

# 2024 PRIOR AUTHORIZATION CRITERIA

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**Prior Authorization Group Description:**

Acthar Gel PA

**Drug Name(s)**

Acthar

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

**1. ONE of the following:**

- a. Patient has a diagnosis of infantile spasm OR
- b. Patient has a diagnosis of nephrotic syndrome AND ONE of the following:
  - i. Patient has failed a conventional agent (i.e., prednisone, tacrolimus) for the requested indication OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a conventional agent OR
- c. Patient has a diagnosis of multiple sclerosis AND ALL of the following:
  - i. Patient is experiencing an acute exacerbation AND
  - ii. If indicated, there is evidence of a claim that the patient is currently being treated with a disease modifying drug (DMD) within the past 90 days [e.g., Avonex, dimethyl fumarate, glatiramer] to control disease progression OR has an intolerance, FDA labeled contraindication, or hypersensitivity to a DMD AND
  - iii. ONE of the following:
    1. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR
    2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy OR

Criteria continues: see Other Criteria

**Age Restriction:**

For diagnosis of infantile spasm, patient is less than 2 years of age.

**Prescriber Restrictions:****Coverage Duration:**

6 months for infantile spasm, 1 month for all other indications

**Other Criteria:**

- d. Patient has a diagnosis of rheumatic disorder (e.g., ankylosing spondylitis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, rheumatoid arthritis) AND ALL of the following:
  - i. The requested agent will be used as adjunct therapy for short-term administration (to tide the patient over an acute episode or exacerbation) AND

- ii. There is evidence of a claim that the patient is currently being treated with a conventional agent within the past 90 days [e.g., DMARD (methotrexate, leflunomide), biologics (Humira)] to control disease progression AND
  - iii. ONE of the following:
    - 1. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days
    - OR
    - 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy OR
  - e. Patient has a diagnosis of systemic lupus erythematosus (SLE) disease AND the patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
  - f. Patient has another FDA approved indication AND ONE of the following:
    - i. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR
    - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy OR
  - g. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
    - i. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR
    - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy AND
2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Prior Authorization Group Description:**

Actimmune PA

**Drug Name(s)**

Actimmune

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Acyclovir Topical PA

**Drug Name(s)**

Acyclovir

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Aimovig PA

**Drug Name(s)**

Aimovig

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
2. The requested agent is being used for migraine prophylaxis AND
3. Patient has 4 migraine headaches or more per month AND
4. ONE of the following:
  - A. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
  - B. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agent OR
  - C. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for migraine prophylaxis AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Alosetron PA

**Drug Name(s)**

Alosetron Hydrochloride

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of irritable bowel syndrome with severe diarrhea (IBS-D) AND
2. Patient's sex is female AND
3. Patient exhibits at least ONE of the following:
  - a. Frequent and severe abdominal pain/discomfort OR
  - b. Frequent bowel urgency or fecal incontinence OR
  - c. Disability or restriction of daily activities due to IBS AND
4. Prescriber has ruled out anatomic or biochemical abnormalities of the gastrointestinal tract

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Alpha-1-Proteinase Inhibitor PA - Prolastin-C

**Drug Name(s)**

Prolastin-C

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of alpha-1 antitrypsin deficiency (AATD) with clinically evident emphysema AND
2. Patient has a pre-treatment serum alpha-1 antitrypsin (AAT) level less than 11 micromol/L (80 mg/dL by immunodiffusion or 57 mg/dL using nephelometry) AND
3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of alpha-1 antitrypsin deficiency (AATD) with clinically evident emphysema AND
3. Patient has had clinical benefit with the requested agent AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Anabolic Steroid PA – Danazol

**Drug Name(s)**

Danazol

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has ONE of the following diagnoses:
  - A. Patient has an FDA labeled indication for the requested agent OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR
  - B. Prescriber has provided information in support of therapy with more than one agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Androgen Oral PA

**Drug Name(s)**

Methyltestosterone

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has ONE of the following diagnoses:

- A. Patient's sex is male with cryptorchidism OR
- B. Patient's sex is male with hypogonadism OR
- C. Patient's sex is male and is an adolescent with delayed puberty OR
- D. Patient's sex is female with metastatic/inoperable breast cancer AND

2. If the patient's sex is male, ONE of the following:

- A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels:
  - i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR
  - ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR
- B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels:
  - i. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR
  - ii. Free serum testosterone level is within OR below the testing laboratory's normal range AND

3. ONE of the following:

- A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR
- B. Prescriber has provided information in support of therapy with more than one agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be 6 months for delayed puberty, 12 months for all other indications

