# GIVLAARI

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## 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 corproporhyria, 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**

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## **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® only):

Initial Authorization

1. Documentation that patient has moderate to severe pain associated with endometriosis  
AND
2. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives

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 trial and failure of, intolerance to, or contraindication to hormonal contraceptives

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

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## MEDICATION(S)

CAMCEVI, ELIGARD, FENSOLVI, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LUPANETA PACK, 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 oncological indications: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

For anemia associated with uterine leiomyomata (fibroids)

1. Documented trial, failure, intolerance or contraindication to at least 30 days of therapy with iron supplementation alone

AND

2. Documentation that Lupron® will be used in combination with iron supplementation

For uterine leiomyomata (fibroids)

1. Documentation that surgical removal of fibroids is planned within four months

For endometriosis:

1. Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel syndrome, interstitial cystitis, urinary tract disorders)

2. For Synarel®: documented trial and failure to Lupron® with add-back progesterone therapy (such as norethindrone acetate) or Lupaneta® Pack.

Reauthorization

For Lupron® requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g., norethindrone) to help prevent bone mineral density loss.

Reauthorization

For Synarel® and Zoladex® is not recommended. Treatment is only recommended for up to six months with these agents for endometriosis

For central precocious puberty

Note, a one-time dose may be approved for diagnostic purposes

For Initial Authorization:

1. 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)

AND

2. Confirmation of diagnosis by one of the following:

a. 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)]

b. Pubertal level of basal LH levels (0.3 IU/L or greater)

c. Bone age advanced one year beyond the chronological age

AND

3. For Synarel®: documented trial and failure or contraindication/intolerance to Lupron® and, either Triptodur® or Supprelin LA®

For Reauthorization:

1. Clinical response to treatment such as pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level, and

2. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression.

Discontinuation of leuprolide should be considered before age 11 years for females and age 12 years for males. However, treatment discontinued at the appropriate age of onset of puberty should be at discretion of the treating provider.

For gender-affirming services:

1. Prescribed by or in consultation with an endocrinologist

2. Demonstration that puberty has progressed to a minimum of Tanner Stage 2

For Endometrial thinning/dysfunctional uterine bleeding:

1. Documentation for use prior to endometrial ablation

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Anemia from fibroids: Authorization will be approved for up to three months. No reauthorization.

Uterine leiomyomata (fibroids): Authorization will be approved for four 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.

CPP: Authorization/reauthorization will be approved for one year.

GID: Authorization/reauthorization will be approved for one year.

Endometrial Thinning/Dysfunctional Uterine Bleeding: Initial authorization for two months. No reauthorization.

Oncological Indications: Authorization/reauthorization will be approved for one year.

In vitro fertilization: Authorization/reauthorization will be approved for one year.

## **OTHER CRITERIA**

N/A

# HEMLIBRA - MEDICAL BENEFIT

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## 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

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### 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

All of the following criteria (1-7) must be met:

1. Documentation of confirmed diagnosis of chronic hepatitis C (HCV) infection (B18.2)
2. Expected survival from non-HCV-associated morbidities more than one year,
3. Documentation that ALL of 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. Current hepatitis B (HBV) status of patient.
    - i. Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with a DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status.
  - c. History of previous HCV treatment and outcome. Retreatment after failure of a DAA due to noncompliance or lost to follow-up will be reviewed on a case-by-case basis.
  - d. Cirrhosis status as clinically determined (e.g., clinical, laboratory, or radiologic evidence)
4. One of the following:
  - a. Attestation that the patient and provider will comply with case management to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority (OHA), including measuring and reporting of a post-treatment viral load OR
  - b. Attestation from the patient and provider that they have opted out of OHA case management.
5. For coverage of non-preferred regimen, the prescriber must submit medical rationale in support of the use of non-preferred drug(s).
6. For coverage of elbasvir/grazoprevir (Zepatier®) in genotype 1a, NS5A resistance testing is required to detect any potential resistant variant.
7. 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

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## MEDICATION(S)

HETLIOZ, HETLIOZ LQ

## 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 (i.e. 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, 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 of melatonin dosed in the morning 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**

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## **MEDICATION(S)**

EVKEEZA, JUXTAPID

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

1. Concomitant use of therapies on this policy
2. Current pregnancy
3. Diagnosis of Heterozygous familial hypercholesterolemia or other hyperlipidemia disorders

## **REQUIRED MEDICAL INFORMATION**

All of 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), or proprotein convertase subtilisin/kexin type 9 (PCSK9) genes
  - b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL and one of the following:
    - i. Presence of xanthomas before the age of 10 years, or
    - ii. Untreated total cholesterol level greater than 250 mg/dL in both parents
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 (e.g., evolocumab), unless contraindicated or prior intolerance
3. Documentation of LDL cholesterol levels 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

# **HORIZANT**

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## **MEDICATION(S)**

HORIZANT

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For Restless Leg Syndrome:

- Documentation of an adequate trial, failure, intolerance or contraindication to ropinirole AND pramipexole.

For Postherpetic Neuralgia:

- Documentation of an adequate trial, failure, intolerance, or contraindication to gabapentin AND pregabalin.

## **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

# HP ACTHAR GEL

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## 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

# HUMAN GROWTH HORMONES

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## 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 Medicaid: 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 (I-III) must be met:

I. Documented evidence of open epiphyses, defined as 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

II. For non-preferred growth hormone (GH) request, documentation that the patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to preferred growth hormone product(s) that is not expected to occur with the requested non-preferred agent (medical record required). Request of lonapegsomatropin (Skytrofa®) to improve compliance or to reduce dosing frequency is considered not medically necessary.

III. Meet criteria listed below for each specific diagnosis:

A. Growth Hormone Deficiency (GHD): must meet criteria for one of the following:

i Newborn with hypoglycemia and both of the following criteria:

1. Serum GH level less than or equal to 5 micrograms per liter (5 mcg/L)

2. One of the following:

a. One additional pituitary hormone deficiency (other than growth hormone)

or

b. Classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk)

ii Patient with extreme short stature [defined as height standard deviation score (SDS) of more than 3 SDS below the mean for chronological age/sex] and all of the following:

1. Insulin-like growth factor (IGF)-1 level at least 2 SDS below normal

2. Insulin-like growth factor binding protein-3 (IGFBP-3) at least 2 SDS below normal
  3. Delayed bone age, defined as bone age that is 2 SDS below the mean for chronological age
- iii Patient has pituitary abnormality (secondary to a congenital anomaly, tumor, or irradiation) and meets both of the following criteria:
1. One additional pituitary hormone deficiency (other than growth hormone)
  2. Evidence of short stature/growth failure by one of the following:
    - a. Height standard deviation score (SDS) of more than 3 SD below the mean for chronological age/sex
    - b. Height for age/sex is below the 3rd percentile (or greater than 2 SD below the mean) AND untreated growth velocity (GV) is below the 25th percentile (must have at least one year of growth data)
    - c. Severe growth rate deceleration (GV measured over one year of more than 2 SD below the mean for age/sex)
- iv All other patients with suspected GHD must meet all the following criteria:
1. Evidence of short stature/growth failure using criteria III.A.iii.2. above
  2. Documented biochemical GHD by one of the following:
    - a. Two GH stimulation tests (using a provocative agent such as arginine, clonidine, glucagon, insulin or levodopa) showing peak GH concentrations of less than 10 ng/ml
    - b. One GH stim test level less than 15 ng/ml and insulin-like growth factor (IGF)-1 and IGFBP-3 levels below normal for bone age/sex
- B. Prader-Willi Syndrome (PWS), Turner Syndrome (TS), Short stature homeobox-containing (SHOX) deficiency, somatropin may be covered if the following criteria are met:
- i Documented confirmation of diagnosis through genetic testing
- AND
- ii Evidence of short stature/growth failure meeting one of the criteria above (III.A.iii.2.)
- C. Noonan Syndrome (somatropin only)
- i Diagnosis confirmed by genetic testing or made by pediatric endocrinologist based on clinical features (i.e., classic facies, congenital heart disease, abnormal skeletal features, factor XI deficiency, hearing loss, developmental delays),
- AND
- ii Evidence of short stature/growth failure meeting one of the criteria above (III.A.iii.2.)
- iii Note: Authorization will be withdrawn after transplantation.
- E. Small for Gestational Age (SGA) (somatropin only)
- i Birth weight and/or length at least two SDs below the mean for gestational age
- AND
- ii Failure to reach catch-up growth by two years of age, defined as height at least two SDs below the mean for age/sex

For Reauthorization, all the following criteria (I-III) must be met:

I. For non-preferred growth hormone (GH) request, documentation that the patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to preferred growth hormone product(s) that is not expected to occur with the requested non-preferred agent (medical record required).

II. Evidence of growth velocity (GV) of greater than 2.5 cm/year

III. Evidence of open epiphyses, defined as 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 once the patient when chronologic age reaches 15 years in male or 13 years in female

#### **AGE RESTRICTION**

N/A

#### **PRESCRIBER RESTRICTION**

Must be prescribed by a pediatric endocrinologist or pediatric nephrologist.

#### **COVERAGE DURATION**

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

#### **OTHER CRITERIA**

N/A



## **IL-5 INHIBITORS - CINQAIR/FASENRA/NUCALA - MEDICAL BENEFIT**

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### **MEDICATION(S)**

CINQAIR, FASENRA, FASENRA PEN, NUCALA

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

### **REQUIRED MEDICAL INFORMATION**

For initial authorization, must meet all of the following criteria:

For eosinophilic asthma:

1. Documentation of eosinophilic asthma by one of the following:
  - a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months
  - b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. Documentation of treatment with maximally tolerated dose of medium to high-dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist) and has been compliant to therapy in the past three months (this may be verified by pharmacy claims information)
3. Documentation of severe asthma with 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 asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
  - c. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit

For Eosinophilic Granulomatosis with Polyangiitis (EGPA):

1. Request is for Nucala®
2. Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)
3. History or presence of asthma
4. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter
5. Documentation of one of the following
  - a. 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)

OR

- b. Failure to achieve remission following a standard induction regimen administered for at least three

months OR recurrence of symptoms of EGPA while tapering of glucocorticoids

i. 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

For Hypereosinophilic Syndrome (HES)

1. Request is for Nucala®
2. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
3. Blood eosinophil count of 1,000 cells/microliter or higher for at least six months
4. Documentation of use of HES therapy including one of the following in the past for the past 12 months:
  - a. chronic or episodic oral corticosteroids (OCS)
  - b. immunosuppressive therapy
  - c. cytotoxic therapy
5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)

Reauthorization 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:

1. Request is for Nucala®
2. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan
3. Documentation of one of the following:
  - a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
  - b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
4. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
5. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab

Reauthorization for CRSwNP:

Documentation of positive clinical response to therapy such as symptom improvement

## **AGE RESTRICTION**

Nucala®: Approved for six years of age or older for eosinophilic asthma, approved for 18 years of age and older for EGPA and CRSwNP, and approved for 12 years of age and older for HES

Cinqair®: Approved for 18 years of age or older

Fasenra®: Approved for 12 years of age or older

## **PRESCRIBER RESTRICTION**

For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)

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

For hypereosinophilic syndrome (HES): must be prescribed by or in consultation with hematologist, immunologist, pulmonologist, cardiologist, or neurologist.

For chronic rhinosinusitis with nasal polyposis: must be prescribed by, or in consultation with, an otolaryngologist, allergist, or pulmonologist.

