



# PRIOR AUTHORIZATION CRITERIA

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This document contains clinical criteria for coverage of certain drugs that may be covered under your pharmacy benefit. This document is accurate as of the last update date and is subject to change.

Please note that additional restrictions and exclusions to drug coverage may apply. You can search for your drugs on the "Drug Search" online tool for your formulary found at:

<https://www.providencehealthplan.com/members/pharmacy-resources>

This is not a guarantee of coverage or benefits. Please check your member handbook to verify coverage or call Providence Health Plan Customer Service at 503-574-7500 or 1-800-878-4445 (TTY: 711). Service is available five days a week, Monday through Friday, between 8 a.m. and 6 p.m.

# ACTINIC KERATOSIS AGENTS

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## MEDICATION(S)

CARAC, FLUOROURACIL 0.5% CREAM, IMIQUIMOD 3.75% CREAM, IMIQUIMOD 3.75% CREAM PUMP, KLISYRI, TOLAK, ZYCLARA

## COVERED USES

N/A

## EXCLUSION CRITERIA

- Treatment of basal cell carcinoma or other skin cancers

## REQUIRED MEDICAL INFORMATION

1. For the treatment of Actinic Keratosis (AK): Documentation of trial and failure\*, contraindication or intolerance to two of the following formulary, generic topical agents:

- a. Diclofenac 3% gel
- b. 5-fluorouracil 2% or 5% cream/solution
- c. Imiquimod 5% cream

\*An adequate trial and failure is defined as failure to achieve clearance of AK lesion(s) after adherence to recommended treatment dosing and duration

Reauthorization:

Requires documentation of a reduction in the number and/or size of lesions of AK and medical rationale for continuing therapy beyond recommended treatment course.

1. For the treatment of external genital and perianal warts/condyloma acuminata (Zyclara® 3.75% only): Documentation of trial and failure\*, contraindication, or intolerance to formulary, generic imiquimod 5% cream.

\*An adequate trial and failure is defined as failure to achieve total clearance of lesions after 16 weeks of therapy.

Reauthorization:

Requires documentation of improvement of the condition with therapy.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

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

**COVERAGE DURATION**

- Tolak®/Carac®/Klisyri®: Initial authorization and reauthorization will be approved for one month
- Zyclara®: Initial authorization and reauthorization will be approved for up to eight weeks

**OTHER CRITERIA**

N/A

# **ACUTE HEREDITARY ANGIOEDEMA THERAPY**

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## **MEDICATION(S)**

BERINERT, FIRAZYR, ICATIBANT, SAJAZIR

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For initiation of therapy, all the following criteria (1-2) must be met:

1. Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following:

a. For HAE Type I and Type II, documentation of the following (per laboratory standard):

i. Serum C4 below the lower limit of normal,

AND

ii. One of the following:

1. C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal, or

2. C1-INH function less than 50 percent of the lower limit of normal

b. For HAE with normal C1-INH or HAE Type III:

i. Confirmed Factor 12 (FXII), ANGPT1, PLG, or KNG1 gene mutation

OR

ii. Positive family history for HAE and attacks that lack response with high dose antihistamines or corticosteroids.

2. For coverage of Berinert®, Kalbitor®, Firazyr®, or Ruconest®: Documentation of trial and failure or contraindication to generic icatibant

For patients established on the requested therapy, all of the following criteria (1-2) must be met:

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

2. For coverage of Firazyr®: Documentation of trial and failure or contraindication to generic icatibant

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

## **AGE RESTRICTION**

Kalbitor® - 12 years and older

Firazyr® - 18 years and older

Ruconest® - 13 years and older

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **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 (such as guideline directed therapy or compendia supported as listed in either the American Hospital Formulary System or Drugdex).
  - ii. Diagnosis of parasite species must be confirmed through validated laboratory testing/identification. If laboratory confirmation is not possible, must be prescribed by or in consultation with an infectious disease specialist.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

See "Required Medical Information"

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for three months.

## **OTHER CRITERIA**

N/A

# ALINIA

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## MEDICATION(S)

ALINIA, NITAZOXANIDE 500 MG TABLET

## COVERED USES

N/A

## EXCLUSION CRITERIA

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

## REQUIRED MEDICAL INFORMATION

For diarrhea caused by *Cryptosporidium*:

1. Confirmed diagnosis of *Cryptosporidium parvum*

For diarrhea caused by *Giardia*:

1. Confirmed diagnosis of *Giardia*

AND

2. Documentation of trial and failure, intolerance, or contraindication to tinidazole

For diagnoses other than listed above:

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

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

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

## OTHER CRITERIA

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

9. For recurrent vulvovaginal candidiasis (RVVC) (oteseconazole only) must meet all of the following criteria:

- a. Documentation that therapy is aligned with FDA approved indication (specifically, patient is a female who is NOT of reproductive potential)

- b. Documentation of compatible clinical symptoms (such as vulvovaginal irritation, burning, pruritus, characteristic discharge, or edema/erythema)

- c. Documentation of suggestive diagnosis by slide (10% KOH prep or saline mount) or fungal culture/histopathology

- d. Documented failure, intolerance, or contraindication to BOTH of the following:

- i. A 7- to 14-day topical azole course

- ii. An oral fluconazole dose (specifically, oral fluconazole given every third day for a total of three doses)

For reauthorization:

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

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, 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 recurrent vulvovaginal candidiasis (RVVC): initial authorization and reauthorization will be approved for six months.

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

**OTHER CRITERIA**

N/A

# ANTIMALARIAL AGENTS

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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 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

# **BENLYSTA**

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## **MEDICATION(S)**

BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

## **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 previous use of dialysis in the past 12 months or currently using dialysis
4. Concurrent use of voclosporin (Lupkynis®) or anifrolumab (Saphnelo®)

## **REQUIRED MEDICAL INFORMATION**

For patients initiating therapy for Systemic Lupus Erythematosus (SLE) and active lupus nephritis, all the following must be met:

1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist

AND

2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following:
  - a. Positive Antinuclear antibody (ANA)
  - b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
  - c. Positive anti-Smith (Anti-Sm)
  - d. Positive anti-Ro/SSA and anti-La/SSB antibodies

AND

3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:
  - a. For SLE without Active Lupus Nephritis:
    - i. Oral corticosteroid(s)
    - ii. Azathioprine
    - iii. Methotrexate
    - iv. Mycophenolate mofetil
    - 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)

For patients established on therapy, the following criteria must be met: :

1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction of renal related events)

2. Patient currently receiving standard therapy for SLE and active lupus nephritis

### **AGE RESTRICTION**

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

## **BEPREVE/LASTACAFT/PAZEO**

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### **MEDICATION(S)**

BEPOTASTINE BESILATE, BEPREVE, ZERVIAE

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Documented trial and failure, contraindication or intolerance to olopatadine 0.2% eye drops (generic for Pataday®)

AND

2. Documented trial and failure, contraindication or intolerance to azelastine ophthalmic solution (Optivar®).

### **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



## **BRAND OVER GENERIC**

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### **MEDICATION(S)**

GLEEVEC, TECFIDERA

### **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

# 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, QULIPTA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

- Concomitant use of more than one calcitonin gene-related (CGRP) agent
- Concomitant use of CGRP agent for migraine prophylaxis with botulinum toxin for cluster headaches or migraine headaches that do not meet criteria outlined above

## **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 the following criteria are met:

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

ii. One of the following:

1. Trial and inadequate response to at least six weeks of at least one prophylactic medication from one of the following categories:

a. Anticonvulsants, specifically divalproex, valproate, or topiramate

b. Beta-blockers, specifically metoprolol, propranolol, or timolol

c. Antidepressants, specifically amitriptyline or venlafaxine

2. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above

iii. The patient has been evaluated for, and does not have, medication overuse headache

iv. For non-preferred CGRP prophylactic agents (Vyepti®, Nurtec ODT®): Trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig®, Emgality®, Qulipta®, or Ajovy®)

v. For patients established on botulinum toxin for migraine prophylaxis, combination therapy may be considered medically necessary if the following criteria are met:

1. The patient has been established on, and adherent to botulinum toxin for at least six months and has a documented 30% reduction in headache days from baseline

2. Patient continues to have at least four headache days per month with headaches lasting four hours or longer, despite use of botulinum toxin prophylaxis monotherapy

3. Combination therapy is prescribed by, or in consultation with, a neurologist

b. For episodic cluster headaches, Emgality® may be covered if all the following criteria are met:

i. A history of at least five cluster headache attacks, with at least two of the cluster periods lasting at least

seven days,

ii. Cluster periods are separated by at least three months of pain-free remission,

iii. One of the following:

1. Inadequate response to at least six weeks trial (while adherent to therapy) of at least one of the following:

a. Verapamil

b. Melatonin

c. Lithium

d. Topiramate

2. Documented intolerance or contraindication to all of the therapies listed above,

iv. The patient has been evaluated for, and does not have, medication overuse headache

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

i. 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)

ii. Documented intolerance to at least two triptan drug entities

iii. 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

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 prophylaxis: Documented reduction in the severity or frequency of headaches.

b. For acute treatment of migraines: Documentation of treatment success, as demonstrated by a reduction of migraine pain or freedom from migraine symptoms

3. For quantity limit exception requests:

a. For migraine prophylaxis: doses above the FDA maximum recommended dose will not be covered.

i. Nurtec ODT® will be allowed at a quantity of 18 tablets per 30 days if coverage for migraine prophylaxis is approved

ii. 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 (Ubrelvy®) has not been established, quantities to treat more than eight migraine headaches (16 tablets)

will not be covered.

ii. Quantities of up to 18 tablets per month of rimegepant (Nurtec ODT®) may be covered if the patient is on prophylactic therapy with a non-CGRP agent (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**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **CAMBIA**

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## **MEDICATION(S)**

CAMBIA, DICLOFENAC POT 50 MG POWDR PKT

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Use for cluster headaches

## **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/capsules

## **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**

N/A

# CAMZYOS

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## MEDICATION(S)

CAMZYOS

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial authorization requires documentation of all the following:

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

Reauthorization requires documentation of a positive clinical response, as evidenced by at least one of the following:

1. Improvement in symptoms (such as dyspnea, fatigue, chest pain, palpitations, dizziness, fainting) OR
2. NYHA class reduction

## AGE RESTRICTION

May be approved for patients aged 18 years and older

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION



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

**OTHER CRITERIA**

N/A

# CFTR MODULATORS

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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)

## AGE RESTRICTION

Tezacaftor/Ivacaftor (Symdeko™): six years or older

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 six months duration, contraindication, or intolerance to ursodiol

AND

3. Documentation that dose does not exceed 16 mg/kg/day (current body weight must be provided)

AND

4. For Medicaid only: Documentation of evidence of cholecystitis (gallstones without cholecystitis is unfunded)

For use in cerebrotendinous xanthomatosis: Documentation of confirmed diagnosis.

Reauthorization: Documentation of positive clinical response to therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

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

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

## COVERAGE DURATION

Initial authorization will be for six months. Reauthorization will be for one year.

Maximum total duration of therapy authorized for treatment of gallstones will be two years.

**OTHER CRITERIA**

N/A

# CHOLBAM

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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

# CONSTIPATION AGENTS

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## MEDICATION(S)

MOTEGRITY, MOVANTIK, SYMPROIC

## 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 (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. Documentation of response to therapy (such as 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 the following indication-specific criteria:
  - i. For chronic idiopathic constipation (CIC):
    - a. Documentation of two or more of the following occurring over the last three months:
      - 1) Fewer than three spontaneous bowel movements per week
      - 2) Straining during defecations
      - 3) Lumpy or hard stools (Bristol Stool Form Scale 1-2)
      - 4) Sensation of incomplete evacuation
      - 5) Sensation of anorectal obstruction/blockage
      - 6) Manual maneuvers to facilitate defecations (e.g., digital evacuation, support of the pelvic floor)
    - 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 weeks treatment) to ALL 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 day per week during the previous three months with two 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 weeks treatment) to ALL 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

d. For Ibsrela®: Failure, contraindication, or intolerance to one of the following medications:

- 1) Lubiprostone (Amitiza®)
- 2) Linaclotide (Linzess®)

iii. For opioid-induced constipation (OIC):

a. Patient is on chronic opioid therapy

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

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

- i. Naloxegol (Movantik®)
- ii. Lubiprostone (Amitiza®)
- iii. Naldemedine (Symproic®)



**AGE RESTRICTION**

lbsrela® may be approved for patients aged 18 years and older

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

For OIC: Initial authorization will be approved for six months. Reauthorization will be approved for one 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 G5 RECEIVER, DEXCOM G5 TRANSMITTER, DEXCOM G5-G4 SENSOR, DEXCOM G6 RECEIVER, DEXCOM G6 SENSOR, DEXCOM G6 TRANSMITTER, DEXCOM G7 RECEIVER, DEXCOM G7 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. 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
7. On a sodium-glucose cotransporter-2 inhibitor (SGLT-2 inhibitor) (specifically, empagliflozin or dapagliflozin), unless contraindicated or did not tolerate
8. 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), in pediatric patients, 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
3. Documentation that patient is currently in normal sinus rhythm with a resting heart rate (HR) as follows:
  - a. 6–12 months: HR at least 105 bpm
  - b. 1–3 years: HR at least 95 bpm
  - c. 3–5 years: HR at least 75 bpm
  - d. 5–18 years: HR at least 70 bpm

#### **AGE RESTRICTION**

N/A

#### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a cardiologist or electrophysiologist.