**Other Criteria:**

**Prior Authorization Group Description:**

Androgen Topical PA

**Drug Name(s)**

Testosterone

Testosterone Pump

Testosterone Topical Solution

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has ONE of the following diagnoses:

A. Patient has AIDS/HIV-associated wasting syndrome AND BOTH of the following:

i. ONE of the following:

a. Unexplained involuntary weight loss (greater than 10% baseline body weight within 12 months, or 7.5% within 6 months) OR

b. Body mass index less than 20 kg/m<sup>2</sup> OR

c. At least 5% total body cell mass (BCM) loss within 6 months OR

d. In men: BCM less than 35% of total body weight and BMI less than 27 kg/m<sup>2</sup> OR

e. In women: BCM less than 23% of total body weight and BMI less than 27 kg/m<sup>2</sup> AND

ii. All other causes of weight loss have been ruled out OR

B. Patient's sex is male with primary or secondary (hypogonadotropic) hypogonadism AND

2. If the patient's sex is male, ONE of the following:

A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels:

i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR

ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR

B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels:

i. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR

ii. Free serum testosterone level is within OR below the testing laboratory's normal range AND

3. ONE of the following:

A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR

B. Prescriber has submitted information in support of therapy with more than one agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Antipsychotics PA

**Drug Name(s)**

Aripiprazole  
Aripiprazole Odt  
Asenapine Maleate Sl  
Chlorpromazine Hydrochloride  
Fanapt  
Fanapt Titration Pack  
Fluphenazine Hydrochloride  
Lybalvi  
Molindone Hydrochloride  
Olanzapine  
Paliperidone Er  
Rexulti  
Secuado  
Versacloz  
Ziprasidone Mesylate  
Zyprexa Relprevv

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

PA does NOT apply to patients less than 65 years of age.

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - b. Prescriber states the patient is currently being treated with the requested agent OR
  - c. ONE of the following:
    - i. Patient has a diagnosis other than dementia-related psychosis or dementia related behavioral symptoms OR
    - ii. Patient has dementia-related psychosis or dementia related behavioral symptoms AND BOTH of the following:
      1. Dementia-related psychosis is determined to be severe or the associated behavior puts the patient or others in danger AND
      2. Prescriber has documented that s/he has discussed the risk of increased mortality with the patient and/or the patient's surrogate decision maker

Approval authorizations will apply to the requested medication only.

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Apomorphine Inj PA

**Drug Name(s)**

Apokyn

Apomorphine Hydrochloride

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. The requested agent will be used to treat acute, intermittent hypomobility, “off” episodes (“end of dose wearing off” and unpredictable “on/off” episodes) associated with advanced Parkinson’s disease AND
2. The requested agent will be used in combination with agents used for therapy in Parkinson’s disease (e.g., levodopa, dopamine agonist, monoamine oxidase B inhibitor) AND
3. Patient will NOT be using the requested agent in combination with a 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Arcalyst PA

**Drug Name(s)**

Arcalyst

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. ONE of the following:

A. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) OR

B. BOTH of the following:

i. Patient has a diagnosis of deficiency of interleukin-1 receptor antagonist AND

ii. The requested agent is being used for maintenance of remission OR

C. BOTH of the following:

i. Patient has a diagnosis of recurrent pericarditis AND

ii. The requested agent is being used to reduce the risk of recurrence AND

2. Patient will NOT be using the requested agent in combination with another biologic agent

**Age Restriction:**

For diagnosis of CAPS including FCAS or MWS, patient is 12 years of age or over

For diagnosis of recurrent pericarditis and reduction in risk of recurrence, patient is 12 years of age or over

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Armodafinil PA

**Drug Name(s)**

Armodafinil

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another target agent (i.e., modafinil)

**Age Restriction:**

Patient is 17 years of age or over

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Atopic Dermatitis PA – Pimecrolimus

**Drug Name(s)**

Pimecrolimus

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ONE of the following:

1. Patient has a diagnosis of atopic dermatitis or vulvar lichen sclerosus AND ONE of the following:
  - A. Patient has tried and had an inadequate response to a topical corticosteroid or topical corticosteroid combination preparation (e.g., hydrocortisone, triamcinolone) OR
  - B. Patient has an intolerance or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation OR
  - C. Patient has an FDA labeled contraindication to a topical corticosteroid or topical corticosteroid combination preparation OR
2. Patient has a diagnosis of facial seborrheic dermatitis associated with HIV infection AND BOTH of the following:
  - A. Patient is currently on an antiretroviral treatment regimen AND
  - B. ONE of the following:
    - i. Patient has tried and had an inadequate response to a topical corticosteroid or topical antifungal treatment (e.g., hydrocortisone, triamcinolone, ketoconazole) OR
    - ii. Patient has an intolerance or hypersensitivity to a topical corticosteroid or topical antifungal treatment OR
    - iii. Patient has an FDA labeled contraindication to a topical corticosteroid or topical antifungal treatment OR
3. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Atopic Dermatitis PA – Tacrolimus