## **COVERAGE DURATION**

For EGPA and HES: Initial authorization and reauthorization will be approved for one year.

For asthma: 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

For chronic rhinosinusitis with nasal polyposis: Initial authorization will be approved for six months and reauthorization will be approved for one year.

## **OTHER CRITERIA**

N/A

# IMCIVREE

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## 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, all the following must be met:

1. 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: Greater than or equal to the 95th percentile using growth chart assessments, AND
2. Confirmation that obesity is due to a homozygous, or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing: proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR), AND
3. 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)

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)**

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### **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 rationale should be provided and exceptions will be considered on a case by case 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 (i.e., common variable immunodeficiency), Hyper-IgM (i.e., 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 (e.g., 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 (e.g., recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics) despite aggressive prophylactic management and treatment with 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 (i.e. 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 (i.e. prednisone or methylprednisolone)
  - b. Documentation of pure motor CIDP

Autoimmune Hemolytic Anemia:

1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. 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 (e.g. unable to

ambulate independently)

AND

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 (e.g., 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 (e.g., pyridostigmine)

b. Corticosteroids (e.g., prednisone, methylprednisolone)

c. Immunosuppressive agents (e.g., 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 (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil).

#### **AGE RESTRICTION**

N/A

#### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an appropriate specialist (e.g., a Neurologist for multiple sclerosis or an immunologist, hematologist or infections disease expert for primary immunodeficiency)

#### **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

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## 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

N/A

**COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

**OTHER CRITERIA**

N/A

# INJECTABLE ANTI-CANCER MEDICATIONS

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## MEDICATION(S)

ABRAXANE, ACTIMMUNE, ADCETRIS, ALIQOPA, ALKERAN 50 MG VIAL, ARRANON, ARZERRA, ASPARLAS, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENDEKA, BESPONSA, BESREMI, BLENREP, BLINCYTO, BORTEZOMIB, COSELA, CYRAMZA, DACOGEN, DANYELZA, DARZALEX, DARZALEX FASPRO, DECITABINE, ELZONRIS, EMPLICITI, ENHERTU, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, FYARRO, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRA, JELMYTO, JEMPERLI, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LIBTAYO, LUMOXITI, LUTATHERA, MARGENZA, MELPHALAN HCL, MONJUVI, MVASI, NELARABINE, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO, PACLITAXEL PROTEIN-BOUND, PADCEV, PEPAXTO, PERJETA, PHESGO, POLIVY, PORTRAZZA, POTELIGEO, ROMIDEPSIN, RYBREVANT, RYLAZE, SARCLISA, SYLATRON, SYNRIPO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TIVDAK, TORISEL, TRAZIMERA, TREANDA, TRODELVY, VECTIBIX, VELCADE, VIDAZA, 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-MEDICAID**

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## **MEDICATION(S)**

AMBIEN, AMBIEN CR, BELSOMRA, DAYVIGO, DOXEPIN HCL 3 MG TABLET, DOXEPIN HCL 6 MG TABLET, ESZOPICLONE, FLURAZEPAM HCL, HALCION, INTERMEZZO, LUNESTA, RAMELTEON, RESTORIL, ROZEREM, SILENOR, TEMAZEPAM, TRIAZOLAM, ZALEPLON, ZOLPIDEM TARTRATE, 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 (i.e. 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 (i.e. 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**

- Palliative care services: Initial and reauthorization will be approved up to one year.
- Insomnia for other conditions: Initial authorization will be approved up to two months. Reauthorization will be approved up to six months.

#### **OTHER CRITERIA**

N/A

## **INTERLEUKIN – 1 INHIBITORS - ARCALYST, ILARIS**

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### **MEDICATION(S)**

ARCALYST, ILARIS

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) confirmed by:

1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3) or CIAS1 (Cold-Induced Auto-inflammatory Syndrome-1),

AND

2. Classic symptoms associated with Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) – recurrent intermittent fever and rash typically associated with natural or artificial cold

For Arcalyst® only:

For maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA):

1. Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist)

2. Current inflammatory remission of DIRA

3. Weight of at least 10 kg

For recurrent pericarditis:

1. Diagnosis of recurrent pericarditis (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

2. Documentation trial and failure, contraindication or intolerance to NSAIDs or glucocorticoids

For Ilaris® only:

For Familial Mediterranean Fever (FMF), and all the following:

1. Documented trial and failure, contraindication or intolerance to colchicine,

AND

2. Classic symptoms associated with FMF (febrile episodes, pain in the abdomen, chest, or arthritis of large joints).



Diagnosis of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) confirmed by:

1. Laboratory evidence of genetic mutation MVK (mevalonate kinase),
- AND
2. Classic symptoms associated with HIDs (abdominal pain, lymphadenopathy, aphthous ulcers).

Diagnosis of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) confirmed by:

1. Laboratory evidence of genetic mutation TNFRSF1A (tumor necrosis factor receptor super family),
- AND
2. Classic symptoms associated with TRAPs (abdominal pain, skin rash, musculoskeletal pain, eye manifestations).

Diagnosis of Active Still's Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease:

1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
- AND
2. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)

Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)

### **AGE RESTRICTION**

Arcalyst®: may be covered for patients aged 12 years and older with CAPS (which includes FCAS, MWS), treatment of recurrent pericarditis (RP), and reduction in risk of recurrence of pericarditis.

Ilaris® may be covered for patients aged four years of age and older in patients with CAPS (which includes FCAS, MWS), Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF

Ilaris® may be covered for patients aged two years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis and Adult Onset Still's Disease (AOSD)

### **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**

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### **MEDICATION(S)**

24 HOUR NASAL ALLERGY, ALLER-CORT, AZELASTINE 0.1% (137 MCG) SPRY, AZELASTINE 0.15% NASAL SPRAY, BECONASE AQ, 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**

Coverage for Medicaid 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 allergic rhinitis:

1. The requested medication is an intranasal corticosteroid (use of non-corticosteroid medications is not funded by Medicaid)
2. Confirmed diagnosis of allergic or non-allergic rhinitis
3. Confirmed diagnosis of one of the following co-morbidities:
  - a. Asthma or reactive airway within the past year
  - i. 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)
  - b. Chronic sinusitis
  - c. Acute sinusitis
  - d. Sleep apnea

AND

4. Documented trial and failure\*, intolerance or contraindication to fluticasone propionate nasal spray (Flonase®), which is available without prior authorization. \*Trial and failure is defined as at least two weeks of therapy.

### **AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

Acute sinusitis comorbidity: Authorization will be approved for one month

All other indications: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

**OTHER CRITERIA**

N/A

# IVERMECTIN

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## 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

All of the following must be met:

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/1.73m<sup>2</sup> 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 trial, contraindication, or intolerance to a Sodium Glucose Co-transporter-2 inhibitor (such as empagliflozin or dapagliflozin)

## 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

## **KETOCONAZOLE (NIZORAL TABLETS)**

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### **MEDICATION(S)**

KETOCONAZOLE 200 MG TABLET

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

Candida, tinea versicolor, or dermatophyte infections

### **REQUIRED MEDICAL INFORMATION**

1. Treatment is for blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis

AND

2. Patient has failed or are intolerant to other therapies for the respective indication

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for three (3) months.

### **OTHER CRITERIA**

# **KETOROLAC INTRAMUSCULAR INJECTION**

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## **MEDICATION(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 (e.g. 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)

## **QUANTITY LIMIT:**

15 mg/mL vials or syringes – 20 mL per 28 days

30 mg/mL vials or syringes – 20 mL per 28 days

60 mg/2 mL vials or syringes – 10 mL per 28 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

# KEVEYIS

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## MEDICATION(S)

KEVEYIS

## COVERED USES

All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

## EXCLUSION CRITERIA

Concomitant high-dose aspirin.

## REQUIRED MEDICAL INFORMATION

1. Documented diagnosis of a periodic paralysis (PP) and/or related variants

AND

2. Documentation of at least a three-month history of distinct regular episodes of weakness, defined as an average frequency of at least one episode per week, but less than three episodes daily

AND

3. Documentation that lifestyle changes (such as increase in exercise, for hyperkalemic PP: high carbohydrate meals and avoiding cold exposure and potassium rich foods, for hypokalemic PP: low sodium, low carbohydrate diet, potassium supplements) have been attempted to identify and avoid potential triggers.

AND

4. Inadequate treatment response, intolerance, or contraindication to acetazolamide (exception may be made for members with sodium voltage gated channel alpha subunit 4 [SCN4A] mutation).

Reauthorization requires documented improvement in severity and frequency of periodic paralysis attacks.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a neurologist or endocrinologist

## COVERAGE DURATION

Initial authorization 3 months. Reauthorization will be approved for 1 year.

## OTHER CRITERIA

N/A

# KORLYM

---

## 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

# KOSELUGO

---

## MEDICATION(S)

KOSELUGO

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For initial authorization:

1. Documentation of inoperable neurofibromatosis type 1 (NF1) plexiform neurofibroma (PN) (defined as one that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN)
2. Patient has significant morbidity related to the target PN (i.e. motor dysfunction, pain, airway dysfunction, visual impairment, and bladder/bowel dysfunction)

For reauthorization: Documentation of adequate response to the medication must be provided.

## AGE RESTRICTION

Approved for ages two years and older

## PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with an oncologist, neuro-oncologist, neurologist, neurosurgeon or a provider at a neurofibromatosis center.

## 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

## KRYSTEXXA - MEDICAL BENEFIT

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### MEDICATION(S)

KRYSTEXXA

### COVERED USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

For initial therapy, all of the following criteria must be met:

- 1) Diagnosis of chronic gout
- 2) Documentation of inadequate response to both of the following medications, unless contraindication to both of the following: xanthine oxidase inhibitor (e.g., allopurinol) and uricosuric (e.g., probenecid).  
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

# KUVAN

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## MEDICATION(S)

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-pqpz)

## 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

# LEMTRADA - MEDICAL BENEFIT

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## MEDICATION(S)

LEMTRADA

## COVERED USES

N/A

## EXCLUSION CRITERIA

- In combination with other disease modifying therapy indicated for the treatment of MS
- For treatment beyond two years or beyond two treatment courses.

## REQUIRED MEDICAL INFORMATION

1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis or active secondary progressive disease

AND

2. Documentation of active disease (e.g. patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial to ocrelizumab (Ocrevus®)

AND

3. Documentation of active disease after at least one additional of the following disease modifying therapies, unless all are contraindicated.