#### **COVERAGE DURATION**

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

#### **OTHER CRITERIA**

N/A

# **DALIRESP**

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## **MEDICATION(S)**

DALIRESP, ROFLUMILAST

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

All of the following criteria must be met:

1. A confirmed diagnosis of severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations

AND

2. Trial (of at least 60 days) and failure, contraindication or intolerance to maintenance treatment with triple therapy including a long-acting beta2 agonist (LABA), long-acting antimuscarinic agonist (LAMA), and an inhaled corticosteroid (ICS).

Note: Use of ICS may be waived if documentation is provided that patient has low likelihood of a beneficial ICS response with blood eosinophils less than 100 cells per microliter.

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

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial authorization will be approved for 12 months

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

## **OTHER CRITERIA**

N/A

# **DENAVIR/SITAVIG/XERESE/ZOVIRAX**

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## **MEDICATION(S)**

ACYCLOVIR 5% OINTMENT, DENAVIR, PENCICLOVIR 1% 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



# 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
5. Baseline absolute neutrophil count (ANC) above 1,900 cells per microliter and platelet count above 150,000 cells per microliter

For reauthorization or if patient is currently established on therapy (Note: starting on samples will not be considered established on therapy) all of the following criteria must be met:

1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
2. Dose will not exceed 50 mg/kg (up to maximum 3,000mg) per day
3. Documentation of absolute neutrophil count (ANC) above 1,900 cells per microliter and platelet count above 150,000 cells per microliter taken within the past six months

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by, or in consultation with a neurologist

## COVERAGE DURATION

Initial authorization and reauthorization will be approved for six months.

## OTHER CRITERIA

N/A



# DISPOSABLE INSULIN PUMPS

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## MEDICATION(S)

OMNIPOD 5 G6 INTRO KIT (GEN 5), OMNIPOD 5 G6 PODS (GEN 5), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4)

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

I. Disposable insulin pumps may be considered medically necessary and covered for the treatment of insulin-dependent diabetes when one of the following criteria are met:

A. The request is for a patient with Type 1 diabetes, or

B. All the following:

1. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and

2. The patient has been on a program of multiple daily injections of insulin (at least two injections per day), and

3. Documented history of inadequate glycemic control despite compliance with frequent self-monitoring (four or more blood glucose readings per day or use of continuous glucose monitor) and patient has any of the following problems controlling blood glucose level:

i. Documented hypoglycemia unawareness, or

ii. Documented recurring episodes (two or more events) of clinically significant hypoglycemia (less than 54 mg/dl) or fasting hyperglycemia (greater than 150 mg/dl), or

iii. Glycosylated hemoglobin level (HbA1C) greater than 7%, or

iv. History of recurring, symptomatic hypoglycemia, or

v. Fasting blood sugars frequently exceeding 200 mg/dL, or

vi. History of severe glycemic fluctuations, or

vii. Documented need for more than five daily injections of insulin.

B. For requests for V-go: failure of Omnipod or medical rationale provided for use of this pump over Omnipod

## Replacement of Disposable Insulin Pumps

II. Upgrade or replacement of existing insulin pump may be considered medically necessary and covered when there is documentation that one or more of the device components meet all the following criteria (A.-C.):

A. Are no longer functional, and

B. Are not under warranty, and

C. Cannot be repaired.

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

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

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

## **DPP-4 INHIBITORS**

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### **MEDICATION(S)**

JANUMET, JANUMET XR, JANUVIA, JENTADUETO, JENTADUETO XR, KOMBIGLYZE XR, ONGLYZA, QTERN, STEGLUJAN, TRADJENTA

### **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

## **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 (such as omalizumab, mepolizumab, benralizumab, reslizumab, upadacitinib)

## REQUIRED MEDICAL INFORMATION

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

For moderate-severe atopic dermatitis:

1. For initial authorization, all the following must be met:

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

i. Patient has a minimum body surface area (BSA) involvement of at least 10% or involvement of the palms of the hand and/or soles of the feet)

ii. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification

iii. For Medicaid only: Documentation that patient is having functional impairment due to atopic dermatitis, defined as a Dermatology Life Quality Index (DLQI) score of at least 11 or Children's Dermatology Life Quality Index (CDLQI) score of at least 13 (or severe score on other validated tool)

b. For Commercial: Documented inadequate response to one of the following (i or ii) or contraindication to all therapies:

i. Systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) for at least three months

ii. Both of the following:

1. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least four weeks

2. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least four weeks

c. For Medicaid: Documentation of inadequate response to all of the therapies outlined in criterion 1b (systemic immunomodulatory agents, moderate to high potency topical corticosteroids, AND a topical calcineurin inhibitor)

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

For moderate to severe asthma:

1. For initiation of therapy, all the following criteria (a-c) must be met:

a. Confirmed diagnosis of one of the following (i or ii):

i. Eosinophilic asthma, defined as one of the following:

1. A blood eosinophil count of at least 150 cells/microliter while on high-dose inhaled corticosteroids or daily oral corticosteroids

2. Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion while on high-dose inhaled corticosteroids or daily oral corticosteroids

3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids

4. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids

ii. Corticosteroid dependent asthma, defined as consistent treatment with oral corticosteroids for the past six months (5 mg to 35 mg of prednisone/prednisolone (or equivalent)). This may be verified by pharmacy claims information.

b. Documentation of adherence to treatment with maximally tolerated doses of the following medications (this may be verified by pharmacy claims information), unless intolerance or contraindication to all therapies:

i. Inhaled corticosteroid plus

ii. One of the following:

1. A long-acting inhaled beta 2-agonist (LABA)

2. A leukotriene receptor antagonist (LTRA)

3. A long-acting muscarinic antagonist (LAMA)

c. Documentation inadequate asthma control despite above therapy, defined as one of the following:

i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score more than 1.5

ii. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months

iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months

2. For continuation of therapy: documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

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

1. For initial authorization, must meet all the criteria below:

a. Evidence of nasal polyposis by direct examination, endoscopy, or sinus computed tomography (CT) scan

b. Documentation of one of the following:

i. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery

ii. Patient had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids

c. Patient had an inadequate response to a three-month trial of intranasal corticosteroids (such as

fluticasone nasal spray) or has a documented intolerance or contraindication to ALL intranasal corticosteroids

d. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with dupilumab

2. For reauthorization for CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement

For Eosinophilic Esophagitis (EoE):

1. For initiation of therapy, all the following must be met

a. Diagnosis of eosinophilic esophagitis, defined as all of the following:

i. Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF)

ii. Symptoms of esophageal dysfunction such as dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting

b. Patient had an inadequate response to, or has an intolerance or contraindication to all of the following therapies:

i. At least eight weeks of at least one proton pump inhibitor

ii. At least one topical glucocorticoid (e.g., fluticasone inhaler, swallowed budesonide)

2. For reauthorization for EoE: documentation of positive clinical response to therapy such as symptom improvement

## **AGE RESTRICTION**

The patient's age must be within FDA labeling for the requested indication

## **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

For atopic dermatitis, eosinophilic esophagitis, 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

# EGRIFTA

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## MEDICATION(S)

EGRIFTA SV

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of HIV-associated lipodystrophy

AND

2. Documentation of patient's waist circumference

a. Waist circumference greater than or equal to 37.4 inches (95 cm) for males

b. Waist circumference greater than or equal to 37 inches (94 cm) for females

AND

3. Documentation of waist-to-hip ratio

a. Waist-to-hip ratio greater than or equal to 0.94 for males

b. Waist-to-hip ratio greater than or equal to 0.88 for females

AND

4. Documentation of a body mass index (BMI) greater than 20 kilograms per meter squared

AND

5. Documentation of fasting blood glucose (FBG) of less than or equal to 150 mg/dL (8.33 mmol/L)

AND

6. Documentation that patient has been on a stable regimen of antiretrovirals for at least eight (8) weeks

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

## AGE RESTRICTION

Adults 18 years of age and older

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial authorization and reauthorization will be approved for 6 months.

**OTHER CRITERIA**

N/A

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

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## **MEDICATION(S)**

CALCIPOTRIENE-BETAMETHASONE, CALCIPOTRIENE-BETAMETHASONE DP, TACLONEX

## **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 (such as 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 (such as 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)

## **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



# 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. 25 mg/kg/day in tuberous sclerosis complex

For Patients Established on Therapy:

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

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Must be prescribed 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

## **REQUIRED MEDICAL INFORMATION**

For patients initiating therapy:

1. All diagnoses, with the exception of 2e (preoperative use in patients scheduled for elective non-cardiac, nonvascular surgery), must have documented Hemoglobin (HGB) levels of less than or equal to 10g/dl within the 30 days prior to initiation of therapy

AND

2. Must meet all of the listed criteria below for each specific diagnosis:

a. Treatment of Anemia in Chronic Kidney Disease (CKD)

i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%

b. Treatment of anemia in patients with cancer:

i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%

AND

ii. One of the following clinical scenarios:

1. Patient has comorbid chronic kidney disease

2. Patient undergoing palliative treatment

3. Patient is currently on myelosuppressive chemotherapy and anemia is not able to be managed by transfusion therapy (for example: refusal due to religious beliefs or shortage of PRBCs)

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

i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%

ii. Must have documented current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL

d. Anemia associated with zidovudine-treated HIV-infection patients

i. Documented current (within last three months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml

ii. Zidovudine dose is less than or equal to 4200 mg/week

- e. Preoperative use in patients scheduled for elective noncardiac and nonvascular surgery, all of the following criteria must be met:
  - i. Member has preoperative HGB between 10 and 13 g/dL
  - ii. The surgery has a high-risk for perioperative blood loss (for example, expected to lose more than two units of blood)
  - iii. Patient is unwilling to donate autologous blood pre-operatively
- f. Mircera only: For the treatment of pediatric patients 5 to 17 years of age who are on hemodialysis and converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
  - i. Documented hemodialysis for at least eight weeks
  - ii. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy
  - iii. Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

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

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

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

Initial authorization and reauthorization will be for one year

**OTHER CRITERIA**

N/A

## **ESBRIET/OFEV**

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### **MEDICATION(S)**

ESBRIET 267 MG TABLET, ESBRIET 801 MG TABLET, OFEV, PIRFENIDONE 267 MG TABLET, PIRFENIDONE 534 MG TABLET, PIRFENIDONE 801 MG TABLET

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

Initial Authorization:

For Idiopathic Pulmonary Fibrosis (IPF)

1. Diagnosis of Idiopathic Pulmonary Fibrosis

a. Note: Confirmed by exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, drug toxicity, or connective tissue disease

AND

2. Presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) or histological pattern of probable or indeterminate UIP and diagnosis is supported by lung biopsy

3. For Ofev® and Esbriet® capsule: Documentation of medical rationale for use over generic pirfenidone tablets

For Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (Ofev® only):

1. Confirmed diagnosis of systemic sclerosis

AND

2. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography

For other chronic fibrosing interstitial lung diseases with a progressive phenotype (Ofev® only):

1. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography

AND

2. One of the following criteria:

a. Relative decline in FVC of at least 10% of predicted value (as reported by spirometry performed on two different dates within the last two years)

b. Relative decline in FVC of at least 5% of predicted value combined with worsening of respiratory symptoms

c. Relative decline in FVC of at least 5% of predicted value combined with increased extent of fibrotic

changes on chest imaging

d. Increased extent of fibrotic changes on chest imaging combined with worsening of respiratory symptoms

e. Increased fibrotic changes on HRCT

Reauthorization:

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

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

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

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

**COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

**OTHER CRITERIA**

N/A

# **EUCRISA**

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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

## **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

# EXTAVIA

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## MEDICATION(S)

EXTAVIA

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

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

1. Must have one of the following confirmed diagnoses:
  - a. Relapsing-remitting multiple sclerosis (RRMS)
  - b. Secondary progressive multiple sclerosis (SPMS)
  - c. Clinically isolated syndrome (CIS)
2. Documentation of ONE of the following:
  - a. Inadequate response (after at least six months of continuous therapy) or intolerance to generic dimethyl fumarate or generic glatiramer OR
  - b. FDA labeled contraindication to BOTH generic dimethyl fumarate and generic glatiramer
3. Documentation of active disease after an adequate trial (defined as at least six months of continuous therapy) of at least one of the following preferred agents unless all are contraindicated OR medical rationale why therapies cannot be tried is provided. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.
  - a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
  - b. Interferon-beta 1b (Betaseron®)
  - c. Teriflunomide (Aubagio®)
  - d. Fingolimod (Gilenya®)
  - e. Ozanimod hydrochloride (Zeposia®)
  - f. Siponimod (Mayzent®)
  - g. Cladribine (Mavenclad®)
  - h. Ofatumumab (Kesimpta®)

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

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



**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **FENTANYL CITRATE**

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## **MEDICATION(S)**

ACTIQ, 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

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of all the following:

1. Treatment of breakthrough cancer pain (prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer)

AND

2. Failure of or intolerance to other oral or parenteral short-acting narcotic formulary agents used for breakthrough pain

AND

3. Pain is not controlled with long-acting narcotic analgesics

AND

4. For Fentora®, Lazanda® and Subsys®:

a. Documented trial and failure, contraindication, or intolerance to generic fentanyl citrate lozenge/troche

Reauthorization:

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

AND

2. Documentation of successful response to the medication

## **AGE RESTRICTION**

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

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist or pain specialist

**COVERAGE DURATION**

Initial authorization for six months. Reauthorization for one year.