**Drug Name(s)**

Tacrolimus

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ONE of the following:

1. Patient has a diagnosis of atopic dermatitis AND ONE of the following:
  - A. Patient has tried and had an inadequate response to a topical corticosteroid or topical corticosteroid combination preparation (e.g., hydrocortisone, triamcinolone) OR
  - B. Patient has an intolerance or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation OR
  - C. Patient has an FDA labeled contraindication to a topical corticosteroid or topical corticosteroid combination preparation OR
2. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Atovaquone PA

**Drug Name(s)**

Atovaquone

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

1. Patient has a diagnosis of mild-to-moderate *Pneumocystis jirovecii* pneumonia OR

2. Patient is using the requested agent for prevention of *Pneumocystis jirovecii* pneumonia AND

ii. ONE of the following:

1. Patient has an intolerance or hypersensitivity to trimethoprim/sulfamethoxazole (TMP/SMX) OR

2. Patient has an FDA labeled contraindication to trimethoprim/sulfamethoxazole (TMP/SMX) OR

B. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Auryxia PA

**Drug Name(s)**

Auryxia

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Requested agent will be used as iron replacement therapy to treat iron deficiency anemia AND FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has a diagnosis of hyperphosphatemia AND BOTH of the following:
  - A. Patient has chronic kidney disease AND
  - B. Patient is on dialysis

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Benlysta IV PA

**Drug Name(s)**

Benlysta IV

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. ONE of the following:
  - a. Patient has a diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
    - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
  - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
    - i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
2. Patient will NOT be using the requested agent in combination with another biologic agent AND
3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
  - a. Patient has diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
    - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
  - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
    - i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another biologic agent AND
5. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

For diagnosis of active systemic lupus erythematosus (SLE) disease, patient is 5 years of age or over. For diagnosis of active lupus nephritis (LN), patient is 5 years of age or over.

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Benlysta SC PA

**Drug Name(s)**

Benlysta SC

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. ONE of the following:
  - a. Patient has a diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
    - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
  - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
    - i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
2. Patient will NOT be using the requested agent in combination with another biologic agent AND
3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
  - a. Patient has diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
    - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
  - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
    - i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another biologic agent AND
5. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

For diagnosis of active systemic lupus erythematosus (SLE) disease, patient is 18 years of age or over.

For diagnosis of active lupus nephritis (LN), patient is 18 years of age or over.

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Benzodiazepines PA – Clobazam

**Drug Name(s)**

Clobazam

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

b. Prescriber states the patient is currently being treated with the requested agent AND

ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

a. Seizure disorder OR

b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Benzodiazepines PA – Diazepam

**Drug Name(s)**

Diazepam

Diazepam Intensol

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND

ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

- a. Seizure disorder OR
- b. Anxiety disorder AND ONE of the following:
  - 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
  - 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR
  - 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR
- c. Skeletal muscle spasms OR
- d. Alcohol withdrawal OR
- e. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Benzodiazepines PA – Sympazan

**Drug Name(s)**

Sympazan

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

b. Prescriber states the patient is currently being treated with the requested agent AND

ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

a. Seizure disorder OR

b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Bexarotene Gel PA

**Drug Name(s)**

Bexarotene Gel

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. ONE of the following:

- A. Patient has a diagnosis of stage IA or IB cutaneous T-cell lymphoma (CTCL) with cutaneous lesions OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- B. Prescriber states the patient is currently being treated with the requested agent OR
- C. ALL of the following:

i. ONE of the following:

1. BOTH of the following:

- a. Patient has a diagnosis of stage IA or IB cutaneous T-cell lymphoma (CTCL) with cutaneous lesions AND
- b. ONE of the following:

- i. Patient has refractory or persistent disease despite a previous treatment trial with a skin-directed therapy (e.g., topical corticosteroid, topical imiquimod) OR
- ii. Patient has an intolerance or hypersensitivity to a previous treatment trial with a skin-directed therapy (e.g., topical corticosteroid, topical imiquimod) OR
- iii. Patient has an FDA labeled contraindication to a previous treatment trial with a skin-directed therapy (e.g., topical corticosteroid, topical imiquimod) OR

2. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

- ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
- iii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
  - A. Patient has a diagnosis of stage IA or IB cutaneous T-cell lymphoma (CTCL) with cutaneous lesions OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Patient has had clinical benefit with the requested agent AND
    - ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
    - iii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Cosentyx