- 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. Diroximel fumarate (Vumerity®)
- h. Ozanimod hydrochloride (Zeposia®)
- i. Siponimod (Mayzent®)

\*Adequate trial is defined as at least six months of continuous therapy. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

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

**OTHER CRITERIA**

N/A

# **LIDOCAINE PATCH**

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## **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**

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## **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**

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### **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, HYDROCODONE BITARTRATE ER, HYDROMORPHONE ER, HYSINGLA ER, KADIAN, 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, 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

### **REQUIRED MEDICAL INFORMATION**

For patients initiating therapy with a long-acting opioid therapy:

1. Request is for a funded condition (new starts to long acting opioids will not be allowed for unfunded condition) Note: Management of pain associated with back or spine conditions with long-acting opioids is not funded by the OHP. Other conditions, such as fibromyalgia, TMJ, neuropathy, tension headache and pelvic pain syndrome are also not funded by the OHP.
2. The following indication-specific criteria must be met:
  - a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease or severe burns:
    - i. Documentation of trial and failure of scheduled short-acting opioid therapy: AND
    - ii. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy
  - b. For other chronic pain:
    - i. Documentation of chronic pain (lasting longer than 3 months) that is severe enough to require around-the-clock analgesic therapy: AND
    - ii. Documentation of trial and failure of scheduled short-acting opioid therapy: AND
    - iii. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy: AND
    - iv. Documentation of trial and failure of non-opioid therapies or these therapies are being used in conjunction with opioid therapy or these therapies are not appropriate (non-opioid therapies include but are

not limited to: nonsteroidal anti-inflammatory drugs [NSAIDs], tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors [SNRIs], anticonvulsants, exercise therapy, acupuncture, weight loss, cognitive behavioral therapy) AND

v. Documentation of a signed pain management agreement between the prescriber and patient

3. The following drug-specific criteria must be met in addition to the above criteria:

a. For Belbuca®: Documentation of trial and failure of Butrans® (buprenorphine transdermal)

b. For morphine sulfate sustained-release (SR) capsules (Kadian/Avinza®): medical rationale for requiring the use of the requested formulation of long-acting morphine over morphine sulfate ER tablets (generic for MS Contin®)

For patients established on 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:

i. Documentation of positive response to therapy

b. For other chronic pain:

i. Documentation that shows an improvement in pain control and level of functioning. If no improved pain control and level of functioning, rationale is provided for continued use of opioid therapy or a plan for taper/discontinuation AND

ii. Documentation of a signed pain management agreement between the prescriber and patient that is reviewed at least annually

2. For requests for un-funded conditions

a. Documentation of a plan to discontinue long acting opioids or documentation that discontinuation of the long acting opioid is not clinically appropriate or unsafe

#### **QUANTITY LIMIT:**

Opioid doses greater than 90 mg Morphine Milligram Equivalent (MME) per day requires additional prior authorization. See Policy Maximum Allowable Opioid Dose (#ORPTCANA031) for clinical coverage criteria.

#### **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 90-day approval may be authorized for patients established on long acting opioids to allow for submission of documentation of appropriate monitoring, medical necessity, and/or plan for discontinuation for un-funded conditions

**OTHER CRITERIA**

N/A

# **LONG ACTING STIMULANT MEDICATIONS**

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## **MEDICATION(S)**

ADDERALL XR, APTENSIO XR, AZSTARYS, CONCERTA, COTEMPLA XR-ODT, DAYTRANA, DEXEDRINE, DEXMETHYLPHENIDATE HCL ER, DEXTROAMPHETAMINE SULFATE ER, DEXTROAMPHETAMINE-AMPHET ER, DYANAVEL XR, FOCALIN XR, JORNAY PM, METADATE ER, METHYLPHENIDATE ER, METHYLPHENIDATE ER (LA), METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA, MYDAYIS, QUILLICHEW ER, RELEXXII, RITALIN LA, VYVANSE

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

A. For adults requesting initiation of a long-acting stimulant medication, all of the following criteria must be met:

1. Request is for a preferred agent
  - a. Requests for a non-preferred agent will require one of the following:
    - i. 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
    - ii. Request is for Vyvanse® for binge eating disorder with a confirmed diagnosis supported by clinical documentation
2. The requested agent will be used for one of the following diagnoses, confirmed while an adult, as follows:
  - a. Attention Deficit Hyperactivity Disorder (ADHD) – diagnosis code F90.x
  - b. Narcolepsy

B. For adult patients established on long-acting stimulant therapy, all of the following criteria must be met:

1. Patient has a confirmed current diagnosis of one of the following funded conditions:
  - a. Attention Deficit Hyperactivity Disorder (ADHD)
  - b. Narcolepsy
  - c. Binge eating disorder
2. Request is for a preferred agent
  - a. Requests for a non-preferred agent will require one of the following:
    - i. 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
    - ii. Request is for Vyvanse® for binge eating disorder with a confirmed diagnosis supported by clinical documentation

3. Documentation of positive response to therapy

C. For pediatric patients requesting a non-preferred stimulant, all of the following must be met:

1. Patient has a confirmed current diagnosis of one of the following funded conditions:

a. Attention Deficit Hyperactivity Disorder (ADHD)

b. Narcolepsy

c. Binge eating disorder

2. One of the following:

a. 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, long-acting vs immediate-release)

b. Request is for Vyvanse® for binge eating disorder with a confirmed diagnosis supported by clinical documentation

D. For all patients (pediatrics and adults):

1. The requested regimen is within Food and Drug Administration (FDA) approved age range and maximum daily dose

a. 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.

2. Requests above the formulary quantity limit must meet one of the following:

a. 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

b. 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.

i. 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**

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

## **OTHER CRITERIA**

N/A





# **LOTIRONEX (ALOSETRON HCL TABLETS)**

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## **MEDICATION(S)**

ALOSETRON HCL, LOTIRONEX

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Patients with constipation

## **REQUIRED MEDICAL INFORMATION**

For initiation, all of the following must be met:

1. Patient is female
2. Documentation of severe diarrhea-predominant irritable bowel disease (IBS-D), defined as having at least one of the following symptoms for at least six months:
  - 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
3. Documentation of trial and failure, contraindication, or intolerance to a 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®)]

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

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## 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 benlimumab (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 (e.g., corticosteroids, mycophenolate, azathioprine)

Reauthorization criteria:

1. Documentation currently receiving standard therapy 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

## **LUXTURNA - MEDICAL BENEFIT**

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### **MEDICATION(S)**

LUXTURNA

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

All of 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 12 weeks.

### **OTHER CRITERIA**

N/A

# MAVENCLAD

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## MEDICATION(S)

MAVENCLAD

## COVERED USES

N/A

## EXCLUSION CRITERIA

Concurrent use with other disease modifying agents for MS

## REQUIRED MEDICAL INFORMATION

1. For initiation of therapy, all of the following criteria must be met:
  - a. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis (MS) or active secondary progressive disease. Note: this therapy is not indicated for us in clinically isolated syndrome (CIS)
  - b. Documented inadequate response or intolerance to generic dimethyl fumarate or glatiramer, or contraindication to BOTH dimethyl fumarate and glatiramer
  - c. Documentation of trial and failure, contraindication, or intolerance to one additional of the following preferred agents OR medical rationale why therapies cannot be tried:
    - i. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
    - ii. Interferon-beta 1b (Betaseron®)
    - iii. Teriflunomide (Aubagio®)
    - iv. Fingolimod (Gilenya®)
    - v. Diroximel fumarate (Vumerity®)
    - vi. Ozanimod hydrochloride (Zeposia®)
    - vii. Siponimod (Mayzent®)
2. For patients established on therapy (samples will not be considered established on therapy):
  - a. Documentation of positive clinical response to therapy
  - b. 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 - MEDICAID**

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### **MEDICATION(S)**

PROLEEVA

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

- L-methylfolate (such as Deplin®) in the treatment of depression
- Use of Relizorb™ is considered experimental and investigational for use with enteral feedings due to the lack of evidence to assess safety and efficacy on health outcomes

### **REQUIRED MEDICAL INFORMATION**

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

#### **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.

#### **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:
  - i. Increased metabolic need resulting from severe trauma
  - ii. 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)
  - iii. 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

## **MEDICATIONS FOR RARE INDICATIONS - ORPHAN DRUGS**

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### **MEDICATION(S)**

BUPHENYL, CARBAGLU, CARGLUMIC ACID, CERDELGA, DOJOLVI, MIGLUSTAT, NULIBRY, RAVICTI, SODIUM PHENYLBUTYRATE, ZAVESCA, ZOKINVY

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **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 (e.g., high-quality peer reviewed literature, guidelines, other clinical information)

### **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 (e.g., 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 Nulibry®: Initial authorization will be approved for three months. Reauthorization will be approved for 12 months.

For all other indications: Initial authorization will be approved for one year and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

**OTHER CRITERIA**

N/A

# MEPRON

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## 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.

## 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

N/A

# **MILLIPRED**

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## **MEDICATION(S)**

MILLIPRED, PREDNISOLONE 10 MG/5 ML SOLN

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

One of the following:

1. Documented trial, failure, intolerance or contraindication to generic prednisolone phosphate solution and prednisone (tablets or solution).

OR

2. Use is for alcoholic hepatitis and Maddrey Discriminant Function (MDF) score is greater than or equal to 32.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial authorization will be approved for 3 months. Reauthorization will be approved for 6 months.

## **OTHER CRITERIA**

## **MIRCERA - MEDICAL BENEFIT**

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### **MEDICATION(S)**

MIRCERA

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the treatment of adults with anemia associated with chronic kidney disease:

1. Documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy
2. 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%

For the treatment of pediatric patients five 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:

1. Documented hemodialysis for at least eight weeks
2. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy
3. Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

Reauthorization:

1. Documentation of continued medical necessity (such as ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12g/dl or HCT levels of less than or equal to 36% within previous 30 days

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

### **OTHER CRITERIA**





# MYALEPT

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## MEDICATION(S)

MYALEPT

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of congenital or acquired generalized lipodystrophy (specifically, not related to HIV, nor obesity not related to leptin deficiency)

AND

2. Documentation of at least one of the following metabolic complications of leptin deficiency:

- a. Diabetes mellitus
- b. Triglyceride levels greater than or equal to 200 mg/dL
- c. Increased fasting insulin levels greater than or equal to 30 microU/mL

AND

3. Documentation that the patient has not had a response to current standards of care for lipid and diabetic management.

Reauthorization: requires documentation of response to therapy as indicated by one of the following:

- a. Sustained reduction in hemoglobin A1c level from baseline
- b. Sustained reduction in triglyceride levels from baseline

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an endocrinologist.

## COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

## OTHER CRITERIA

N/A

# NARCOLEPSY AGENTS

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## MEDICATION(S)

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 of the following criteria must be met:

a. For treatment of Type 1 narcolepsy (aka narcolepsy with cataplexy) 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 one of the following:

1. Excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score of 12 or higher, or

2. 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 Type 2 narcolepsy (excessive daytime sleepiness in narcolepsy without cataplexy) 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. Other causes of sleepiness have been ruled out or treated (i.e. 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 (e.g., amphetamine, 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®)

2. For excessive daytime sleepiness associated with obstructive sleep apnea (OSA), solriamfetol (Sunosi®) may be covered if the following criteria are met:

a. Diagnosis of OSA as confirmed by sleep study

b. 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

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

d. Failure of a three month trial, intolerance or contraindication of armodafinil or modafinil

3. 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 (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent

### **AGE RESTRICTION**

solriamfetol (Sunosi®) and pitolisant (Wakix®) may be covered for patients aged 18 years and older

### **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

# **NATPARA**

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## **MEDICATION(S)**

NATPARA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Concomitant use of Natpara® with alendronate

## **REQUIRED MEDICAL INFORMATION**

For initial authorization, all the following must be met:

1. Patient must be diagnosed with permanent/chronic hypoparathyroidism (Acute post-surgical hypoparathyroidism is not covered)
2. Documentation of failure to maintain stable serum-albumin corrected calcium despite the chronic use of calcium and active vitamin D supplementation (such as calcitriol) for a minimum of six months.
3. Documentation that Natpara® will be used concurrently with calcium and active vitamin D
4. Serum albumin corrected calcium is above 7.5 mg/dL (1.9 mmol/L)
5. Documentation serum 25-hydroxyvitamin D stores are sufficient per laboratory reference range (Note: 20 ng/mL [50 nmol/L] or greater is generally considered adequate)

Reauthorization requires annual documentation of regular monitoring of serum calcium levels with appropriate dosage adjustments to meet patient specific goal.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an endocrinologist.