**OTHER CRITERIA**

N/A

## **FERTILITY AND RELATED MEDICATIONS**

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### **MEDICATION(S)**

CHORIONIC GONAD 10,000 UNIT VL, CHORIONIC GONAD 12,000 UNIT VL, CHORIONIC GONAD 6,000 UNIT VL, FOLLISTIM AQ, FYREMADEL, GANIRELIX ACETATE, NOVAREL, 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**

N/A

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

For Patients Established on therapy:

Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy

## AGE RESTRICTION

Must be 2 years of age or older

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A

# **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

# **GATTEX**

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## **MEDICATION(S)**

GATTEX

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For initiation of therapy (patients not established on therapy), all the following must be met:

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

For patients already established on therapy, the following must be met:

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

1. Documentation that parenteral nutrition support requirement has decreased since initiation of teduglutide

## **AGE RESTRICTION**

Approved for one year and older

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A



# **GNRH ANTAGONISTS**

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## **MEDICATION(S)**

ORIAHNN, ORILISSA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

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

## **REQUIRED MEDICAL INFORMATION**

For endometriosis (Orilissa® and Myfembree® only):

Initial Authorization

1. Documentation that patient has moderate to severe pain associated with endometriosis  
AND
2. Documentation that patient has failed a three-month trial of hormonal contraceptives unless they are not tolerated, or contraindicated

Reauthorization:

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

For management of heavy menstrual bleeding associated with uterine leiomyomas/fibroids (OriaHnn® and Myfembree® only):

Initial Authorization

1. Documentation of confirmed diagnosis of uterine fibroids (e.g., ultrasound), AND
2. Documentation of heavy menstrual bleeding  
AND
3. Documentation that patient has failed a three-month trial of hormonal contraceptives unless they are not tolerated, or contraindicated

Reauthorization:

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

## **AGE RESTRICTION**

Approved for patients 18 years and older

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **GONADOTROPIN RELEASING HORMONE AGONISTS**

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## **MEDICATION(S)**

ELIGARD, LEUPROLIDE 2WK 14 MG/2.8 ML KT, SYNAREL

## **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

# HEPATITS C-DIRECT ACTING ANTIVIRALS

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## MEDICATION(S)

LEDIPASVIR-SOFOSBUVIR, MAVYRET, SOFOSBUVIR-VELPATASVIR, VOSEVI

## COVERED USES

N/A

## EXCLUSION CRITERIA

All regimens containing a protease inhibitor (such as Mavyret® and Vosevi®) are not covered in patients with moderate to severe hepatic impairment (Child-Pugh B and C)

## REQUIRED MEDICAL INFORMATION

1. Documentation of confirmed diagnosis of chronic hepatitis C virus (HCV) infection (B18.2)

AND

2. Documentation of genotype (tested within the past three years) is only required for the following population:

a. Patients with cirrhosis

b. Patients with any prior treatment experience,

c. For regimens which are not pan-genotypic (e.g., Harvoni®, Zepatier®)

AND

3. Documentation of HCV treatment history and response to therapy. Treatment failure with a NS5A inhibitor due to noncompliance will be reviewed on a case-by-case basis.

AND

4. Documentation of cirrhosis status. In patients with clinical evidence of liver cirrhosis, Child-Pugh score is required

AND

5. For coverage of non-preferred regimens, the prescriber must submit medical rational in support of its use over formulary alternatives. Coverage of non-preferred regimens will be reviewed based on evidence and medical necessity over preferred regimens

6. For coverage of oral Harvoni® or Eplclusa® pellets, the prescriber must submit medical rational in support of its use over the available generic tablet formulation (such as inability to swallow)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Eight to 16 weeks based on FDA approved labeling.

**OTHER CRITERIA**

N/A

# HETLIOZ

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## MEDICATION(S)

HETLIOZ, HETLIOZ LQ, TASIMELTEON

## COVERED USES

N/A

## EXCLUSION CRITERIA

Sleep disorders other than Non-24 and SMS.

## REQUIRED MEDICAL INFORMATION

For Non-24-Hour Sleep-Wake Disorder (Non-24):

All of the following criteria must be met:

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

Reauthorization criteria:

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

For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS):

All of the following criteria must be met:

1. Documented diagnosis of SMS, as characterized by:
  - a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene
2. Documented sleep study to exclude other sleep disorders
3. Documentation of at least one of the following:
  - a. difficulties falling asleep
  - b. shortened sleep cycles
  - c. frequent and prolonged nocturnal awakenings
  - d. excessive daytime sleepiness



e. daytime napping

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

Reauthorization Criteria:

Documentation of improvement in sleep quality or total sleep time.

**AGE RESTRICTION**

Non-24: 18 years or older for capsules

SMS: 3-15 years old for suspension and 16 years or older for capsules

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (FH) AGENTS**

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## **MEDICATION(S)**

JUXTAPID

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

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

## **REQUIRED MEDICAL INFORMATION**

For initial authorization, all 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 (such as, evolocumab), unless contraindicated or prior intolerance
3. Documentation of LDL cholesterol levels (taken within the last six months) of greater than 100 mg/dL despite at least six months of use of the therapies outlined above

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

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# 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 FOR ADULTS**

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## **MEDICATION(S)**

GENOTROPIN, NORDITROPIN FLEXPRO

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Treatment of idiopathic short stature

## **REQUIRED MEDICAL INFORMATION**

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).

AND

Meet criteria listed below for each specific diagnosis:

1. For Growth Hormone Deficiency (GHD) in adults with GHD as a child: continuation of GH therapy will require the following criteria to be met:

a. Patient has congenital defects, genetic defects, organic hypothalamic-pituitary disease (e.g., suprasellar mass with irreversible damage from previous surgery and irradiation) or other history of destructive lesions of the hypothalamic region such as traumatic brain injury

AND

b. One of the following:

i. At least three pituitary hormone deficiencies (other than growth hormone)

ii. Less than three pituitary hormone deficiencies, or insulin-like growth factor (IGF)-1 level below normal for age/sex, and one of the following confirmatory stimulation tests (for appropriate IGF-1 levels by age check the Mayo Clinic Interpretive Handbook at <https://www.mayocliniclabs.com/test-catalog/overview/62750#Clinical-and-Interpretive>

1. Insulin Tolerance Test (ITT) with peak GH less than or equal to 5.0 microgram/L

2. Glucagon Stimulation Test (GST) with low peak GH based on body mass index (BMI), as follows:

a. BMI less than 25: Peak GH less than or equal to 3 microgram/L

b. BMI 25-30: Peak GH less than/equal to 1 microgram/L. For patients with high clinical suspicion of GHD, peak GH less than 3 microgram/L may be considered

c. BMI greater than/equal to 30: Peak GH less than/equal to 1 microgram/L

3. If both the ITT and GST are contraindicated, macimorelin with peak GH less than or equal to 2.8 microgram/L

2. For GHD in adults:

a. For patients with history of destructive lesions of the hypothalamic region (e.g., hypothalamic-pituitary

tumors, surgery, or cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, Rathke's cleft cysts, autoimmune hypophysitis), all of the following:

- i. Insulin-like growth factor (IGF)-1 level below normal for age/sex
  - ii. One of the confirmatory stimulation tests outlined in criterion 1.a.ii. above
- b. For patients with organic disease of the hypothalamic region from congenital or genetic defects one of the following:
- i. At least three pituitary hormone deficiencies (other than growth hormone), or
  - ii. Less than three pituitary hormone deficiencies, or IGF-1 level below normal for age/sex, and one of the confirmatory stimulation tests outlined in criterion 1.a.ii. above
3. Reauthorization for GHD requires evidence of improved quality of life, good tolerability and annual documentation of IGF-1 levels with appropriate dosage adjustments. (GH requirements often decrease with age).
4. For HIV associated wasting/cachexia, all of the following criteria must be met:
- a. Involuntary loss of at least 10% body weight
  - b. Absence of other related illnesses contributing to weight loss
  - c. Documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents.
5. For Short Bowel Syndrome, all of the following criteria must be met
- a. Ability to ingest solid food
  - b. Must be receiving specialized nutrition support (e.g., high carbohydrate, low-fat diet, enteral feedings, parenteral nutrition)

#### **AGE RESTRICTION**

N/A

#### **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, an endocrinologist or for the treatment of short bowel syndrome, may be prescribed by or in consultation with a gastroenterologist.

#### **COVERAGE DURATION**

Authorization for short-bowel syndrome will be approved for a maximum of four weeks.

Authorization for AIDS wasting will be approved for a maximum of 12 months.

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

#### **OTHER CRITERIA**

N/A

# HUMAN GROWTH HORMONES FOR PEDIATRICS

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## MEDICATION(S)

GENOTROPIN, NORDITROPIN FLEXPRO

## COVERED USES

N/A

## EXCLUSION CRITERIA

Treatment of idiopathic short stature.

## REQUIRED MEDICAL INFORMATION

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.)

D. Chronic Renal Insufficiency (somatropin only)

- i Other causes of growth failure have been ruled out and nutritional status has been optimized

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

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### MEDICATION(S)

FASENRA PEN, NUCALA

### COVERED USES

N/A

### EXCLUSION CRITERIA

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

### REQUIRED MEDICAL INFORMATION

#### A. Eosinophilic asthma

1. For patients initiating therapy for eosinophilic asthma, all the following criteria (a-c) must be met:

a. Confirmed diagnosis of one of the following (i or ii):

i. Eosinophilic asthma, defined as one of the following:

1. A blood eosinophil count of at least 150 cells/microliter while on high-dose inhaled corticosteroids or daily oral corticosteroids

2. Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion while on high-dose inhaled corticosteroids or daily oral corticosteroids

3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids

4. History of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids

b. Documentation of adherence to treatment with maximally tolerated doses of the following medications (this may be verified by pharmacy claims information), unless intolerance or contraindication to all therapies:

i. Inhaled corticosteroid plus

ii. One of the following:

1. A long-acting inhaled beta 2-agonist (LABA)

2. A leukotriene receptor antagonist (LTRA)

3. A long-acting muscarinic antagonist (LAMA)

c. Documentation inadequate asthma control despite above therapy, defined as one of the following:

i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score more than 1.5

ii. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months

iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months

2. For patients established on therapy for eosinophilic asthma: documentation of response to therapy, such as lower rate of exacerbations, decreased need for rescue medication, improved quality of life

## B. Eosinophilic Granulomatosis with Polyangiitis (EGPA)

1. For initiation of therapy for EGPA, Nucala® (mepolizumab) may be covered if the following criteria are met:

- a. Confirmed diagnosis of EGPA
  - b. History or presence of asthma
  - c. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter
  - d. Documentation of one of the following:
    - i. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent)
    - ii. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering off glucocorticoids
1. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