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year

## **OTHER CRITERIA**

N/A

## NEW FORMULATION WITHOUT ESTABLISHED BENEFIT

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### MEDICATION(S)

ABSORICA, ABSORICA LD, ACANYA, ACTICLATE, ADAPALENE 0.1% LOTION, ADHANSIA XR, ADZENYS ER, ADZENYS XR-ODT, AMPHETAMINE, 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, COMBIGAN, CONJUPRI, CONSENSI, CONZIP, CUPRIMINE, CYCLOBENZAPRINE HCL ER, DESLORATADINE 2.5 MG ODT, DESLORATADINE 5 MG ODT, DESONATE, 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 HYCLATE 150 MG TAB, DOXYCYCLINE HYCLATE 75 MG TAB, DOXYCYCLINE IR-DR, DOXYCYCLINE MONO 150 MG CAP, DOXYCYCLINE MONO 75 MG CAPSULE, DUEXIS, DUOBRII, DURLAZA, DUTOPROL, DYMISTA, ECOZA, EDLUAR, ELEPSIA XR, EVEKEO ODT, EZALLOR SPRINKLE, FENOFIBRATE 150 MG CAPSULE, FENOFIBRATE 50 MG CAPSULE, FORTAMET, FOSAMAX PLUS D, GLUMETZA, GOCOVRI, GONITRO, GRALISE, HALOBETASOL PROP 0.05% FOAM, HEMADY, HYDROCORT BUTY 0.1% LIPID CRM, HYDROCORT BUTY 0.1% LIPO CREAM, HYDROCORTISONE BUTYR 0.1% LOTN, IBUPROFEN-FAMOTIDINE, IMPEKLO, IMPOYZ, INDOMETHACIN 20 MG CAPSULE, ISOSORBIDE DINIT-HYDRALAZINE, ISOTRETINOIN 25 MG CAPSULE, ISOTRETINOIN 35 MG CAPSULE, KENALOG, KITABIS PAK, LEVAMLODIPINE MALEATE, LEXETTE, LICART, LIDOVIX, LIPOFEN, LOCOID 0.1% LOTION, LOCOID LIPOCREAM, LOFENA, LORZONE, LYMEPAK, LYRICA CR, MELOXICAM 10 MG CAPSULE, MELOXICAM 5 MG CAPSULE, METFORMIN ER GASTRIC, METFORMIN ER OSMOTIC, METOCLOPRAMIDE HCL ODT, 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, MONDOXYNE NL 75 MG CAPSULE, MONODOX 75 MG CAPSULE, NALOCET, NAPRELAN, NAPROXEN SODIUM CR, NAPROXEN SODIUM ER, NEO-SYNALAR 0.5%-0.025% CREAM, NORITATE, OKEBO, OMEPRAZOLE-SODIUM BICARBONATE, ONEXTON, ONZETRA XSAIL, ORACEA, ORTIKOS, OXYCODONE-ACETAMINOPHN 2.5-300, PENICILLAMINE 250 MG CAPSULE, PENNSAID, PRAMIPEXOLE ER, PREGABALIN ER, PRESTALIA, RAYOS, RELAFEN DS, REQUIP XL, RETIN-A MICRO, RETIN-A MICRO PUMP, ROPINIROLE HCL ER 12 MG TABLET, ROPINIROLE HCL ER 6 MG TABLET, ROPINIROLE HCL ER 8 MG TABLET, ROSUVASTATIN-EZETIMIBE, ROSZET, RYVENT, SERNIVO, SEYSARA, SOLIQUA 100-33, SOLODYN, SORILUX, SPRITAM, SUMATRIPTAN SUCC-NAPROXEN SOD, SYMPAZAN, TARGADOX, TELMISARTAN-AMLODIPINE, TIVORBEX, TOBRAMYCIN PAK 300 MG/5 ML, TOLSURA,

TOPICORT 0.25% SPRAY, TOSYMRA, TRAMADOL HCL 100 MG TABLET, TRAMADOL HCL ER 100 MG CAPSULE, TRAMADOL HCL ER 150 MG CAPSULE, TRAMADOL HCL ER 200 MG CAPSULE, TRAMADOL HCL ER 300 MG CAPSULE, TRETIN-X 0.05% COMBO PACK, TRETIN-X 0.075% CREAM, TRETIN-X 0.1% COMBO PACK, TRETINOIN MICROSPHERE, TREXIMET, TRIAMCINOLONE 0.147 MG/G SPRAY, TUXARIN ER, TWYNSTA, ULTRAVATE, VELTIN, VERDESO, VIVLODEX, WHYTEDESK TDPAK, WHYTEDESK TRILASIL PAK, XIMINO, XOLEGEL, XULTOPHY 100-3.6, ZEGERID, ZEGERID OTC, ZEMBRACE SYMTOUCH, ZIANA, ZIPSOR, ZOLPIMIST, ZORVOLEX, ZTLIDO, ZUPLLENZ

#### **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**

N/A

# **NEXLETOL/NEXLIZET**

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## **MEDICATION(S)**

NEXLETOL, NEXLIZET

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For Initial Authorization:

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 (i.e., 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 (e.g., 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**

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

## **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**

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### **MEDICATION(S)**

BAFIERTAM, VUMERITY

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following:

1. Documented trial and failure (defined as worsening disease after at least three months of therapy) of generic dimethyl fumarate

OR

2. Documented intolerable side effects or contraindication to dimethyl fumarate (brand or generic formulation).

### **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

# **NORTHERA**

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## **MEDICATION(S)**

DROXIDOPA, NORTHERA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For initial authorization all of the following criteria must be met:

1. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH)
2. Documentation that neurogenic orthostatic hypotension is caused by one of the following:
  - a. Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure)
  - b. Dopamine beta-hydroxylase deficiency
  - c. Non-diabetic autonomic neuropathy
3. Documentation of a screen for treatable causes of orthostatic hypotension and currently being treated for the identified treatable cause of orthostatic hypotension
4. Documentation of an adequate trial of non-pharmacotherapy measure has been ineffective
5. Documented trial, failure, intolerance or contraindication to both midodrine and fludrocortisone

Reauthorization will require:

1. Documented response to initial therapy (improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out)
2. Documentation that periodic evaluations are being done to assess continued efficacy and medical rationale for continuing therapy, as none of the clinical trials demonstrated continued efficacy beyond two weeks of treatment.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a cardiologist or neurologist.

## **COVERAGE DURATION**

Initial authorization will be for three months. Reauthorization will be approved for one year.

## **OTHER CRITERIA**

N/A

# **NOURIANZ**

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## **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 (e.g. dopamine agonist, COMT inhibitor, or 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

# NUCYNTA

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## MEDICATION(S)

NUCYNTA

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Trial and failure of tramadol

AND

2. Documentation of trial and failure of a formulary short-acting opioid analgesic (such as oxycodone)

## AGE RESTRICTION

Approved for 18 years of age and older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A

# NUCYNTA ER

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## MEDICATION(S)

NUCYNTA ER

## COVERED USES

N/A

## EXCLUSION CRITERIA

As needed (prn) use

## REQUIRED MEDICAL INFORMATION

For Chronic Pain:

1. Documentation of trial and failure, contraindication, or intolerance to:

a. Extended-release tramadol

AND

b. Extended-release morphine sulfate

2. Documentation of persistent pain (expected to last longer than three months)

For Chronic Pain associated with diabetic peripheral neuropathy (DPN):

1. Documentation of trial and failure, contraindication, or intolerance to:

a. Gabapentin or pregabalin

AND

b. One tricyclic antidepressant (TCA), selective serotonin reuptake inhibitor (SSRI) or serotonin–norepinephrine reuptake inhibitor (SNRI)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A

# **NUEDEXTA**

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## **MEDICATION(S)**

NUEDEXTA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Current use, or use within the past 14 days, of monoamine oxidase inhibitors (MAOIs).

Patient's diagnosed with a prolonged QT interval, congenital long QT syndrome, or a history suggesting torsades de pointes.

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of pseudobulbar affect (PBA)

AND

2. Documentation of a neurologic disease or brain injury (such as traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis (ALS), or Parkinson's disease).

Reauthorization:

Documentation of response to therapy, defined as a reduction in episodes of laughing, crying, and/or emotional lability.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

## **OTHER CRITERIA**

N/A



# **OCALIVA**

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## **MEDICATION(S)**

OCALIVA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Use for 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 six 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

Reauthorization Criteria:

1. Maintenance of biochemical response, defined as alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, total bilirubin (tBili) less than or equal to ULN, and ALP decrease of at least 15%
2. Documentation that ursodiol will be continued, if tolerated
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: EYLEA, LUCENTIS, MACUGEN**

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### **MEDICATION(S)**

BEOVU, EYLEA, LUCENTIS, MACUGEN

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Must have one of the following diagnoses and meet any required criteria:

1. Neovascular (wet) age-related macular degeneration (AMD)

a. For ranibizumab (Lucentis®), aflibercept (Eylea®), brolucizumab (Beovu®)

i. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)

OR

ii. Rationale is provided why therapy with bevacizumab is not appropriate for the patient

a. For pegaptanib (Macugen®):

i. Documentation that bevacizumab and either ranibizumab (Lucentis®) or aflibercept (Eylea®) has been ineffective, not tolerated, or contraindicated

OR

ii. Rationale is provided why therapy is not appropriate for the patient

2. Diabetic macular edema or Diabetic retinopathy

a. For ranibizumab (Lucentis®) or aflibercept (Eylea®):

i. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)

OR

ii. Request is for aflibercept (Eylea®) and patients baseline visual acuity is 20/50 or worse

OR

iii. Rationale is provided why therapy with bevacizumab is not appropriate for member

3. Macular edema following retinal vein occlusion

a. For ranibizumab (Lucentis®) or aflibercept (Eylea®):

- i. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)  
OR
- ii. Rationale is provided why therapy with bevacizumab is not appropriate for the patient

4. Myopic Choroidal Neovascularization (mCNV)

- a. Request is for ranibizumab (Lucentis®)

Reauthorization or continuation of therapy:

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

**QUANTITY LIMITS:**

Approval may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines and are subject to medical claims audits

**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

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## MEDICATION(S)

OPZELURA

## COVERED USES

N/A

## EXCLUSION CRITERIA

Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants

## REQUIRED MEDICAL INFORMATION

For initial authorization, must meet all of the following criteria:

1. Diagnosis of mild to moderate atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of 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

AND

2. Documentation of trial and failure of an adequate treatment course with at least one agent from each of the following treatment modalities:

- 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

AND

3. For Medicaid only:

- a. Documentation that condition is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction

AND

- b. Documentation of one of the following

- i. At least 10% of body surface area involved

OR

- ii. Hand, foot, 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

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 and reauthorization 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

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### MEDICATION(S)

ABIRATERONE ACETATE, AFINITOR, AFINITOR DISPERZ, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, AYWAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI 75 MG CAPSULE, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, 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, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, LAPATINIB, LENALIDOMIDE, LENVIMA, LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYSODREN, MEKINIST, MEKTOVI, MELPHALAN, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, 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 20 MG CAPSULE, TEMODAR 250 MG CAPSULE, TEMODAR 5 MG CAPSULE, TEMOZOLOMIDE, TEPMETKO, TIBSOVO, TRETINOIN 10 MG CAPSULE, TRUSELTIQ, TUKYSA, TURALIO, TYKERB, UKONIQ, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, 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 commercial members only, the following drug-specific criteria must be met:

a. For ribociclib (Kisqali®) for advanced or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to palbociclib (Ibrance®) 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 abiraterone acetate (Zytiga®): May also be prescribed by a urologist

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A



## ORAL RINSES

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### MEDICATION(S)

AQUORAL, BOCASAL, CAPHOSOL, EPISIL, GELCLAIR, GELX, MUGARD, NEUTRASAL, XEROSTOMIA RELIEF

### COVERED USES

Mucositis/stomatitis secondary to chemotherapy or radiation

Xerostomia secondary to chemotherapy or radiation

Sjögren's syndrome

### EXCLUSION CRITERIA

Other indications not outlined above

### 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, failure, intolerance or contraindication to TWO of the following:

a. Over-the-counter oral anesthetics (e.g. benzocaine products such as OraGel®, Anbesol®)

b. Prescription oral anesthetics (e.g. viscous lidocaine 2%)

c. Saliva substitutes (e.g. 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 (e.g., continued chemotherapy and/or radiation)

2. Documentation of initial response to therapy (e.g., 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 xerostomia secondary to chemotherapy or radiation OR Sjögren's syndrome

AND

2. Documented trial, failure, intolerance or contraindication to both of the following:

a. TWO over the counter saliva substitutes (e.g. Biotene®, Mouth Kote®)

b. Saliva stimulants (e.g., 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 6 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

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## MEDICATION(S)

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

## COVERED USES

N/A

## EXCLUSION CRITERIA

For Evenity®: 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 (e.g., 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 (e.g., 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 (e.g., 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 (e.g., alendronate)
        - c. IV bisphosphonate therapy (such as zoledronic acid).
2. For female patients requesting Forteo®:
- a. Documentation of trial and failure to Tymlos® (abaloparatide). Failure is defined as a new fracture or worsening bone mineral density while adherent to Tymlos® (abaloparatide).

AND

b. Total duration of treatment with Tymlos® (abaloparatide) has not exceeded two years.

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

For Forteo® and Tymlos®: May be approved for up to two years, ensuring the cumulative duration of osteoanabolic therapy does not exceed two years in a lifetime. Duration of osteoanabolic therapy is defined as cumulative duration spent on any of the three therapies: abaloparatide, teriparatide, or romosozumab.

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

# OXAYDO

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## MEDICATION(S)

OXAYDO

## COVERED USES

N/A

## EXCLUSION CRITERIA

Treatment of opioid dependence

## REQUIRED MEDICAL INFORMATION

Initial authorization:

1. Documentation that patient has used at least one non-opiate therapy, such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (such as etodolac, diclofenac, meloxicam), or antidepressants/anticonvulsants for neuropathic pain (such as duloxetine, gabapentin, amitriptyline) unless all are contraindicated or not indicated or patient has active cancer pain
2. Documentation of high risk for opioid abuse:
  - a. Based on provider clinical judgment or screening assessment (including having a history of opioid abuse) OR
  - b. Family or household member with a history of opioid abuse

Reauthorization:

1. Documentation of a positive response to therapy
2. Documentation that patient continues to need an abuse deterrent formulation
3. Documentation that patient is not using other opioid medications unless they are also abuse deterrent formulations (may be verified by claims)

## QUANTITY LIMIT:

See Policies Maximum Allowable Opioid Dose and Maximum Allowable Opioid Dose - Medicaid  
ORPTCANA031 and ORPTCANA048

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

**OTHER CRITERIA**

N/A

# **OXBRYTA**

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## **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





# OXERVATE

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## 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 (e.g. 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

## QUANTITY LIMIT:

Cenegermin-bkbj ophthalmic solution 0.002% (Oxervate®): 1 mL (one vial) per day (If both eyes are being treated a quantity of 2 mL (two vials) a day will be allowed

## 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

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## 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/1.73m<sup>2</sup>

## 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 3 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 3 months with no significant improvement in urine oxalate concentration

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 3 liters per meter-squared BSA per day) and pyridoxine (unless individual is a pyridoxine non-responder)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

**COVERAGE DURATION**

Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.

**OTHER CRITERIA**

N/A

# **OXYMORPHONE**

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## **MEDICATION(S)**

OXYMORPHONE HCL

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial authorization

1. All of the following:

- a. Trial and failure, contraindication or intolerance to at least one non-opiate therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (such as etodolac, diclofenac, meloxicam), or antidepressants/anticonvulsants for neuropathic pain (such as duloxetine, gabapentin, amitriptyline) unless using for active cancer pain
- b. Trial and failure, contraindication or intolerance to immediate release morphine sulfate
- c. Trial and failure, contraindication or intolerance to immediate release oxycodone

Opioid doses greater than 90 mg Morphine Milligram Equivalent (MME) per day require additional prior authorization. See Policy Maximum Allowable Opioid Dose (#ORPTCANA031) and Policy Maximum Allowable Opioid Dose - Medicaid (#ORPTCANA048) for clinical coverage criteria.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A

# **PALFORZIA**

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## **MEDICATION(S)**

PALFORZIA

## **COVERED USES**

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 3mm 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 (e.g., 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® (e.g., recurrent asthma exacerbations, persistent loss of asthma control, persistent heartburn, dysphagia, persistent abdominal pain)
3. Provider attestation that the patient continues to be to comply 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

# **PALYNZIQ**

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## **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

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### MEDICATION(S)

LEQVIO, PRALUENT PEN, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

### COVERED USES

N/A

### EXCLUSION CRITERIA

N/A

### 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 80 mg daily or rosuvastatin 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. LDL-C greater than 190 mg/dL and two of the following:
  - a. Presence of tendon xanthomas in patient or in first- or second-degree relatives
  - b. Personal history of premature atherosclerotic cardiovascular disease (ASCVD) in men less than 55 years or women less than 60 years
  - c. First-degree relative with premature ASCVD (men less than 55 years, women less than 60 years)
- 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**

- For ASCVD: must be prescribed by or in consultation with a cardiologist
- For FH: must be prescribed by or in consultation with a cardiologist, endocrinologist, or board certified lipidologist

#### **COVERAGE DURATION**

- Initial authorization for six months.
- Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

#### **OTHER CRITERIA**

N/A

# **PEDIATRIC ANALGESICS**

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## **MEDICATION(S)**

ACETAMINOPHEN-CODEINE, ASA-BUTALB-CAFFEINE-CODEINE, ASCOMP WITH CODEINE, BUTALB-ACETAMINOPH-CAFF-CODEIN, BUTALBITAL COMPOUND-CODEINE, CAPCOF, CARISOPRODOL-ASPIRIN-CODEINE, CODEINE PHOSPHATE, CODEINE SULFATE, CODEINE-GUAIFENESIN, CODITUSSIN AC, FIORICET WITH CODEINE, FIORINAL WITH CODEINE #3, G TUSSIN AC, GUAIIATUSSIN AC, GUAIFENESIN AC, GUAIFENESIN DAC, GUAIFENESIN-CODEINE, LORTUSS EX, M-CLEAR WC, M-END PE, MAR-COF BP, MAR-COF CG, MAXI-TUSS AC, NINJACOF-XG, POLY-TUSSIN AC, PROMETHAZINE VC-CODEINE, PROMETHAZINE-CODEINE, PROMETHAZINE-PHENYLEPH-CODEINE, QDOLO, RYDEX, TRAMADOL HCL 25 MG/5 ML CUP, TRAMADOL HCL 50 MG TABLET, TRAMADOL ER 100 MG TABLET, TRAMADOL ER 200 MG TABLET, TRAMADOL ER 300 MG TABLET, TRAMADOL HCL ER 100 MG TABLET, TRAMADOL HCL ER 200 MG TABLET, TRAMADOL HCL ER 300 MG TABLET, TRAMADOL HCL-ACETAMINOPHEN, TUZISTRA XR, TYLENOL-CODEINE NO.3, ULTRACET, ULTRAM, VIRTUSSIN AC, VIRTUSSIN DAC

## **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

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## MEDICATION(S)

ISTURISA, LANREOTIDE ACETATE, MYCAPSSA, 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 disease, Signifor®, Isturisa®, or Signifor® LAR may be covered if all the following are met:
  - a. Diagnosis of endogenous Cushing's disease
  - b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery
3. For carcinoid tumors, for the symptomatic treatment of diarrhea or flushing, Sandostatin® LAR or Somatuline® Depot may be covered if all the following are met:
  - a. Documentation that patient has severe diarrhea or flushing caused by a carcinoid tumor
4. For vasoactive intestinal peptide tumors, for the symptomatic treatment of diarrhea, Sandostatin® LAR, Somatuline® Depot, may be covered if all the following are met:
  - a. Documentation that patient has severe diarrhea caused by vasoactive intestinal peptide tumors
5. 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
6. 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

(Lomotil®)

c. Documentation of good response and tolerability to short-acting octreotide

7. 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 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, 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

# POTASSIUM LOWERING AGENTS

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## MEDICATION(S)

LOKELMA, VELTASSA

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

All the following criteria are required:

1. Documentation of confirmed diagnosis of hyperkalemia (greater than or equal to 5.1 mEq/L)

AND

2. If patient is receiving concurrent angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) therapy: documentation of an attempt to optimize the dose of all current renin-angiotensin –aldosterone (RAAS) inhibitors (e.g., ACE-I, ARB, aldosterone antagonists) to minimize hyperkalemia

Reauthorization will require all of the following criteria:

1. Documentation that patient achieved normal potassium levels (3.5-5.0 mEq/L) within the last three months

AND

2. Patient is continuing on RAAS inhibitor therapy or medical rationale is provided for continuing therapy (e.g., patient remains at high risk for recurrence of hyperkalemia)

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial authorization: six months

Reauthorization: 12 months

## OTHER CRITERIA

N/A

# PREVYMIS

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## MEDICATION(S)

PREVYMIS

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. All the following must be met:
  - a. Member is within 100 days post- allogeneic transplant
  - b. Cytomegalovirus (CMV) Recipient positive
  - c. Member has ONE of the following:
    - i. Graft Versus Host Disease (GVHD) requiring greater than or equal to 1 mg/kg/day use of prednisone [or equivalent]
    - ii. Receipt of lymphocyte depleting therapy (such as antithymocyte globulin [ATG], antithymocyte globulin equine [ATGAM], antithymocyte globulin rabbit [thymoglobulin], alemtuzumab, fludarabine) within the previous 6 months
    - iii. Transplant was a cord blood allograft
    - iv. History of CMV drug resistance within the past six months
  - d. If IV letermovir is being requested, rationale for not using oral formulation must be provided (such as patient is unable to swallow)

## AGE RESTRICTION

May be approved for 18 years and older.

## PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a hematologist, oncologist, or Infectious Disease specialist.

## COVERAGE DURATION

Authorization will be approved for three months, up to 100 days post-transplant

## OTHER CRITERIA

N/A



# PROCYSBI

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## MEDICATION(S)

PROCYSBI

## COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

## 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

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## 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**

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### **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

# **PULMONARY ARTERIAL HYPERTENSION**

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## **MEDICATION(S)**

ADCIRCA, ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, EPOPROSTENOL SODIUM, FLOLAN, LETAIRIS, OPSUMIT, ORENITRAM ER, REMODULIN, REVATIO 10 MG/12.5 ML VIAL, REVATIO 10 MG/ML ORAL SUSP, SILDENAFIL 10 MG/12.5 ML VIAL, SILDENAFIL 10 MG/ML ORAL SUSP, TADALAFIL 20 MG TABLET, TRACLEER, TREPROSTINIL, TYVASO, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT, UPTRAVI, VELETTRI, 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 initial authorization 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 25 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®, and Ventavis: Class III or IV

b. Tyvaso®: Class III or IV

c. 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® only, WHO Group 3 classification PH-ILD

AND

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

Reauthorization: Documentation of response to therapy such as lack of disease progression, improvement in WHO functional class

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a pulmonologist or cardiologist

**COVERAGE DURATION**

Initial authorization for 12 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

**OTHER CRITERIA**

N/A

## **QUDEXY XR, TROKENDI XR**

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### **MEDICATION(S)**

QUDEXY XR, TOPIRAMATE ER, TROKENDI XR

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Confirmed diagnosis of one of the following conditions:

- a. Seizure disorder
- b. Migraine Headaches

AND

2. Documented trial and failure, intolerance or contraindication to immediate release topiramate

AND

3. If the request is for Trokendi XR® or brand Qudexy® XR documented trial and failure, intolerance or contraindication to generic extended release topiramate ER

Reauthorization for migraine headaches requires documented positive response to therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Migraine Headaches: Initial authorization will be approved for three months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

For seizure disorders: Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

### **OTHER CRITERIA**

N/A

# **RADICAVA - MEDICAL BENEFIT**

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## **MEDICATION(S)**

RADICAVA

## **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 2 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

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## 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
4. Documented baseline Hgb level of at least 9 g/dL, drawn within the previous 30 days

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) and 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 9 weeks. Reauthorization will be for one (1) year.

MDS-RS: Initial authorization will be for 6 months. Reauthorization will be for one (1) year

### **OTHER CRITERIA**

N/A

# REGRANEX

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## MEDICATION(S)

REGRANEX

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For initiation, must submit the following:

1. Documentation of adequate blood tissue supply to the affected area.

AND

2. The record must demonstrate use of good ulcer care for a minimum of eight weeks prior to request for initiation of therapy. Good ulcer care will generally include documentation of the following:
  - a. Establishment of adequate blood supply as indicated above
  - b. Determination of adequate nutritional status with a serum albumin level of greater than 2g/dL
  - c. Appropriate debridement to remove dead tissue with ongoing debridement as necessary
  - d. No weight on affected area to relieve pressure points
  - e. Systemic treatment of wound infections, if present
  - f. Maintenance of a moist wound environment (dressing changes including alginates, foams, hydrocolloids, hydro gels, and transparent films).

For reauthorization for a second 90 day course, documentation must show an adequate response defined as a 30% reduction or greater in ulcer size. There is no medical evidence to justify ongoing treatment after 180 days of Regranex® treatment.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial authorization and one reauthorization will be approved for 90 days.

## OTHER CRITERIA

N/A



## **RESCUE MEDICATIONS FOR EPILEPSY**

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### **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 may be reviewed annually to assess continued medical necessity and effectiveness of medication

### **OTHER CRITERIA**

N/A

# REVCovi

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## 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 (e.g., 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 a 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

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## MEDICATION(S)

REYVOW

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Diagnosis of migraine headaches AND one of the following:

1. Trial of and inadequate response or intolerance to two oral triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) and one additional triptan formulation (e.g. oral disintegrating tablet, nasal spray, injection) OR
2. One of the following cardiovascular or non-coronary vascular contraindications to use of triptans:
  - a. Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
  - b. History of stroke or transient ischemic attack (TIA)
  - c. Peripheral vascular disease
  - d. Ischemic bowel disease
  - e. Uncontrolled hypertension
  - f. History of hemiplegic or basilar migraine

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

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a headache specialist [e.g., neurologist, pain management specialist or specialist with United Council for Neurologic Subspecialties (UCNS)]

## 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

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## 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

# RITUXIMAB

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## 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:

A. 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

B. For Rheumatoid Arthritis:

1. 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
2. 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.

C. For Vasculitis, including antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)] and refractory polyarteritis nodosa (resistant to cyclophosphamide):

1. Documentation that rituximab will be given in combination with glucocorticoids  
AND
2. Documentation of severe disease (for example, critical organ system involvement)

D. For Immune Thrombocytopenia (ITP):

1. Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy  
AND
2. Documentation of active bleeding, or high-risk of bleeding, or a platelet count less than 30,000 cells per microliter

E. For Relapsing and Remitting Multiple Sclerosis (RRMS): One of the following:

1. Documentation of trial, failure, or intolerance to at least two disease modifying therapies indicated for RRMS
- OR
2. Documentation that patient has highly active or aggressive disease

F. For Refractory Myasthenia Gravis:

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 (for example, pyridostigmine)
    - b. Corticosteroids (for example, prednisone, methylprednisolone)
    - c. Immunosuppressive agents (for example, azathioprine, cyclosporine, mycophenolate)
    - d. Plasma exchange

G. For Autoimmune Hemolytic Anemia (AIHA):

1. Diagnosis of warm AIHA and documentation of trial, failure, intolerance, or contraindication to glucocorticoids
- OR
2. Diagnosis of cold AIHA or cold agglutinin disease

H. Confirmed diagnosis of Neuromyelitis Optica

I. 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**

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

## **RUKOBIA/TROGARZO - MEDICAL BENEFIT**

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### **MEDICATION(S)**

RUKOBIA, TROGARZO

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Initial Authorization:

1. Inadequate response to six months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last eight weeks
  - a. Defined as persistent viremic failure
  - b. Failure must not be due to non-adherence (adherence may be verified by pharmacy claims)
2. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance to at least one antiretroviral medication from each of the three following classes:
  - a. Non-nucleoside reverse transcriptase inhibitor
  - b. Nucleoside reverse transcriptase inhibitor
  - c. Protease inhibitor
3. Documentation of baseline viral load
4. Confirmation that patient will take an optimized background regimen of anti-retroviral therapy (ART) along with the requested therapy

Re-authorization or continuation of therapy:

1. Patient has previously received treatment with the requested therapy
2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy)
3. Confirmation that patient will continue to take an optimized background regimen of anti-retroviral therapy (ART) with the requested therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an infectious disease specialist.

### **COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# SABRIL

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## MEDICATION(S)

SABRIL, VIGABATRIN, VIGADRONE

## 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





# SAPHNELO

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## 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

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## 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 protoporphyria (EPP) or X-linked protoporphyria (XLP) with significant hepatic involvement

## REQUIRED MEDICAL INFORMATION

For initial authorization:

1. Confirmed diagnosis of erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) by one of the following:
  - a. Gene sequencing showing an FECH, CLPX, or ALAS2 mutation
  - b. Elevated total erythrocyte protoporphyrin greater than 80 mcg/dL
  - c. Erythrocyte fractionation shows more than 50% metal-free vs. zinc protoporphyrin
2. Documentation of characteristic symptoms of EPP/XLP phototoxicity (e.g., intolerance to light with symptoms including itching, burning, pain, erythema, or scarring of the skin on contact with sunlight)
3. Documentation that sun avoidance and use of sunscreen and protective clothing have proven inadequate in controlling EPP/ XLP -associated painful skin reactions
4. Documentation that the condition is having a significant impact on quality of life (QOL)

For reauthorization:

1. Documentation of a positive response to therapy by one of the following:
  - a. Decreased severity and number of phototoxic reactions
  - b. Increased duration of sun exposure
  - c. Increased quality of life
2. 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, e.g. 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**

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### **MEDICATION(S)**

12 HOUR ALLERGY-D, 24HR ALLERGY RELIEF, ALAVERT, ALAVERT D-12, KRO ALL DAY ALLERGY 10 MG SFGL, ALL DAY ALLERGY RELIEF, ALL DAY ALLERGY-D, ALLEGRA ALLERGY, 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 10 MG ODT, ALLERGY RELIEF 180 MG TABLET, ALLERGY RELIEF 60 MG TABLET, ALLERGY RLF(CETRZN) 10 MG SFGL, CVS ALLERGY RELIEF 180 MG TAB, CVS ALLERGY RELIEF 5 MG TABLET, CVS ALLERGY RELIEF 60 MG TAB, CVS ALLERGY(CETRZN) 10 MG SFGL, EQ ALLERGY RELIEF 180 MG TAB, 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, RA ALLERGY RELIEF 180 MG TAB, SM ALLERGY RELIEF 10 MG ODT, SM ALLERGY RELIEF 60 MG TABLET, ALLERGY RELIEF D, ALLERGY RELIEF D-12, ALLERGY RELIEF D-24HR, 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, CVS CHILD ALLERGY RLF 30 MG/5, CHILD CETIRIZINE 10 MG CHEW TB, CHILD CETIRIZINE 5 MG CHEW TAB, CHILDREN'S WAL-FEX, CHILD'S WAL-ZYR 10 MG CHEW TAB, CHILDREN'S ZYRTEC ALLERGY, CLARINEX, 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, QC FEXOFENADINE HCL 180 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, 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 LIQUID GELS, ZYRTEC 10 MG ODT, ZYRTEC-D

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Coverage for Medicaid 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

1. Confirmed diagnosis of allergic rhinitis, allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharyngitis
  2. Confirmed diagnosis of one of the following co-morbidities:
    - a. Asthma or reactive airway disease exacerbated by chronic/allergic rhinitis or allergies
    - i. Patient must be using an asthma controller medication (e.g. inhaled corticosteroid, leukotriene antagonist, and/or inhaled rescue beta-agonist) within the previous six months
    - b. Acute or chronic inflammation of the orbit
    - c. Chronic sinusitis
    - d. Acute sinusitis
    - e. Sleep apnea
    - f. Wegener's Granulomatosis
- AND
3. For non-preferred products: Documented trial and failure\*, intolerance or contraindication to preferred products (e.g., cetirizine tablets/solution AND loratadine tablet/syrup). \*Trial and failure is defined as at least one month of therapy with insufficient response.

#### **AGE RESTRICTION**

Please see specific product information for age restrictions.

#### **PRESCRIBER RESTRICTION**

N/A

#### **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

#### **OTHER CRITERIA**

N/A

## **SGLT-2 INHIBITORS - MEDICAID**

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### **MEDICATION(S)**

FARXIGA, INVOKAMET, INVOKAMET XR, INVOKANA, JARDIANCE, SEGLUROMET, STEGLATRO, SYNJARDY, SYNJARDY XR, XIGDUO XR

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For type 2 diabetes, empagliflozin (Jardiance/Synjardy/Synjardy XR®) and dapagliflozin (Farxiga/Xigduo XR®) will be covered with trial (history of paid claim), intolerance, or contraindication to metformin. For all other SGLT-2 agents, all of the following criteria must be met:

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. Documentation of a trial and failure, contraindication or intolerance to empagliflozin and dapagliflozin. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.

AND

3. A documented HbA1c, obtained within the last six months, which is greater than or equal to 7% and less than or equal to 10%.