2. For patients established on therapy for EGPA, Nucala® (mepolizumab) may be covered if the following criteria are met: documentation of response to therapy, such as lower rate of relapse or decreased need for corticosteroid therapy

## C. Hypereosinophilic Syndrome (HES)

1. For initial authorization for HES, Nucala® (mepolizumab) may be covered if the following criteria are met:

- a. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
- b. Blood eosinophil count of 1,000 cells/microliter or higher for at least six months prior to initiation of therapy
- c. Documentation of use of conventional HES therapy, including one of the following in the 12 months prior to initiation of therapy:
  - i. Chronic or episodic oral corticosteroids (OCS)
  - ii. Immunosuppressive therapy
  - iii. Cytotoxic therapy
- d. Documentation of at least two HES flares in the 12 months prior to initiation of therapy (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)

2. For Reauthorization for HES: documentation of response to therapy (such as attainment and maintenance of remission or decrease in number of relapses)

## D. Adjunct therapy for chronic rhinosinusitis with nasal polyp (CRSwNP)

1. For initial authorization for CRSwNP, Nucala® (mepolizumab) may be covered if the following criteria are met:

- a. Evidence of nasal polyposis by direct examination, endoscopy, or sinus computed tomography (CT) scan

b. Documentation of one of the following:

- i. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
  - ii. Inadequate response to, or has an intolerance or contraindication to, trial of oral corticosteroids
- c. Documentation of inadequate response to a three-month trial of intranasal corticosteroids (such as fluticasone) within six months of initiating therapy, or has a documented intolerance or contraindication to ALL intranasal corticosteroids
- d. Documentation that patient will continue standard maintenance therapy (such as nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab
2. For Reauthorization for CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement

### **AGE RESTRICTION**

- Cinqair®: Approved for 18 years of age or older
- Fasenra®: Approved for 12 years of age or older
- 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

### **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:

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

ii. For BBS: Greater than or equal to the 97th percentile using growth chart assessments

For reauthorization, the following must be met:

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

**AGE RESTRICTION**

May be approved for patients aged six years and older

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **IMMUNE GAMMA GLOBULIN (IGG)**

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## **MEDICATION(S)**

CUTAQUIG, GAMMAKED, GAMUNEX-C, HIZENTRA, HYQVIA, 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 (common variable immunodeficiency), Hyper-IgM (X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome

1. The patient has one of the following:

a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy

b. The patient has abnormal Bruton tyrosine kinase (BTK) gene or absence of BTK protein

c. The patient has an absence of B lymphocytes

d. The patient meets all of the following:

i. One of the following:

1. The patient has selective IgG subclass deficiency [Defined as deficiency of one or more IgG subclasses (e.g., IgG1, IgG2, IgG3, or IgG4) more than two standard deviations (SD) below age-specific mean, assessed on two separate occasions during infection free period

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

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

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

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

#### Reauthorization:

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

#### Prevention of infections in patients with B-cell chronic lymphocytic leukemia (CLL):

1. Documented pre-treatment endogenous IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient's age

OR

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

#### Kawasaki Disease:

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

#### Idiopathic or Immune Thrombocytopenic Purpura (ITP):

(Platelet counts expressed per microliter and should be obtained within the past 30 days)

#### For children with ITP:

1. Documentation of one of the following:

a. Platelet count less than 20,000 and significant mucous membrane bleeding

b. Platelet count less than 10,000 and minor purpura

c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss

#### Pregnant Women with ITP:

1. Documentation of one of the following:

a. Platelet count is less than 100,000

b. Past history of splenectomy

c. Past history of delivered infant with autoimmune thrombocytopenia

#### Adult Patients with ITP:



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

Dermatomyositis and polymyositis:

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

Reauthorization: Documented response to therapy

Chronic inflammatory demyelinating polyneuropathy (CIDP):

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

Autoimmune Hemolytic Anemia:

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

Guillain-Barre Syndrome:

1. Documentation that symptom onset is within two weeks or symptoms are severe (such as being unable to ambulate independently)  
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 (such as glatiramer, interferon beta, dimethyl fumarate)

Myasthenia Gravis:

Myasthenic exacerbation:

1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month:

a. Difficulty swallowing

b. Acute respiratory failure

c. Major functional disability responsible for the discontinuation of physical activity

Refractory disease:

1. Documentation that patient has severely impaired function due to myasthenia gravis

AND

2. Documented trial, failure, intolerance or contraindication to at least two of the following conventional therapies:

a. Acetylcholinesterase inhibitors (such as pyridostigmine)

b. Corticosteroids (such as prednisone, methylprednisolone)

c. Immunosuppressive agents (such as azathioprine, cyclosporine, mycophenolate)

d. Plasma exchange

Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:

1. Documentation of one of the following:

a. Therapy is requested for use within 100 days after transplantation (transplantation date must be documented)

OR

b. Documentation that patient has an IgG less than 400 mg/dL with a history of recurrent infections

Autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid

gestationis, linear IgA bullous dermatosis

1. Documentation of biopsy proven disease

AND

2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (such as azathioprine, cyclophosphamide, mycophenolate mofetil).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS):

1. Clinical documentation must be provided detailing patient's primary symptom complex along with baseline clinical testing(s) using validated instrument(s)

AND

2. A clinically appropriate trial of two or more less-intensive treatments was either not effective, not tolerated, or did not result in sustained improvement in symptoms, as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex. For example, treatments may include appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, or short-course antibiotic therapy). These trials may be done concurrently.

Reauthorization in PANDAS/PANS:

1. Documentation that a reevaluation at three months post treatment have been performed by an appropriate specialist

AND

2. Documentation of objective clinically meaningful improvement posttreatment as defined by an improvement in the clinical testing with a validated instrument

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

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

### **OTHER CRITERIA**

N/A

# INCRELEX

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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

## **INFUSION THERAPY SITE OF CARE**

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### **MEDICATION(S)**

CUTAQUIG, GAMMAKED, GAMUNEX-C, HIZENTRA, HYQVIA, XEMBIFY

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Prior authorization for the medication must be obtained, if necessary. Refer to individual drug specific policies for clinical criteria.
    - a. For medications that require prior authorization for clinical criteria, the approval or denial of administration in an unapproved hospital outpatient setting is not indicative of approval or denial of the prior authorization for the medication based on clinical criteria.
  2. The unapproved hospital-based outpatient infusion center may be considered medically necessary if one of the following criteria is met:
    - a. The patient has concomitant conditions or clinical history that may increase the risk of infusion reactions or drug specific adverse events, defined as one of the following:
      - i. Recent documented history of severe adverse drug reactions or anaphylaxis to prior treatments of the same or similar therapy.
      - ii. Concomitant complex medical conditions that may increase the risk of infusion reactions or complications to therapy. For example, the presence of antibodies that may increase the risk of infusion reactions, severely compromised cardiac and respiratory function.
      - iii. Use of multiple concurrent therapies of which one or more require infusion services at a higher level of care (e.g., cytotoxic chemotherapy, CAR-T given over same treatment period as requested medication)
      - iv. Chronic vascular access complications that require hospital-based interventions or equipment not available to home infusion providers
      - v. Mental health or cognitive changes that require increased level of care for the safe administration of infusions
    - b. The unapproved hospital based infusion center is deemed a more appropriate option, as defined by BOTH of the following criteria:
      - i. An approved site of care would require an additional 15 miles of travel from the member's home as compared to unapproved hospital based infusion center in the vicinity.
- AND
- ii. Home infusion services are not an option because the member's home is ineligible for infusion services. The eligibility of a member's home for home infusion can be affected by such factors as:

1. The location of the member's home being outside of the infusion provider's service area, or
2. Upon inspection, the home infusion provider considers the member's home to be unfit or unsafe for home infusion services.
3. The first 60 days after the drug authorization will be covered at an unapproved site of care, to accommodate for initial doses to be administered without delay to therapy. The purpose of the initial 60-day period is to allow for the determination of infusion tolerability at a higher level of care. This period will also allow for the timely submission and review of a prior authorization for the unapproved site of care, and the coordination of transition to an approved site, when the unapproved site of care has been determined to be not medically necessary.
4. An exception to the 60 days at an unapproved site will be granted for patients starting a new enzyme replacement medication. These drugs will be noted by an asterisk on table 1. Due to the prolonged concern with anaphylaxis reactions, an enzyme replacement drug that is new to the patient will be authorized for six months at an unapproved site of care.

### **AGE RESTRICTION**

This policy applies to those members who are 13 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**

Definitions:

- 1.Site of Care – the physical location where the infusion therapy is administered (e.g., an inpatient hospital, outpatient hospital-based infusion center, stand-alone infusion center, healthcare provider's office, or home infusion)
- 2.Alternative Site of Care – any outpatient infusion site of care outside of an outpatient hospital-based infusion center (e.g., such as provider's office or home infusion service providers)
- 3.Approved Site of Care - alternative sites of care or approved hospital-based infusion centers
- 4.Unapproved Site of Care – any site of care that has been deemed as medically unnecessary, including unapproved hospital based infusion centers that increase the cost of care compared to approved sites of care

# **INJECTABLE ANTI-CANCER MEDICATIONS**

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## **MEDICATION(S)**

ACTIMMUNE, SYNRIBO

## **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



# **INTRANASAL MEDICATIONS**

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## **MEDICATION(S)**

OMNARIS, ZETONNA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Documented adequate trial and failure, intolerance or contraindication to fluticasone propionate nasal spray (generic Flonase®), either prescription or over-the-counter (OTC).

AND

2. Documented adequate trial and failure, intolerance or contraindication to one additional formulary or OTC corticosteroid intranasal medication used for the treatment of allergic rhinitis [e.g. flunisolide nasal spray, triamcinolone nasal spray, mometasone (Nasonex®) nasal spray]

Note: An adequate trial is defined as at least one month of 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

# **IVERMECTIN**

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## **MEDICATION(S)**

IVERMECTIN 3 MG TABLET, STROMEKTOL

## **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

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## 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

# **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 (such as frovatriptan, naratriptan, rizatriptan, sumatriptan, Zomig® nasal spray)

AND

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

AND

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

Reauthorization criteria:

1. Documentation of a positive clinical response to the requested therapy
2. Documentation that ketorolac tromethamine use will not exceed a total of five days of treatment per treatment course (Note: The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed five days)

## **AGE RESTRICTION**

Approved in 17 years and older

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

**OTHER CRITERIA**

N/A

# KUVAN

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## MEDICATION(S)

JAVYGTOR, KUVAN, SAPROPTERIN DIHYDROCHLORIDE

## COVERED USES

N/A

## EXCLUSION CRITERIA

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

# 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**

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A



# LONG ACTING OPIOIDS

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## MEDICATION(S)

BUPRENORPHINE, BUTRANS, DISKETS, DURAGESIC, FENTANYL 100 MCG/HR PATCH, FENTANYL 12 MCG/HR PATCH, FENTANYL 25 MCG/HR PATCH, FENTANYL 50 MCG/HR PATCH, FENTANYL 75 MCG/HR PATCH, HYDROCODONE ER 10 MG CAPSULE, HYDROCODONE ER 15 MG CAPSULE, HYDROCODONE ER 20 MG CAPSULE, HYDROCODONE ER 30 MG CAPSULE, HYDROCODONE ER 40 MG CAPSULE, HYDROCODONE ER 50 MG CAPSULE, HYDROMORPHONE ER, METHADONE 40 MG TABLET DISPR, METHADONE HCL 10 MG TABLET, METHADONE HCL 5 MG TABLET, METHADOSE 40 MG TABLET DISPR, NUCYNTA ER, OXYMORPHONE HCL ER, XTAMPZA ER, ZOHYDRO ER

## COVERED USES

N/A

## EXCLUSION CRITERIA

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

## REQUIRED MEDICAL INFORMATION

For ALL requests: chart notes demonstrating assessment of painful conditions within the last six months must be provided with the following:

1. Outline of current treatment regimen including all opioids with daily dose and frequency, all non-opioid therapy, and/or non-pharmacological therapy
2. Comprehensive documentation including an appropriate patient medical history, physical examination, screening for substance use disorder and interacting medications and treatment plan

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

1. The following indication-specific criteria must be met:
  - a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease, or severe burns: documentation of all the following:
    - i. Active pain directly related to the condition(s) mentioned above
    - ii. Inadequate pain relief from current and consistent regimen (of at least two weeks length within the previous 30 days) that includes four or more doses per day of short-acting opioid therapy for around-the-clock management of pain
    - iii. Inadequate pain relief, after at least two weeks of consistent use, from a stable dose (within the previous 30 days), of long-acting morphine sulfate therapy or documented contraindication/intolerance to long-acting

morphine sulfate therapy

b. For chronic pain, ALL the following must be documented:

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

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

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

For patients established on therapy with a long-acting opioid therapy, defined as consistent use for at least three months (may be verified by pharmacy claims):

1. The following indication-specific criteria must be met:

- a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease or severe burns, all the following must be documented:
  - i. Positive response to therapy

- ii. Continued active pain directly related to the condition(s) mentioned above
- b. For chronic pain, all the following must be documented:
  - i. Improvement from baseline in pain control/level of functioning, or no worsening of pain control
  - ii. Appropriate monitoring (including review of Prescription Drug Monitoring Program) with no concerns for adverse events (such as no unmonitored dose escalation, no excess sedation, no signs of developing substance use disorder)
  - iii. There is a pain management agreement and/or treatment/monitoring plan between the prescriber and patient that includes monitoring plans and functional goals that has been reviewed within the previous six months.

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

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

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

**OTHER CRITERIA**

N/A

# LOTRONEX

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## MEDICATION(S)

ALOSETRON HCL, LOTRONEX

## COVERED USES

N/A

## EXCLUSION CRITERIA

Patients with constipation

## REQUIRED MEDICAL INFORMATION

For initiation, all the following must be met:

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

For reauthorization:

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

## AGE RESTRICTION

Age 18 years or older

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

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

**OTHER CRITERIA**

N/A

# LUPKYNIS

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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 belimumab (Benlysta®), anifrolumab (Saphnelo®) or cyclophosphamide

## REQUIRED MEDICAL INFORMATION

For initial authorization for active lupus nephritis, all of the following must be met:

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

Reauthorization criteria:

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

## AGE RESTRICTION

May be approved for patients aged 18 years and older.

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# MAVENCLAD

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## MEDICATION(S)

MAVENCLAD

## COVERED USES

N/A

## EXCLUSION CRITERIA

Concurrent use with other disease modifying agents for multiple sclerosis

## REQUIRED MEDICAL INFORMATION

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

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

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

1. Documentation of positive clinical response to therapy
2. Documentation that therapy has not exceeded two years in the patient's lifetime

## AGE RESTRICTION

Approved for patients age 18 years of age and older

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

May be approved for up to two years, ensuring the cumulative duration of therapy does not exceed two



years in a lifetime. Treatment beyond two years will not be authorized.

**OTHER CRITERIA**

N/A

## **MEDICATIONS FOR RARE INDICATIONS**

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### **MEDICATION(S)**

BUPHENYL, CARBAGLU, CARGLUMIC ACID, CERDELGA, MIGLUSTAT, RAVICTI, SODIUM PHENYLBUTYRATE, ZAVESCA

### **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 such as high-quality peer reviewed literature, guidelines, other clinical information

AND

3. For Pheburane Pellet (sodium phenylbutyrate): Documented trial and failure or intolerance to formulary generic sodium phenybutyrate powder

### **REAUTHORIZATION CRITERIA:**

The following must be met:

1. Documentation of successful response to therapy

AND

2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information

AND

3. For Nulibry®: Genetic testing to confirm mutation in the MOCS1 gene (Nulibry® should be discontinued if the MoCD Type A diagnosis is not confirmed by genetic testing)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with a specialist in the respective disease state.

**COVERAGE DURATION**

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

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

**OTHER CRITERIA**

N/A

# MEPRON

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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, pulmonologist, hematologist, or oncologist

## COVERAGE DURATION

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

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

## OTHER CRITERIA

N/A



# 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)**

SODIUM OXYBATE, SUNOSI, WAKIX, XYREM, XYWAV

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

Combination use of sodium oxybates, solriamfetol, and/or pitolisant

For solriamfetol (Sunosi®): idiopathic central nervous system hypersomnia

## **REQUIRED MEDICAL INFORMATION**

1. For initial authorization, all the following indication-specific criteria must be met:

a. For treatment of narcolepsy with cataplexy (Type 1 narcolepsy) the following criteria must be met:

i. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay)

ii. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

iii. Documentation of at least three weekly cataplexy attacks

iv. For Xyrem®/Xywav™ in adults: Documentation of inadequate response (after at least three months of therapy), intolerance, or contraindication to pitolisant (Wakix®)

b. For treatment of excessive daytime sleepiness in narcolepsy without cataplexy (Type 2 narcolepsy) the following criteria must be met:

i. Diagnosis of narcolepsy as confirmed by sleep study

ii. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

iii. Other causes of sleepiness have been ruled out or treated (such as obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders)

iv. Documentation of inadequate response (after three months of therapy), intolerance, or contraindication to both of the following:

1. Stimulant (such as amphetamine or methylphenidate)

2. Modafinil or armodafinil

v. For Wakix®: Documentation of inadequate response (after at least three months of therapy), intolerance, or contraindication to solriamfetol (Sunosi®)

vi. For Xyrem®/Xywav™ in adults: Documentation of inadequate response (after at least three months of therapy), intolerance, or contraindication to solriamfetol (Sunosi®) AND pitolisant (Wakix®)

c. For excessive daytime sleepiness associated with obstructive sleep apnea (OSA), solriamfetol (Sunosi®)

may be covered if the following criteria are met:

- i. Diagnosis of OSA as confirmed by sleep study
  - ii. Documented evidence of residual sleepiness and functional impairment despite compliant positive airway pressure use (compliance is defined as using positive airway pressure at least four hours each night for 70% of the nights) for at least three months
  - iii. The modalities to treat the underlying airway obstruction (such as continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent
  - iv. Failure of a three-month trial, intolerance, or contraindication to armodafinil or modafinil
- d. For idiopathic hypersomnia, Xywav® may be covered if all the following criteria are met (Refer to covered uses section for additional criteria for Medicaid):
- i. Diagnosis of idiopathic hypersomnia confirmed by sleep study
  - ii. Documentation that sleepiness is not due to another medical, behavioral, or psychiatric disorder condition, including but not limited to insufficient sleep (less than seven hours per night), depression, sedating medications, and sleep-related breathing disorders
  - iii. Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months
  - iv. Documentation of inadequate response (after three months of therapy), intolerance, or contraindication to modafinil

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

- a. For narcolepsy: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks.
- b. For OSA [solriamfetol (Sunosi®) only]:
  - i. Reduction in symptoms of excessive daytime sleepiness
  - ii. The modalities to treat the underlying airway obstruction (for example, continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent
- c. For idiopathic hypersomnia: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness

### **AGE RESTRICTION**

Age must be appropriate based on FDA-approved indication

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

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

### **OTHER CRITERIA**

N/A



# **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 MEDICATIONS AND FORMULATIONS WITHOUT ESTABLISHED BENEFIT**

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### **MEDICATION(S)**

SYMPAZAN

### **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

## **NON-PREFERRED FUMARATE PRODUCTS**

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### **MEDICATION(S)**

VUMERITY

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For initiation of therapy (new starts), one of the following must be met:

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

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

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

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

### **OTHER CRITERIA**

N/A

## **NON-PREFERRED INSULINS**

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### **MEDICATION(S)**

APIDRA, APIDRA SOLOSTAR

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Documented trial and failure (defined as worsening of glucose control after at least three months of therapy), intolerance, or contraindication to the preferred formulary alternative(s) for the requested insulin product

OR

2. A supporting statement from the provider outlining medical rationale for inability to use the preferred agents above (such as member is established on an insulin pump with another product or patient has a physical or a mental disability that would prevent them from using a preferred insulin agent)

### **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

## **NON-PREFERRED TRIPTAN THERAPY**

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### **MEDICATION(S)**

FROVA, FROVATRIPTAN SUCCINATE

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documented failure or intolerance to all available formulary triptans, specifically: sumatriptan, rizatriptan, eletriptan, naratriptan, and zolmitriptan. Failure is defined as inability to achieve pain-free remission from migraine headaches.

### **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

# **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 [such as. dopamine agonist, catechol-O-methyltransferase (COMT) inhibitor, or monoamine oxidase B (MAO-B) inhibitor] to reduce number and frequency of OFF episodes

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

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A

# **NUEDEXTA**

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## **MEDICATION(S)**

NUEDEXTA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

1. Current use, or use within the past 14 days, of monoamine oxidase inhibitors (MAOIs).
2. Patient has been diagnosed with a prolonged QT interval, congenital long QT syndrome, or a history suggesting torsades de pointes.

## **REQUIRED MEDICAL INFORMATION**

For initial authorization:

1. Confirmed 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).

For 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

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

## REQUIRED MEDICAL INFORMATION

For the diagnosis of primary biliary cholangitis:

1. Confirmed diagnosis of primary biliary cholangitis as evidenced by two of the following criteria:
  - a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values]
  - b. Presence of antimitochondrial antibody (AMA)
  - c. Histologic evidence of primary biliary cirrhosis from liver biopsy

AND

2. Both of the following:
  - a. Use of ursodiol for a minimum of 12 months and has had an inadequate response according to prescribing physician

AND

- b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol

For reauthorization, all the following criteria must be met:

1. Maintenance of biochemical response, defined as all the following:
  - a. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, and
  - b. total bilirubin (tBili) less than or equal to ULN, and
  - c. ALP decrease of at least 15%

AND

2. Documentation that ursodiol will be continued, if tolerated

AND

3. Hepatic function is assessed at least annually

## AGE RESTRICTION



N/A

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

## ORAL ANTI-CANCER MEDICATIONS

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### MEDICATION(S)

ABIRATERONE ACETATE 250 MG TAB, AFINITOR, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, AYVAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI 75 MG CAPSULE, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA 60 MG TABLET, ERLOTINIB HCL, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, EXKIVITY, FARYDAK, FOTIVDA, GAVRETO, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA 140 MG CAPSULE, IMBRUVICA 420 MG TABLET, IMBRUVICA 560 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, KOSELUGO, 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, SORAFENIB, SPRYCEL, STIVARGA, SUNITINIB MALATE, SUTENT, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TARCEVA, TARGRETIN, TASIGNA, TAZVERIK, TEMODAR 100 MG CAPSULE, TEMODAR 140 MG CAPSULE, TEMODAR 180 MG CAPSULE, TEMODAR 250 MG CAPSULE, TEMOZOLOMIDE, TEPMETKO, TIBSOVO, TRETINOIN 10 MG CAPSULE, TRUSELTIQ, TUKYSA, TURALIO, TYKERB, UKONIQ, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VOTRIENT, WELIREG, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

### COVERED USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

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

1. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

AND

2. For requests for abiraterone (Zytiga®): only generic abiraterone 250 mg tablets will be covered when criterion 1 is met

3. For requests for everolimus tablet for suspension, must meet one of the following criteria (a or b):

a. Use for adjunctive treatment of tuberous sclerosis complex-associated partial-seizures

b. Documentation of a physical or medical condition that either makes swallowing tablets a choking hazard,

or requires solution for administration (such as young age, dysphagia, feeding tube)

4. For commercial members only, the following drug-specific criteria must be met:

a. For 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 pacritinib (Vonjo®): May also be prescribed by a hematologist

For abiraterone acetate (Zytiga®): May also be prescribed by a urologist

#### **COVERAGE DURATION**

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

#### **OTHER CRITERIA**

N/A

# OSTEOANABOLIC AGENTS

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## MEDICATION(S)

FORTEO, TERIPARATIDE, TYMLOS

## COVERED USES

N/A

## EXCLUSION CRITERIA

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

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

## REQUIRED MEDICAL INFORMATION

For the treatment or prevention of osteoporosis

1. Must meet ONE of the following criteria (a-e):

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

For authorization for teriparatide use exceeding two years in a lifetime, must meet both of the following criteria:

1. Documentation that previous treatment with teriparatide showed clinical improvement, defined as absence/decrease in frequency of new fragility fracture or stable/increased BMD T-score while on teriparatide

2. One of the following:

a. Patient continues to be at very high risk for fracture, defined as one of the following while on teriparatide:

i. BMD T-score continues to be less than or equal to -3.0

ii. New vertebral or fragility fracture

b. Documentation of worsening disease, defined as one of the following:

i. A repeat BMD after discontinuation of therapy demonstrates a decline in BMD

ii. New onset fragility fracture after discontinuation

#### **AGE RESTRICTION**

N/A

#### **PRESCRIBER RESTRICTION**

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

#### **COVERAGE DURATION**

For Forteo®: Initial authorization may be approved for up to two years. For use beyond two years, may be approved for one year.