For heart failure (with or without diabetes), dapagliflozin and empagliflozin may be covered if the following criteria are met:

1. Documented diagnosis of heart failure with reduced ejection fraction (HFrEF) with New York Heart Association (NYHA) functional class II-IV

2. Documented left ventricular ejection fraction of less than or equal to 40% that has been present for at least two months

For chronic kidney disease (with or without diabetes):

1. Dapagliflozin may be covered in adult patients if the following criteria are met:

a. Patient has a documented current estimated glomerular filtration rate (eGFR) of at least 25, but less than or equal to 75 mL/min/1.73m<sup>2</sup> (using CKD-EPI Formula)

b. Urinary albumin-to-creatinine ratio (UACR) of at least 200 and less than or equal to 5000 mg/g



- c. Patient is currently taking a stable dose (at least four weeks) of maximum tolerated daily dose of one of the following, or intolerance/contraindication to both classes
    - i. Angiotensin converting enzyme (ACE) inhibitor
    - ii. Angiotensin receptor blocker (ARB)
  - d. Patient does not have any of the following: Autosomal dominant or autosomal recessive polycystic kidney disease, lupus nephritis, or anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis
2. Canagliflozin may be covered for patients with type 2 diabetes with a documented trial, intolerance of contraindication to dapagliflozin

For cardiovascular disease in patient's with diabetes:

- 1. Empagliflozin may be covered if the patient is at high risk for cardiovascular events defined as one of the following:
  - a. A history of myocardial infarction
  - b. Coronary artery disease
  - c. Unstable angina
  - d. History of stroke
  - e. Peripheral artery 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

# **SOLIRIS - MEDICAL BENEFIT**

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## **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 (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (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 (e.g., 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 (e.g., dysphagia or abdominal pain)

v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

AND

3. 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. 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:

- Maintenance of platelet counts, meaning improvements or reductions less than 25%
- Reductions in LDH
- Reduction in number of needed plasmaphoresis or plasma infusion events
- 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. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Myasthenia Gravis (MG):

1. Initial reauthorization may require documentation of improvement in MG-ADL by at least two points from baseline.

2. Dose and frequency is in accordance with FDA-approved labeling

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 or contraindication to rituximab

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.

## **OTHER CRITERIA**

N/A

# **SPINRAZA - MEDICAL BENEFIT**

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## **MEDICATION(S)**

SPINRAZA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

1. Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)
2. Use in combination with risdiplam (Evrysdi®)
3. Advanced symptoms of SMA (e.g., 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 of 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): 6MWT, 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

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## 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 (HAM-D17) 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

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## 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
  - c. Current radiographic evidence of widespread skeletal demineralization, pseudofractures, and skeletal deformities due to recurrent fractures and/or widened metaphyseal

Reauthorization:

Pediatric patients: Documentation of response to therapy with improvements in at least one of the following: respiratory status, bone mineralization, or mobility

Adult patients: Initial reauthorization requires documentation of response to therapy with all the following:

1. Increased mobility, and

2. Decreased pain, and

3. Evidence of improved bone mineralization (such as radiographic findings, decrease in number of fractures, improvement in fracture healing, decrease in pseudofractures)

Subsequent reauthorization requires documentation of stabilization or improvement in all the above criteria (1-3).

**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

# **SUBLINGUAL IMMUNOTHERAPY WITH ALLERGEN-SPECIFIC POLLEN EXTRACTS (SLIT)**

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## **MEDICATION(S)**

GRASTEK, ODACTRA, ORALAIR, RAGWITEK

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For treatment with sublingual immunotherapy, patients must meet all the following for initial authorization:

1. Diagnosis of allergic rhinitis, with or without conjunctivitis, AND
2. Documentation that member remains symptomatic despite treatment with both of the following:
  - a) An intranasal steroid
  - b) An oral anti-histamine, AND
3. Documentation that the sublingual immunotherapy will begin at least 12 weeks (for Grastek® or Ragwitek®) or 16 weeks (for Oralair®) before the start of the allergy season, AND
4. Documentation of a positive skin test or pollen specific antibodies to the relevant allergen:
  - a) Grastek: Timothy grass or cross-reactive grass
  - b) Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass
  - c) Ragwitek: Short Ragweed
  - d) Odactra: House dust mite, AND
5. Subcutaneous immunotherapy will not be used concurrently

For reauthorization: Consistent use during treatment period for allergy season previously approved for coverage

For coverage by Medicaid members: Sublingual immunotherapy treatment requires prior authorization for Medicaid members and is approvable only when allergic rhinitis impacts another condition designated as a covered line item by the Oregon Health Services Commission (i.e. an above the line diagnosis).

Additional Criteria for Medicaid members include:

1. Confirmed diagnosis of one of the following co-morbidities:
  - a. Asthma or reactive airway disease within the past year
  - b. Chronic sinusitis
  - c. Acute sinusitis

d. Sleep apnea

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

These allergen extracts must be prescribed by, or in consultation with, an allergist, an immunologist, an otolaryngologist, or other physician currently providing subcutaneous immunotherapy to patients in their practice.

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# SUCRAID

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## 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

## **SYLVANT - MEDICAL BENEFIT**

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### **MEDICATION(S)**

SYLVANT

### **COVERED USES**

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

### **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

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 1 year.

### **OTHER CRITERIA**

N/A



# **SYMLINPEN**

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## **MEDICATION(S)**

SYMLINPEN 120, SYMLINPEN 60

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Patients that require the use of drugs known to alter gastrointestinal motility (i.e. GI anticholinergics, metoclopramide)

Patients with a confirmed diagnosis of gastroparesis

## **REQUIRED MEDICAL INFORMATION**

Initial Authorization:

All of the following criteria must be met:

1. Patient is an insulin dependent diabetic

AND

2. Patient's HbA1c is greater than or equal to 7% and is less than or equal to 9%

AND

3. Documentation of the failure of achieving glycemic control despite multiple titrations and adjustments with various basal and bolus insulin dosing regimens

Reauthorization: HbA1c remains less than or equal to 9%.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, an endocrinologist or credentialed diabetic specialist.

## **COVERAGE DURATION**

Initial authorization for six (6) months and reauthorization will be approved for one (1) year subject to effective response criteria.

## **OTHER CRITERIA**

N/A

# TAFAMIDIS

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## 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 (e.g. left ventricular assist device (LVAD))
4. Used in combination with other therapies for the treatment of transthyretin-mediated amyloidosis e.g., patisiran (Onpattro®), inotersen (Tegsedi®)

## REQUIRED MEDICAL INFORMATION

Initial authorization:

1. Documentation of genetic testing results for mutations of the transthyretin (TTR) gene (patient may have a genetic variation or be wild type)
2. Confirmation of amyloid deposits showing cardiac involvement by ONE of the following:
  - a. A positive (99m)Technetium-Pyrophosphate (99mTc-PYP) scan
  - 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
3. Documentation of patient's NYHA functional class (functional class IV is excluded from coverage)
4. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels)

Reauthorization:

1. Documentation of a positive clinical response by at least one of the following:
  - a. Evidence of slowing of clinical decline
  - b. Reduced number of cardiovascular hospitalizations
  - c. Improvement or stabilization of the 6-minute walk test
  - d. Improvement or stabilization in the KCCQ-OS

## 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

# TARPEYO

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## 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) great than or equal to 1.5 g/g

AND

4. eGFR great than or equal to 35 mL/min/1.73 m<sup>2</sup>

## 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

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## MEDICATION(S)

TAVNEOS

## COVERED USES

N/A

## EXCLUSION CRITERIA

Cirrhosis

## REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following criteria (1-5) 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 patient is currently receiving standard therapy (cyclophosphamide or rituximab) including glucocorticoids for induction of remission, unless clinically significant adverse effects are experienced or are contraindicated
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
4. Documentation of estimated glomerular filtration rate (eGFR) equal to or greater than 15 mL/min/1.72m<sup>2</sup>
5. Documentation of baseline liver function tests (ALT, AST, alkaline phosphatase, total bilirubin)

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

# TEPEZZA

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## 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 two 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 of at least three
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) in combination with mycophenolate
  - a. For patients who have intolerance or contraindication to mycophenolate: Trial and failure of at least two weeks of monotherapy with high-dose intravenous (IV) glucocorticoid therapy will be required unless the patient is unable to use intravenous (IV) glucocorticoids due to a contraindication (such as evidence of viral hepatitis, significant hepatic dysfunction, severe cardiovascular morbidity, or psychiatric disorders)

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 eight infusions

**OTHER CRITERIA**

N/A



# **TESTOSTERONE REPLACEMENT THERAPY (TRT)**

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## **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, TESTOSTERONE 30 MG/1.5 ML PUMP, TLANDO, XYOSTED

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Use for improvement of sexual signs and symptoms (e.g., decreased libido, sexual dysfunction)

## **REQUIRED MEDICAL INFORMATION**

1. One of the following:

a. Diagnosis of gender dysphoria or gender identity disorder

OR

b. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism

2. Documented trial and failure (defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms) of the following:

a. For topical products: Generic topical testosterone 1%

b. For injectable products: Generic injectable testosterone cypionate

c. For all other products including pellets, oral and nasal products: Both generic topical testosterone 1% and generic injectable testosterone cypionate

## **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

## **THERAPEUTIC IMMUNOMODULATORS (TIMS)- MEDICAID**

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### **MEDICATION(S)**

ACTEMRA, ACTEMRA ACTPEN, AVSOLA, CIMZIA, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, ENTYVIO, 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, ILUMYA, INFLECTRA, INFLIXIMAB, KEVZARA, KINERET, OLUMIANT, ORENCIA, ORENCIA CLICKJECT, OTEZLA, REMICADE, RENFLEXIS, RINVOQ, SILIQ, SIMPONI, SIMPONI ARIA, SKYRIZI, SKYRIZI (2 SYRINGES) KIT, SKYRIZI PEN, 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
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®) will require failure, intolerance, or contraindication to the preferred infliximab biosimilar products (Inflectra® and Renflexis®)

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®) will require failure, intolerance, or contraindication to the preferred infliximab biosimilar products (Inflectra® and Renflexis®), in addition the indication-specific criteria below.

ii. For Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Psoriatic Arthritis, all of 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 of 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 (e.g., severity of disease activity)

2. Preferred products [(adalimumab, infliximab biosimilars (Inflectra® and Renflexis®), or vedolizumab (for ulcerative colitis)] 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 of 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:
      - i. At least 10% of body surface area involve
      - ii. Hand, foot or mucous membrane involvement
  - 2. Documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to each of the following first-line agents:
    - a. Topical high-potency corticosteroids (e.g., betamethasone 0.05%, clobetasol 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%, triamcinolone 0.5%)
    - b. Another topical agent (e.g., calcipotriene, tazarotene)
    - c. Phototherapy
    - d. Systemic therapy (e.g., 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 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®)
- vi. 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
- vii. 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® will be approved for FDA-labeled dosing for this condition (90 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

# THIOLA

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## MEDICATION(S)

THIOLA, THIOLA EC, TIOPRONIN 100 MG TABLET

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

All of the following criteria must be met:

1. Confirmation of cystinuria by at least one 24-hour urine collection with measurement of urinary cysteine levels greater than 500 mg/day
2. Documented of failure to conservative treatment with increased fluid intake (at least 2.5 liters/day), a diet restricted in sodium and protein, and urine alkalization with potassium citrate (to achieve pH greater than 7).

Failure is defined by:

- a. Failure to lower the urine cysteine concentration to below 243 mg/L and to raise the urine pH to above 7 in a 24 urine (or, if available, failure to lower the urinary supersaturation of cysteine to below 1)
- b. Persistence of cysteine crystals visualized by urinalysis

Reauthorization requires documentation of urine cysteine concentration less than 300 mg/L or reduction in production of cysteine stones.