For 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

# 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 (such as preservative-free artificial tears, topical antibiotic eye drops, therapeutic contact lenses, amniotic membrane transplant, tarsorrhaphy)
3. The request specifies the affected eye(s) intended for treatment

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an ophthalmologist

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A

# **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)

PRALUENT PEN, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

## COVERED USES

N/A

## EXCLUSION CRITERIA

- Concomitant use with another PCSK9 inhibitor
- Non-familial hyperlipidemia/hypercholesterolemia
- Primary prevention of ASCVD

## REQUIRED MEDICAL INFORMATION

For initial authorization

1. One of the following:

a. Provider attestation of a trial and failure of at least eight weeks of therapy with a high-intensity statin therapy (specifically, atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering

OR

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

2. Must meet listed criteria below for each specific diagnosis:

a. For familial hypercholesterolemia (FH), one of the following must be met:

i. A “possible” diagnosis of FH via Simon Broome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix)

OR

ii. 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 ARH adaptor protein 1/LDLRAP1

OR

iii. LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns

OR

- iv. Presence of xanthomas
  - b. For ASCVD, attestation of LDL-C greater than or equal to 70 mg/dL and history of clinical ASCVD, defined as one of the following:
    - i. Acute coronary syndromes
    - ii. History of myocardial infarction
    - iii. Stable/unstable angina
    - iv. Coronary or other arterial revascularization
    - v. Stroke or transient ischemic attack
    - vi. Peripheral artery disease presumed to be of atherosclerotic origin
    - vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin
3. For Praluent® or Leqvio®:
- a. Documented trial and failure, intolerance, or contraindication to evolocumab (Repatha®)

For initial reauthorization: Provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

Initial authorization for one year. 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-ACETAMIN-CAF-COD 50-325, BUTALBITAL COMPOUND-CODEINE, CARISOPRODOL-ASPIRIN-CODEINE, CODEINE SULFATE, CODEINE-GUAIFENESIN, G TUSSIN AC, GUAIIATUSSIN AC, GUAIFENESIN AC, GUAIFENESIN DAC, GUAIFENESIN-CODEINE, MAXI-TUSS AC, PROMETHAZINE VC-CODEINE, PROMETHAZINE-CODEINE, PROMETHAZINE-PHENYLEPH-CODEINE, 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, ULTRACET, 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

\*All over-the-counter (OTC) formulations for commercial members are a benefit exclusion

## **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)**

MYCAPSSA, SIGNIFOR, SOMAVERT

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For initiation of therapy, must meet indication-specific criteria below:

1. For acromegaly, Signifor® LAR, Sandostatin® LAR, Somatuline® Depot, Somavert®, or Mycapssa® may be covered if all the following are met:
  - a. Confirmed diagnosis of acromegaly
  - b. Documentation that the patient has persistent disease (such as biochemical or clinical) following surgical resection or is not a candidate for surgical resection
  - c. For coverage of Somavert® or Signifor® LAR, documentation of trial and failure, intolerance or contraindication to octreotide injection therapy or lanreotide subcutaneous depot
  - d. For coverage of Mycapssa®, patient has been maintained (for at least six months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy
2. For Cushing's syndrome (includes Cushing's disease), Recorlev® may be covered if all the following are met:
  - a. Diagnosis of endogenous Cushing's syndrome (E24.9)
  - b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery
  - c. Documentation of baseline urinary free cortisol
  - d. Documentation of baseline liver enzyme function tests
  - e. Documentation of trial and failure of oral ketoconazole
3. For Cushing's disease, Signifor®, Isturisa®, or Signifor® LAR may be covered if all the following are met:
  - a. Diagnosis of endogenous Cushing's disease (E24.0)
  - b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery
4. For carcinoid tumors, 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
5. 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
6. For chemotherapy induced diarrhea, Sandostatin LAR® may be covered if all the following are met:

- a. Documentation that patient has severe diarrhea caused by chemotherapy
  - b. Documentation of an inadequate response or contraindication to loperamide
  - c. Documentation of good response and tolerability to short-acting octreotide
7. For AIDS-related diarrhea, Sandostatin LAR® may be covered if all the following are met:
- a. Documentation that patient has severe diarrhea
  - b. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate (Lomotil®)
  - c. Documentation of good response and tolerability to short-acting octreotide
8. For oncologic diagnoses, use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

For patients established on therapy, documentation of a positive clinical response must be provided. Appropriate documentation may include:

- For acromegaly, a reduction or normalization of IGF-1/GH level for same age and sex or reduction in tumor size
- For Cushing's syndrome/Cushing's disease, clinically meaningful reduction and maintenance in late-night salivary cortisol or 24-hour urinary free cortisol levels, or improvement in signs or symptoms of the disease
- For diarrhea, an improvement in the number of diarrhea episodes
- For carcinoid tumors, 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

# PREVYMIS

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## MEDICATION(S)

PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. All the following must be met for the prevention of cytomegalovirus (CMV) infection and disease:
  - a. Member is within 100 days post- allogeneic transplant
  - b. CMV Recipient positive
  - c. 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

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial Authorization:

All of the following:

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

## AGE RESTRICTION

1 year of age and older

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A



# PROPHYLACTIC HEREDITARY ANGIOEDEMA THERAPY

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## MEDICATION(S)

HAEGARDA, ORLADEYO, TAKHZYRO 300 MG/2 ML SYRINGE, TAKHZYRO 300 MG/2 ML VIAL

## 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

# **PULMONARY ARTERIAL HYPERTENSION**

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## **MEDICATION(S)**

ADCIRCA, ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, LETAIRIS, OPSUMIT, REVATIO 10 MG/ML ORAL SUSP, SILDENAFIL 10 MG/ML ORAL SUSP, TADALAFIL 20 MG TABLET, TRACLEER, TYVASO, TYVASO DPI, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT, UPTRAVI 1,000 MCG TABLET, UPTRAVI 1,200 MCG TABLET, UPTRAVI 1,400 MCG TABLET, UPTRAVI 1,600 MCG TABLET, UPTRAVI 200 MCG TABLET, UPTRAVI 200-800 TITRATION PACK, UPTRAVI 400 MCG TABLET, UPTRAVI 600 MCG TABLET, UPTRAVI 800 MCG TABLET

## **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 patients initiating therapy, the following criteria must be documented:

1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization as defined by:

i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest

AND

ii. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg

AND

iii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)

AND

2. Patient has one of the following:

i. World Health Organization (WHO) Group 1 classification PAH with WHO/New York Heart Association (NYHA) functional class as outlined below:

a. Flolan®, Veletri®, Tyvaso®, Tyvaso® DPI and Ventavis: Class III or IV

b. All other therapies: Class II, III, or IV

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

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

AND

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

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

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a pulmonologist or cardiologist

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# PYRUKYND

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## MEDICATION(S)

PYRUKYND

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For initiation of therapy, the following criteria must be met:

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

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

1. Sustained increase in hemoglobin (Hb) of at least 1.5 mg/dL from pre-treatment level. Note: initial hemoglobin level prior to treatment plus a recent level (within the last three months) must be provided OR
2. Documentation of a reduction in transfusion burden in the previous 6 months, compared with prior to treatment

## AGE RESTRICTION

May be approved for patients aged 18 years and older

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A

# **QBREXZA**

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## **MEDICATION(S)**

QBREXZA

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial authorization:

1. Diagnosis of severe primary axillary hyperhidrosis
2. Documentation that patient has had axillary hyperhidrosis for at least six months
3. Documentation that member's hyperhidrosis is causing social anxiety, depression, or other issues that are impacting quality of life
4. Documented trial and failure of Drysol® for a least one month, unless contraindicated or clinically significant adverse effects were experienced
5. For age more than 18 years only: Documented trial and failure of botulinum toxin for at least six months, unless contraindicated or clinically significant adverse effects were experienced

## **AGE RESTRICTION**

Approved for nine years old and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist.

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A

# **QUDEXY XR/TROKENDI XR**

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## **MEDICATION(S)**

QUDEXY XR, TOPIRAMATE ER

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For seizure disorders, one of the following must be met:

1. The patient is currently established on therapy with the requested medication (Note: starting on samples will not be considered established on therapy)

OR

2. Documentation of trial and failure, intolerance or contraindication to topiramate immediate release AND one additional formulary anti-epileptic medication: e.g. valproic acid, clonazepam or lamotrigine AND if the request is for Trokendi® XR or brand Qudexy® XR generic topiramate extended release

OR

3. Prescriber is a neurologist.

For migraine prophylaxis all of the following criteria must be met:

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

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

3. Documentation of trial and failure (An adequate trial and failure is defined as minimal to no improvement after at least three months of therapy), intolerance, or contraindication to at least one prophylactic medication from at least three of the following categories:

a. Anticonvulsants other than topiramate (e.g., divalproex, valproate)

b. Beta-blockers (e.g., metoprolol, propranolol, timolol)

c. Antidepressants (e.g., amitriptyline, venlafaxine)

d. Botulinum toxin

e. CGRP antagonist [e.g, erenumab (Aimovig®) or galcanezumab(Emgality®)]

## **AGE RESTRICTION**

N/A



**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **RADICAVA**

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## **MEDICATION(S)**

RADICAVA ORS

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

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

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A

# 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



# RELYVRIO

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## MEDICATION(S)

RELYVRIO

## COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For initiation of therapy, all the following criteria (a-d) must be met:
  - a. Documentation of diagnosis of amyotrophic lateral sclerosis (ALS)
  - b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R)
  - c. Forced vital capacity (FVC) greater than 60% of predicted (taken within the past three months)
  - d. Documentation that patient is not dependent on invasive ventilation or tracheostomy
2. For patients established on therapy, all the following criteria (a-b) must be met:
  - a. Documentation of a clinical benefit from therapy such as stabilization of disease or slowing of disease progression from pre-treatment baseline ALSFRS-R scores
  - b. Documentation that patient is not dependent on invasive ventilation or tracheostomy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

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

## OTHER CRITERIA

N/A

## **RESCUE MEDICATIONS FOR EPILEPSY**

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

### **OTHER CRITERIA**

N/A

# REVCIVI

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## MEDICATION(S)

REVCIVI

## 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

1. For initial authorization, the following criteria must be met (a and b):

a. Diagnosis of migraine headaches

b. One of the following:

i. For Commercial: Inadequate response to two oral triptans (such as sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) and one additional triptan formulation (such as oral disintegrating tablet, nasal spray, injection)

ii. For Medicaid: Inadequate response to two triptan products (such as sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan)

iii. Documented intolerance to at least two triptan drug entities

iv. Documented contraindication to the use of triptans, such as:

- Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
- History of stroke or transient ischemic attack (TIA)
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- History of hemiplegic or basilar migraine

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

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

**OTHER CRITERIA**

N/A

# REZUROCK

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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

# 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



# SAVELLA

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## MEDICATION(S)

SAVELLA

## COVERED USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For fibromyalgia: Documentation of an adequate trial and failure (defined as adherence to at least six weeks of therapy without improvement in symptoms), intolerance, or contraindication to the following:

1. Gabapentin OR pregabalin (Lyrica®)

AND

2. One of the following:

a. A Selective serotonin reuptake inhibitors/Serotonin-norepinephrine reuptake inhibitors (SSRI)/(SNRI) (such as, fluoxetine, duloxetine)

b. A tricyclic antidepressant (TCA) medication (such as, amitriptyline)

## 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

## **SELF-ADMINISTERED DRUG (SAD) EXCLUSION**

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### **MEDICATION(S)**

ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, ACTHAR, ACTIMMUNE, AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, AJOVY SYRINGE, ARIXTRA, AVONEX, AVONEX PEN, BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE, BETASERON, CABLIVI, CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT, COPAXONE, CORTROPHIN, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, DUPIXENT PEN, DUPIXENT SYRINGE, EGRIFTA SV, EMGALITY PEN, EMGALITY SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, ENOXAPARIN SODIUM, EXTAVIA, FASENRA PEN, FIRAZYR, FONDAPARINUX SODIUM, FORTEO, FRAGMIN, FUZEON, GATTEX, GENOTROPIN, GLATIRAMER ACETATE, HAEGARDA, HUMIRA, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS, ICATIBANT, IMITREX 4 MG/0.5 ML CARTRIDGES, IMITREX 4 MG/0.5 ML PEN INJECT, IMITREX 6 MG/0.5 ML CARTRIDGES, IMITREX 6 MG/0.5 ML PEN INJECT, IMITREX 6 MG/0.5 ML VIAL, INCRELEX, KESIMPTA PEN, KINERET, LOVENOX, MYALEPT, NATPARA, NORDITROPIN FLEXPOR, NUCALA, ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT, OZEMPIC, PEGASYS, PLEGRIDY, PLEGRIDY PEN, PRALUENT PEN, REBIF, REBIF REBIDOSE, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE, SAJAZIR, SIGNIFOR, SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI ON-BODY, SKYRIZI PEN, SOMAVERT, STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE, STRENSIQ, SUMATRIPTAN 4 MG/0.5 ML CART, SUMATRIPTAN 4 MG/0.5 ML INJECT, SUMATRIPTAN 6 MG/0.5 ML CART, SUMATRIPTAN 6 MG/0.5 ML INJECT, SUMATRIPTAN 6 MG/0.5 ML SYRNG, SUMATRIPTAN 6 MG/0.5 ML VIAL, SYMLINPEN 120, SYMLINPEN 60, TAKHZYRO 300 MG/2 ML SYRINGE, TAKHZYRO 300 MG/2 ML VIAL, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TERIPARATIDE, TREMFYA, TRULICITY, TYMLOS, VICTOZA 2-PAK, VICTOZA 3-PAK

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Relevant chart notes are required and must document medical rationale for requiring administration by a healthcare professional.

Healthcare provider administration may be considered medically necessary if one of the following criteria is met:

1. History of anaphylaxis in the past five years, from any cause, that either required the use of epinephrine or resulted in hospitalization
2. History of allergic reaction to the requested medication
3. Documentation that the patient has one of the following that prevents self-administration:
  - a. Mental health or cognitive changes that require increased level of care for the safe administration of medications
  - b. Physical conditions or dexterity issues that impede clean handling of medication and safe administration technique
  - c. Inability to recognize symptoms of anaphylaxis and/or act to treat anaphylaxis reactions appropriately
  - d. Needle-phobia diagnosed by a mental health provider that is congruent with the most current DSM criteria for phobia. Please note that this does not include general fear of needles.

**AGE RESTRICTION**

Refer to applicable clinical policy and/or formulary documents

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

Authorization and reauthorization for coverage under the medical benefit will be approved for one year.

**OTHER CRITERIA**

N/A



## **SGLT-2 INHIBITORS**

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### **MEDICATION(S)**

INVOKAMET, INVOKAMET XR, INVOKANA, SEGLUROMET, STEGLATRO

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For type 2 diabetes, all of the following must be met:

1. Documented trial and failure of empagliflozin and dapagliflozin,

AND

2. A documented HbA1c, obtained within the last six months, which is greater than or equal to 7% and less than or equal to 10%. A1c must be taken after at least three months of continuous therapy with empagliflozin or dapagliflozin

For chronic kidney disease, canagliflozin may be covered if the following criteria are met

1. Patient has type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 200 mg/day,

AND

2. Documented intolerance or contraindication to dapagliflozin

### **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

# 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

# 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

# **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 such as left ventricular assist device (LVAD)
4. Used in combination with patisiran (Onpattro®) or 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 such as dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels.

Reauthorization requires documentation of a positive clinical response. Appropriate documentation may include evidence of slowing of clinical decline, reduced number of cardiovascular hospitalizations, or improvement or stabilization of the 6-minute walk test.

## AGE RESTRICTION

Approved for patients 18 years of age and older

## PRESCRIBER RESTRICTION

Must be written by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis

## COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

**OTHER CRITERIA**

N/A



## **THERAPEUTIC IMMUNOMODULATORS (TIMS)**

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### **MEDICATION(S)**

ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, 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, KINERET, ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT, OTEZLA, RINVOQ, SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI ON-BODY, SKYRIZI PEN, STELARA 45 MG/0.5 ML SYRINGE, STELARA 90 MG/ML SYRINGE, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TREMFYA, XELJANZ, XELJANZ XR

### **COVERED USES**

N/A

### **EXCLUSION CRITERIA**

- Combination therapy with another therapeutic immunomodulator (TIM) agent
- Treatment of alopecia areata

### **REQUIRED MEDICAL INFORMATION**

1. For all requests, the patient must have an FDA labeled indication for the requested agent or use to treat the indication is supported in drug compendia (such as the American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.)

AND

2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent

AND

3. One of the following:

a. For patients already established on the requested therapeutic immunomodulator:

i. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).

ii. 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.

b. Patients not established on the requested therapeutic immunomodulator must meet ALL the following indication-specific criteria (note: if indication is not listed below, the requested drug may be covered if it is a FDA approved indication for the requested drug):

i. For moderate to severe Ulcerative Colitis, adalimumab (Humira®) or ustekinumab (Stelara®) may be

covered. Other therapies may be covered as outlined below:

1. Golimumab (Simponi®), tofacitinib (Xeljanz/Xeljanz XR®), and upadacitinib (Rinvoq®) require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to adalimumab (Humira®)
2. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to adalimumab (Humira®), ustekinumab (Stelara®), or tofacitinib (Xeljanz/Xeljanz XR®)
  - ii. For moderate to severe non-fistulizing Crohn's Disease, adalimumab (Humira®), ustekinumab (Stelara®), or risankizumab-rzaa (Skyrizi®) may be covered. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to both of the following:
    - a. Adalimumab (Humira®)
    - b. One of the following: ustekinumab (Stelara®) or risankizumab-rzaa (Skyrizi®)
  - iii. For Rheumatoid Arthritis, all the following criteria (1 and 2) must be met:
    2. Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to at least one of the following conventional therapies: methotrexate, leflunomide, hydroxychloroquine, minocycline, or sulfasalazine
3. Etanercept (Enbrel®) and adalimumab (Humira®) may be covered. Other therapies may be covered as outlined below:
  - a. Tofacitinib (Xeljanz/Xeljanz XR®) and upadacitinib (Rinvoq®) require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to one TNF inhibitor
  - b. Tocilizumab (Actemra®) requires documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to adalimumab (Humira®)
  - c. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to two of the following agents:
    - i. etanercept (Enbrel®)
    - ii. adalimumab (Humira®)
    - iii. upadacitinib (Rinvoq®)
    - iv. tofacitinib (Xeljanz/Xeljanz XR®)
- iv. For Polyarticular Juvenile Idiopathic Arthritis (PJIA), all the following criteria (1 and 2) must be met:
  1. Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to at least one of the following conventional therapies: methotrexate, leflunomide, hydroxychloroquine, minocycline, or sulfasalazine)
  2. Etanercept (Enbrel®) and adalimumab (Humira®) may be covered. Other therapies may be covered as outlined below:
    - a. Tofacitinib (Xeljanz/Xeljanz XR®) requires documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to one TNF inhibitor
    - b. Tocilizumab (Actemra®) requires documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to adalimumab (Humira®)
    - c. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to two of the following:

- i. adalimumab (Humira®)
- ii. etanercept (Enbrel®)
- iii. tocilizumab (Actemra®)
- iv. tofacitinib (Xeljanz/Xeljanz XR®)
- v. For moderate to severe Plaque Psoriasis, all the following criteria (1 and 2) must be met:
  - 1. Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to at least one of the following conventional therapies: methotrexate, tazarotene, topical corticosteroids, calcitriol, coal tar products, anthralin, calcipotriene, acitretin, tazarotene, cyclosporine, methoxsalen, tacrolimus, pimecrolimus, or phototherapy
  - 2. Preferred therapies may be covered. Other therapies may be covered as outlined below:
    - a. Ixekizumab (Taltz®) and brodalumab (Siliq®) require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to three of the following preferred agents:
      - i. adalimumab (Humira®)
      - ii. apremilast (Otezla®)
      - iii. etanercept (Enbrel®)
      - iv. secukinumab (Cosentyx®)
      - v. ustekinumab (Stelara®)
      - vi. guselkumab (Tremfya®)
      - vii. risankizumab-rzaa (Skyrizi®)

AND

- b. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to two of the following preferred agents:
  - i. adalimumab (Humira®)
  - ii. etanercept (Enbrel®)
  - iii. guselkumab (Tremfya®)
  - iv. risankizumab-rzaa (Skyrizi®)
  - v. secukinumab (Cosentyx®)
  - vi. ustekinumab (Stelara®)
  - vii. apremilast (Otezla®)

- vi. For Psoriatic Arthritis, all the following criteria (1 and 2) must be met:
  - 1. Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to at least one of the following conventional therapies: methotrexate, leflunomide, hydroxychloroquine, minocycline, or sulfasalazine
  - 2. Adalimumab (Humira®), etanercept (Enbrel®), guselkumab (Tremfya®), secukinumab (Cosentyx®), ustekinumab (Stelara®), risankizumab-rzaa (Skyrizi®), or apremilast (Otezla®) may be covered. Other therapies may be covered as outlined below:
    - a. Upadacitinib (Rinvoq®) and tofacitinib (Xeljanz/Xeljanz XR®) require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to one TNF inhibitor
    - b. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to two of the following preferred agents:

- i. adalimumab (Humira®)
- ii. apremilast (Otezla®)
- iii. etanercept (Enbrel®)
- iv. guselkumab (Tremfya®)
- v. secukinumab (Cosentyx®)
- vi. tofacitinib (Xeljanz/Xeljanz XR®)
- vii. ustekinumab (Stelara®)
- viii. risankizumab-rzaa (Skyrizi®)
- vii. For Ankylosing Spondylitis, adalimumab (Humira®), etanercept (Enbrel®), or secukinumab (Cosentyx®) may be covered. Other therapies may be covered as outlined below
  1. Tofacitinib (Xeljanz/Xeljanz XR®) requires documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to one TNF inhibitor
  2. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to two of the following preferred agents:
    - a. adalimumab (Humira®)
    - b. etanercept (Enbrel®)
    - c. secukinumab (Cosentyx®)
    - d. tofacitinib (Xeljanz/Xeljanz XR®)
- viii. For uveitis or Hidradenitis Suppurativa, adalimumab (Humira®) may be covered. All other therapies require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to adalimumab (Humira®)
- ix. For giant cell arteritis: Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to systemic corticosteroid therapy
- viii. For Non-radiographic axial spondyloarthritis with objective signs of inflammation (such as elevated C-reactive protein or sacroiliitis on MRI), certolizumab (Cimzia®) or secukinumab (Cosentyx®) may be covered. Other therapies may be covered as outlined below
  1. Upadacitinib (Rinvoq®) may be covered with documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to one TNF inhibitor
  2. All other therapies require documentation trial and failure (after at least three months of therapy), intolerance or contraindication to two of the following preferred agents: certolizumab (Cimzia®), secukinumab (Cosentyx®), or upadacitinib (Rinvoq®)
- x. For active oral ulcers associated with Behcet's disease, apremilast (Otezla®) may be covered if the following criteria are met:
  1. Patient has had at least three occurrences of active oral ulcers within the previous 12 months
  2. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., corticosteroids)
- xi. For systemic sclerosis associated Interstitial Lung Disease, tocilizumab (Actemra®) may be covered if the following criteria are met:
  1. Patient has interstitial lung disease, as evidence by high-resolution computed tomography (HRCT)
- xii. For atopic dermatitis, upadacitinib (Rinvoq®) may be covered if the following criteria are met:

1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all the following:
  - a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or involvement of the palms of the hand and/or soles of the feet)
  - b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification
2. Documented inadequate response to one of the following (a or b) or contraindication to all therapies:
  - a. Systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) for at least three months
  - b. Both of the following:
    - i. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least four weeks
    - ii. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least four weeks

Notes:

- Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent for the same indication
- Conventional therapy and preferred agent requirements may be waived with clinically appropriate medical rationale

For quantity limit exception requests

1. For patients already established on the requested dose and frequency, the following criteria must be met: Documentation of response to therapy with increased dosing. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
2. For patients not established on requested dose and frequency (e.g., requesting dose escalation, previous dose escalation sponsored by manufacturer not previously approved by a health plan), one of the following must be met:
  - a. Requested dose is FDA-labeled for the indication. For example:
    - i. For Crohn's disease: Stelara® and Skyrizi® will be approved for FDA-labeled dosing for this condition (Stelara: 90 mg every eight weeks, Skyrizi: 360 mg every eight weeks)
    - ii. For Hidradenitis Suppurativa: Humira® will be approved for FDA-labeled dosing for this condition (40 mg once weekly)
    - iii. For psoriasis: Cimzia® will be approved for FDA-labeled dosing for this condition (800 mg every four weeks)
    - iv. For ulcerative colitis: Simponi® will be approved for FDA-labeled dosing for this condition (100 mg every 28 days)
  - b. For requests for dose escalation in inflammatory bowel disease (such as Crohn's disease or ulcerative colitis), adalimumab 40 mg once weekly or ustekinumab 90 mg every six weeks may be covered if all of the following criteria are met:

- i. Documentation that patient initially responded to the medication, but has experienced an inadequate response, or waning of response, to the medication. Patient must have used the medication at the FDA-labeled dosing for at least six months.
- ii. Documentation of current and active inflammation on endoscopy or imaging [such as computed tomography enterography (CTE) or magnetic resonance enterography (MRE)] obtained after at least six months of treatment on the FDA-approved dosing outlined above. Results must have been obtained within the last six months prior to this request.
- c. For other disease states: requests for dose escalation are considered experimental/investigational and are not covered

### **AGE RESTRICTION**

Age must be appropriate based on FDA-approved indication

### **PRESCRIBER RESTRICTION**

- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, juvenile idiopathic arthritis: must be prescribed by, or in consultation with, a rheumatologist
- Psoriasis, Hidradenitis Suppurativa: must be prescribed by, or in consultation with, a dermatologist
- Psoriatic arthritis, Behcet's disease: must be prescribed by, or in consultation with, a dermatologist or rheumatologist
- Inflammatory Bowel Disease: must be prescribed by, or in consultation with, a gastroenterologist
- Giant cell arteritis: must be prescribed by, or in consultation with, a rheumatologist or neurologist
- Systemic sclerosis: must be prescribed by, or in consultation with, a rheumatologist or pulmonologist
- Uveitis: must be prescribed by, or in consultation with, an ophthalmologist

### **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, and reauthorization will be approved for one year. FDA-labeled dosing will be approved until no longer eligible with the plan, subject to formulary and/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, PROMACTA

## COVERED USES

N/A

## EXCLUSION CRITERIA

Concomitant use with other thrombopoietin receptor agonists (e.g., Mulpleta®, Promacta®, Nplate®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

## REQUIRED MEDICAL INFORMATION

For initiation of therapy, must meet indication-specific criteria below:

1. For Oncologic Diagnoses: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
  
2. For Immune Thrombocytopenia (ITP), Doptelet®, Nplate®, Promacta®, or Tavalisse®, may be covered if all the following criteria (a-c) are met:
  - a. Diagnosis of chronic immune thrombocytopenia (ITP)
  - b. Platelet count of less than 30,000 cells per microliter
  - c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated:
    - i. Systemic corticosteroids
    - ii. Immune globulin
    - iii. Splenectomy
    - iv. Rituximab
  
3. For Chronic Hepatitis C-associated Thrombocytopenia, Promacta® may be covered if all the following criteria (a-b) are met:
  - a. Platelet count of less than 75,000 cells per microliter
  - b. Patient will be initiating and maintaining interferon-based therapy or is currently receiving interferon-based therapy
  
4. For Severe Aplastic Anemia, Promacta® may be covered if there is documentation that the patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter
  
5. For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD), all the following criteria (a-d) must be met:
  - a. Request is for Doptelet® or Mulpleta®



- i. For Mulpleta®: Documented trial, failure, intolerance, or contraindication to Doptelet®
  - b. Diagnosis of chronic liver disease
  - c. Platelet count of less than 50,000 cells per microliter,
  - d. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started prior to the procedure as follows:
    - i. For Doptelet: 10-13 days prior to the procedure
    - ii. For Mulpleta: 8-14 days prior to the procedure
6. For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], Nplate® may be covered if patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

For patients established on therapy, must meet indication-specific criteria below:

1. For oncologic diagnoses: Documentation of improved platelet levels from baseline
2. For ITP or severe aplastic anemia:
  - a. Documentation of improved platelet levels from baseline
  - b. Documentation the continued therapy is medically necessary to maintain a platelet count of at least 50,000 cells per microliter
3. For Chronic Hepatitis C-associated Thrombocytopenia:
  - a. Documentation of improved platelet levels from baseline
  - b. Patient continues to receive interferon-based therapy
4. For CLD or HSARS: Patient must meet the initial approval criteria above for each request

#### **AGE RESTRICTION**

N/A

#### **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, an oncologist, hematologist, gastroenterologist or hepatologist.

#### **COVERAGE DURATION**

- For ITP, chronic hepatitis C-associated thrombocytopenia, severe aplastic anemia and oncologic diagnoses: Initial authorization will be approved for six months. Reauthorization will be approved for one year
- For CLD: Authorization will be approved for one month for one treatment course
- For HSARS: Authorization will be approved for three months

#### **OTHER CRITERIA**

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

# **TRANSTHYRETIN (TTR) LOWERING AGENTS**

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## **MEDICATION(S)**

TEGSEDI

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

- New York Heart Association (NYHA) Heart Functional class III or IV
- History of liver transplantation
- Peripheral neuropathy attributed to causes other than hATTR
- Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis [such as Amvuttra® (vutrisiran), inotersen (Tegsedi®), patisiran (Onpattro®), or tafamidis (Vyndaqel®, Vyndamax®)]

## **REQUIRED MEDICAL INFORMATION**

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

1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy  
AND
2. Documentation of a pathogenic TTR mutation  
AND
3. Patient has a baseline polyneuropathy disability (PND) score of less than or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II  
AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130  
AND
5. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
  - a. Peripheral sensorimotor polyneuropathy (such as tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
  - b. Autonomic neuropathy symptoms (such as orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])
6. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization:

1. Documentation that patient is tolerating applicable therapy (vutrisiran (Amvuttra®), 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**

Confirmed diagnosis of Wilson's Disease

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or genetic specialist

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for one year.

## **OTHER CRITERIA**

N/A

# UCERIS

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## MEDICATION(S)

BUDESONIDE ER, UCERIS 9 MG ER TABLET

## 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

## **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.

**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

N/A

## 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, TETRABENAZINE, XENAZINE

## COVERED USES

N/A

## EXCLUSION CRITERIA

- Active suicidality
- Untreated or inadequately treated depression
- Hepatic Impairment
- Use in combination with monoamine oxidase inhibitors, other VMAT2 inhibitors or reserpine

## REQUIRED MEDICAL INFORMATION

1. For chorea associated with Huntington disease [tetrabenazine (Xenazine®) or deutetrabenazine (Austedo®) only]
  - a. Initiation of therapy requires all of the following must be met:
    - i. Diagnosis of Huntington Disease confirmed by all of the following:
      1. DNA testing showing CAG expansion of more than 36, AND
      2. Family history (if known), AND
      3. Classic presentation (choreiform movements, psychiatric problems, and dementia), AND
    - ii. Documentation that chorea is causing functional impairment, AND
    - iii. For deutetrabenazine (Austedo®): Documented trial (of at least eight weeks) and failure or intolerance to tetrabenazine.
  - b. For reauthorization: Documented benefit of therapy, as evidence by improved function through reduction in choreiform movements.
2. For Tardive Dyskinesia
  - a. For initiation of therapy, all of the following criteria must be met:
    - i. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent (e.g. first or second generation antipsychotics, metoclopramide), AND
    - ii. Documentation of moderate to severe tardive dyskinesia that is causing functional impairment, defined as an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of items 1 through 9 (see supplemental information) OR tardive dyskinesia that is interfering with activities of daily living (ADLs), AND
    - iii. For deutetrabenazine (Austedo®) and valbenazine (Ingrezza®): Documented trial (of at least eight weeks) and failure or intolerance of tetrabenazine.
  - b. For reauthorization: Documentation of positive clinical response to therapy, as demonstrated by improved function or activities of daily living (ADLs), or a decrease in AIMS score



**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

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

**COVERAGE DURATION**

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

**OTHER CRITERIA**

N/A

# **WEIGHT MANAGEMENT MEDICATIONS**

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## **MEDICATION(S)**

QSYMIA, SAXENDA, WEGOVY

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

For liraglutide (Saxenda) and semaglutide (Wegovy): Concurrent use with another GLP-1 receptor agonist

## **REQUIRED MEDICAL INFORMATION**

1. For initial authorization, all the following criteria must be met:
  - a. Member's benefit provides coverage for weight loss management
  - b. Documentation of current height and weight (measured within the previous month) indicating one of the following:
    - i. Body mass index (BMI) of at least 30
    - ii. BMI of at least 27 with the presence of at least one weight-related comorbidity (such as hypertension, type 2 diabetes mellitus, dyslipidemia, sleep apnea)
  - c. Documentation of one of the following:
    - i. Attestation from provider that patient is engaged in behavioral and lifestyle modifications
    - ii. Enrollment in an employer- or health plan- approved comprehensive weight loss program
  - d. Documentation that patient will continue with lifestyle modifications as part of the treatment program.
2. For initial reauthorization, the following criteria must be met:
  - a. Documentation of at least a 5% weight loss from baseline body weight
  - b. Documentation of continuation of lifestyle modifications
3. For on-going reauthorization, the following criteria must be met:
  - a. Documentation that patient has maintained weight loss and has not returned to baseline body weight (or higher)
  - b. Documentation of continuation of lifestyle modifications

## **AGE RESTRICTION**

Per FDA label for the requested medication

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial authorization and reauthorization will be approved for six months

**OTHER CRITERIA**

N/A

# XIFAXAN

---

## MEDICATION(S)

XIFAXAN

## COVERED USES

N/A

## EXCLUSION CRITERIA

More than three treatment courses in a rolling 6-month period for IBS-D.

## REQUIRED MEDICAL INFORMATION

Traveler's diarrhea (200 mg tablets):

1. Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. Xifaxan® is not covered if documentation shows diarrhea that is complicated by fever or blood in stool.

Hepatic Encephalopathy (550 mg tablets):

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

Irritable Bowel Syndrome with Diarrhea (IBS-D) with or without small intestinal bacterial growth (SIBO) for 550 mg tablets):

1. Documentation of trial and failure, contraindication, or intolerance to a tricyclic antidepressant [such as amitriptyline (Elavil®)]

Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms. Limited to three total 14-day course treatments per rolling 6-month period (initial treatment and two reauthorizations).

- A response is defined as a 50% or more decrease from baseline in number of days per week with loose and watery stool AND improvement in abdominal pain for at least 2 out of 4 weeks after treatment
- A recurrence is defined as a loss of treatment response for either weekly abdominal pain or stool consistency for at least 3 weeks of a consecutive, rolling 4-week period

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

For irritable bowel syndrome with diarrhea (IBS-D): Must be prescribed by, or in consultation with, a gastroenterologist

**COVERAGE DURATION**

IBS-D (550 mg tablets):

Initial authorization: One-time 14-day treatment course per three months

Reauthorization: Will be approved for up to two additional 14-day treatment courses (total of three treatment courses within six months)

Traveler's diarrhea (200 mg tablets): One-time three-day treatment course (Quantity of nine tablets)

Hepatic Encephalopathy (550 mg tablets): Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

**OTHER CRITERIA**

N/A

# 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 (such as apremilast, adalimumab)

## **REQUIRED MEDICAL INFORMATION**

Initial authorization for multiple sclerosis (MS), all the following criteria must be met:

1. Must have one of the following confirmed diagnoses:
  - a. Relapsing-remitting disease (RRMS)
  - b. Secondary progressive multiple sclerosis (SPMS)
  - c. Clinically isolated syndrome (CIS)
2. The prescriber has performed an electrocardiogram within six months prior to initiating treatment

Initial authorization for ulcerative colitis (UC), all the following criteria must be met:

1. Documentation of moderately to severely active disease
2. Documentation of one of the following:
  - a. Trial and failure, or intolerance to one of the following conventional therapies for UC: 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, or sulfasalazine, OR
  - b. Documented FDA labeled contraindication to ALL the therapies outlined above, OR
  - c. Documentation of history of use of another therapeutic immunomodulatory (TIM) agent for the treatment of UC, TIM agent 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), upadacitinib (Rinvoq®), or Xeljanz® (tofacitinib)/Xeljanz XR® (tofacitinib extended release)
  - b. FDA Labeled contraindication to ALL the therapies outlined above (3.a.)
4. The prescriber has performed an electrocardiogram within six months prior to initiating treatment

## **AGE RESTRICTION**

May be approved for patients aged 18 years and older

## **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, a 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



# ZTALMY

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## **MEDICATION(S)**

ZTALMY

## **COVERED USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

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

1. Diagnosis of CDKL5 deficiency disorder (CDD) confirmed with genetic testing
2. Documented trial and failure with three or more antiepileptic drugs
3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
4. The dose requested is within FDA labeled dosing based on the patient's weight (patient's weight must be provided)

For patients established on therapy, the following criteria must be met:

1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
2. The dose requested is within FDA labeled dosing based on the patient's weight (updated weight must be provided)

## **AGE RESTRICTION**

The patient's age must be within FDA labeling for the requested indication

## **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

N/A

## ZYFLO CR

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### **MEDICATION(S)**

ZILEUTON ER

### **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