## 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 6 months and reauthorization will be approved for one year.

## OTHER CRITERIA

N/A

# THROMBOCYTOPENIA MEDICATIONS

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## 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 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
4. 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
5. For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], Nplate® may be covered if all the



following criteria (a-b) are met:

- a. Documentation of acute exposure to radiation, and
- b. Documentation of myelosuppression defined as leukopenia, thrombocytopenia, or anemia

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 CLD or HSARS: Members 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, 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**

N/A

# TOLVAPTAN

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## 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 m<sup>2</sup> per year over one year
  - b. eGFR decline of at least 2.5 mL/min/1.73 m<sup>2</sup> 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. Evidence that initiation and re-initiation of 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.

#### **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

# TOPICAL ANDROGEN RECEPTOR INHIBITORS

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## MEDICATION(S)

WINLEVI

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Documented trial and failure of ALL of the following:

- a. A topical generic tretinoin gel or cream (any strength)
- b. A topical antibiotic\* (e.g. clindamycin or erythromycin)
- c. A topical benzoyl peroxide product

\* Topical antibiotics should not be used alone due to risk of bacterial resistance, use in conjunction with benzoyl peroxide is recommended

AND

2. For Medicaid only: Documentation that patient has one (1) of the following conditions (must be supported by chart notes):

- a. Acne Fulminans
- b. Acne Conglobata with recurrent abscesses or communicating sinuses
- c. Severe Cystic Acne with persistent or recurrent inflammatory nodules and cysts AND ongoing scarring

## QUANTITY LIMIT:

Calscoterone cream (Winlevi®): 60 grams per 30 days

## AGE RESTRICTION

May be approved for patients aged 12 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



## **TOTAL PARENTERAL NUTRITION (TPN)**

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### **MEDICATION(S)**

AMINOSYN, AMINOSYN II, AMINOSYN II WITH ELECTROLYTES, AMINOSYN M, AMINOSYN WITH ELECTROLYTES, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E, CLINISOL, CLINOLIPID, FREAMINE III, HEPATAMINE, INTRALIPID, NEPHRAMINE, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, SYNTHAMIN 17 WITHOUT ELTYE, 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**

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## **MEDICATION(S)**

ONPATTRO, TEGSEDI

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

- New York Heart Association (NYHA) Heart Functional class III or IV
- Patients with type I or type II diabetes
- Uncontrolled cardiac arrhythmia or unstable angina
- History of liver transplantation
- Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis [such as 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:

- Peripheral sensorimotor polyneuropathy (e.g., 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)
- Autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])

Reauthorization:

1. Documentation that patient is tolerating applicable therapy (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

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## MEDICATION(S)

CLOVIQUE, SYPRINE, TRIENTINE HCL

## COVERED USES

N/A

## EXCLUSION CRITERIA

Cystinuria or rheumatoid arthritis

## REQUIRED MEDICAL INFORMATION

Documentation of severe or intolerable adverse effects to penicillamine tablet (Depen®)

## 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

# **TYSABRI - MEDICAL BENEFIT**

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## **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

AND

- 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

# UCERIS

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## MEDICATION(S)

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

N/A

**COVERAGE DURATION**

Initial authorization and reauthorization will be approved for eight weeks.

**OTHER CRITERIA**

N/A

# ULTOMIRIS

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## 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 glycosphosphatidylinositol (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:
      - iii. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
      - iv. Disabling fatigue
      - v. End-organ complications
      - vi. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
      - vii. 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®) 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.
  - 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, or improvement in PNH related symptoms, and
  - 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

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

Initial authorization for up to three months and reauthorization will be approved for up to one year.

## OTHER CRITERIA

N/A



# **UPLIZNA**

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## **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 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

## **UPNEEQ**

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### **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

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## 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

# VASCEPA

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## MEDICATION(S)

ICOSAPENT ETHYL, VASCEPA

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For Hypertriglyceridemia all of 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. Men equal to or greater than 55 years of age or women equal to or greater than 65 years of age
    - 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 1.73m<sup>2</sup>)
    - 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 documented statin intolerance 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.

3. A triglyceride level within the past six months that is equal to or greater than 150 mg/dL.
4. A low-density lipoprotein cholesterol (LDL-C) level within the past six months that is less than or equal to 100 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**

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## **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

# VERQUVO

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## 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 of 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 both of the following, unless contraindicated or not tolerated:
  - a. Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol)
  - b. 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

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## 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

# VMAT2 INHIBITORS

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## 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 37, AND
      2. Family history (if known), AND
      3. Classic presentation (choreiform movements, psychiatric problems, and dementia).
      4. 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 of 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, 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)

## 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

**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

**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

# **VUITY**

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## **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

# VYLEESI

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## MEDICATION(S)

VYLEESI

## COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

## EXCLUSION CRITERIA

- Uncontrolled hypertension
- Known cardiovascular disease

## REQUIRED MEDICAL INFORMATION

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

## AGE RESTRICTION

Approved for patients aged 18 years and older

## PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an obstetrician, gynecologist, urologist, and/or women's health nurse practitioner

## COVERAGE DURATION

Initial authorization will be approved for 8 weeks and reauthorization will be approved for 1 year

## OTHER CRITERIA

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), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
  - a. A co-existing medical or psychiatric condition
  - b. Problems within the relationship
  - c. 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



QUANTITY LIMIT:

Four (4) auto injectors per 30 days

# VYVGART

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## 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

# **XERMELO**

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## **MEDICATION(S)**

XERMELO

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

All of the following criteria must be met:

1. Diagnosis of carcinoid syndrome diarrhea
2. Patient is experiencing four (4) or more bowel movements per day, despite use of long-acting somatostatin analog therapy, such as octreotide LAR (Sandostatin LAR®) or lanreotide (Somatuline®), for at least three (3) months
3. Documentation of trial and failure of both of the following agents for breakthrough symptoms: loperamide and short-acting octreotide (Sandostatin®)
4. 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 (1) year

## **OTHER CRITERIA**

N/A

# **XHANCE**

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## **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 generic or over-the-counter (OTC) intranasal corticosteroid (e.g., fluticasone)

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:

1. Documentation of clinical benefit with the requested agent (e.g., decrease in nasal congestion, decrease in pain, decrease in pressure, decrease in rhinorrhea, increased sense of smell, 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

# XIAFLEX

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## MEDICATION(S)

XIAFLEX

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For Dupuytren's contracture:

1. Both of the following diagnostic criteria:
  - a. Finger flexion contracture with a palpable cord of at least one finger (other than the thumb) of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a 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:

1. Patient's disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a stable curvature of the penis that is between 30 and 90 degrees with a palpable plaque 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. Isolated hourglass deformity
  - d. Ventral curvature
  - e. Calcified plaque
  - f. 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 effects)

Reauthorization after the initial two treatment cycles (four injections) will require documentation that the

curvature of the penis remains greater than 15 degrees

**AGE RESTRICTION**

Approved for 18 years and older

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

For Dupuytren's contracture: Authorization will be approved for three months for a maximum of two treatment courses.

For Peyronie's disease: 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

# XIFAXAN

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## MEDICATION(S)

XIFAXAN

## COVERED USES

N/A

## EXCLUSION CRITERIA

More than three treatment courses 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 medication from each of the following medication classes:

- a. Tricyclic antidepressant [such as amitriptyline (Elavil®)]
- b. Opioid mu receptor agonist [such as loperamide (Imodium®), diphenoxylate (Lomotil®)]

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 (initial treatment and two reauthorizations).

## 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 per lifetime)

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

## **XOLAIR - MEDICAL BENEFIT**

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### **MEDICATION(S)**

XOLAIR

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication

### **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

For chronic idiopathic urticaria, must meet all of the following criteria:

1. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out

AND

2. Trial and failure of a second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine)

AND

3. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (e.g., montelukast), first generation H1 antihistamine (e.g., diphenhydramine), or histamine H2-receptor antagonist (e.g., famotidine, ranitidine)

Reauthorization for chronic idiopathic urticaria will require documentation of response to therapy (e.g. reduction in flares or oral steroid dose).

For nasal polyps, must meet all the following criteria:

1. Evidence of bilateral nasal polyposis by direct examination, endoscopy or sinus CT scan
2. Documentation of one of the following:
  - a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
  - b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
3. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
4. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids, nasal saline irrigation) in combination with omalizumab

Reauthorization for nasal polyps requires documentation of positive clinical response to therapy such as symptom improvement

### **AGE RESTRICTION**

Treatment of asthma: Approved for six years of age or older.

Treatment of urticaria: Approved for 12 years of age or older.

Treatment of nasal polyps: Approved for 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist

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

Nasal polyps: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist or immunologist

### **COVERAGE DURATION**

Urticaria and nasal polyps: Initial authorization will be for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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

### **OTHER CRITERIA**

N/A

# **XURIDEN**

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## **MEDICATION(S)**

XURIDEN

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Confirmed diagnosis of hereditary orotic aciduria by an appropriate specialist
2. Documented therapeutic failure of uridine dietary supplements

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an endocrinologist, hematologist, medical geneticist, or metabolic specialist

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year

## **OTHER CRITERIA**

N/A

# **ZEPOSIA**

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## **MEDICATION(S)**

ZEPOSIA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Concomitant use with another TIM agent (e.g., apremilast, adalimumab)

## **REQUIRED MEDICAL INFORMATION**

Initial Authorization for multiple sclerosis (MS), all of 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. Highly active disease, defined as both of the following:
    - i. Two or more relapses in the previous year
    - 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, OR
  - b. Documented inadequate response or intolerance to generic dimethyl fumarate or 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 of 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 of 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), Stelara® (ustekinumab), or Xeljanz® (tofacitinib)/Xeljanz XR® (tofacitinib extended release)

b. FDA Labeled contraindication to ALL of 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**

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## **MEDICATION(S)**

ZINPLAVA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Patients with existing heart failure

## **REQUIRED MEDICAL INFORMATION**

All of the following criteria must be met for *Clostridioides difficile* infection (CDI):

1. Previous trial of standard-of-care antibiotic regimen for recurrent CDI (e.g., oral vancomycin, fidaxomicin)  
AND

2. Patient has at least one risk factor for higher likelihood of recurrent CDI (e.g. an age of 65 years or older, a history of *C. difficile* infection in the previous six months, compromised immunity, clinically severe *C. difficile* infection (defined as a Zar score greater than or equal to 2, scores range from 1 to 8, with higher scores indicating more severe infection))  
AND

3. Bezlotoxumab (Zinplava®) must be used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin)

Reauthorization requires:

1. Previous dose was at least 12 months prior  
AND

2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline  
AND

3. Bezlotoxumab (Zinplava®) is used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin)

## **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 dose at 10 mg/kg

(subject to audit).

**OTHER CRITERIA**

N/A



# **ZOLGENSMA**

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## **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 (e.g., 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

## ZYFLO CR

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### MEDICATION(S)

ZILEUTON ER, ZYFLO

### COVERED USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

1. Documentation that the patient has been taking an inhaled corticosteroid controller medication (e.g., Flovent HFA®) continuously for at least one month and continues to have persistent asthma symptoms (e.g., coughing, wheezing, shortness of breath)

AND

2. Documentation of an adequate trial and failure, contraindication or intolerance to both montelukast and zafirlukast. An adequate trial and failure is defined as at least one month of continuous use.

### AGE RESTRICTION

Approved for 12 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