**Drug Name(s)**

Cosentyx

Cosentyx Sensoready Pen

Cosentyx Uno Inj

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. Patient’s medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
  - D. Patient’s diagnosis does NOT require a conventional prerequisite agent OR
  - E. Patient’s medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
  - F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
  - G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis or plaque psoriasis

NO prerequisites are required for diagnoses of ankylosing spondylitis, enthesitis related arthritis, hidradenitis suppurativa, or non-radiographic axial spondyloarthritis

Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine

Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Cyltezo

**Drug Name(s)**

Cyltezo

Cyltezo Pen

Cyltezo Pen-Cd/Uc/Hs Starter Pack

Cyltezo Pen-Ps Starter Pack

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. Patient’s medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
  - D. Patient’s diagnosis does NOT require a conventional prerequisite agent OR
  - E. Patient’s medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
  - F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
  - G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be 12 weeks for initial use for ulcerative colitis, 12 months for all others

**Other Criteria:**

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, Crohn's disease, or moderate ulcerative colitis

NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, severe ulcerative colitis, or uveitis

Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine

Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Enbrel

**Drug Name(s)**

Enbrel

Enbrel Mini

Enbrel Sureclick

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. Patient’s medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
  - D. Patient’s diagnosis does NOT require a conventional prerequisite agent OR
  - E. Patient’s medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
  - F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
  - G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile psoriatic arthritis, or juvenile idiopathic arthritis

NO prerequisites are required for a diagnoses of ankylosing spondylitis or severe juvenile psoriatic arthritis

Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, juvenile psoriatic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Humira

**Drug Name(s)**

Humira

Humira Pediatric Crohns Disease Starter Pack

Humira Pen

Humira Pen-Cd/Uc/Hs Starter

Humira Pen-Pediatric Uc Starter Pack

Humira Pen-Ps/Uv Starter

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. Patient’s medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
  - D. Patient’s diagnosis does NOT require a conventional prerequisite agent OR
  - E. Patient’s medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
  - F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
  - G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be 12 weeks for initial use for ulcerative colitis, 12 months for all others

**Other Criteria:**

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, Crohn's disease, or moderate ulcerative colitis

NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, severe ulcerative colitis, or uveitis

Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine

Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Kineret

**Drug Name(s)**

Kineret

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. Patient's diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
      - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
      - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
      - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
    - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

NO preferred agent is required for diagnoses of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Orencia

**Drug Name(s)**

Orencia

Orencia Clickject

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. Patient’s diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
      - a. Patient’s medication history indicates use of preferred biologic immunomodulator agent(s) OR
      - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
      - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
    - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Xeljanz tablets, or Xeljanz oral solution) is required for diagnosis of juvenile idiopathic arthritis

Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Cyltezo, Enbrel, Humira, Otezla, Rinvoq, Stelara, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of psoriatic arthritis

NO preferred agent is required for diagnosis of prophylaxis of acute graft vs host disease

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Renflexis

**Drug Name(s)**

Renflexis

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. Patient’s diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
      - a. Patient’s medication history indicates use of preferred biologic immunomodulator agent(s) OR
      - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
      - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
    - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of TWO preferred agents (Cyltezo, Enbrel, or Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Cyltezo, Enbrel, Humira, Otezla, or Stelara) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Cyltezo, Enbrel, Humira, Otezla, or Stelara) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Cyltezo, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Cyltezo, Humira, or Stelara) is required for diagnosis of adult Crohn's disease

Use of TWO preferred agents (Cyltezo, Humira, or Stelara) is required for diagnosis of adult ulcerative colitis

Use of ONE preferred agent (Cyltezo or Humira) is required for diagnosis of pediatric Crohn's disease

Only the preferred agent Humira is required for diagnosis of pediatric ulcerative colitis

NO preferred agent is required for diagnosis of adult fistulizing Crohn's disease

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Riabni

**Drug Name(s)**

Riabni

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:

A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

2. ALL of the following:

A. ONE of the following:

i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:

a. Patient’s medication history indicates use of preferred biologic immunomodulator agent(s) OR

b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR

c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR

ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND

B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND

C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND

D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

3. ONE of the following:

- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- B. Prescriber states the patient is currently being treated with the requested agent OR
- C. ALL of the following:
  - i. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
  - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
  - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Rinvoq

**Drug Name(s)**

Rinvoq

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. BOTH of the following:
      - a. Patient has an FDA labeled indication other than moderate to severe atopic dermatitis for the requested agent AND
      - b. ONE of the following:
        1. Patient’s medication history indicates use of preferred TNF agent(s) OR
        2. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
        3. Patient has an FDA labeled contraindication to preferred TNF agent(s) OR
        4. The request is for an FDA labeled indication that is not covered by preferred TNF agent(s) OR
    - ii. Patient has a diagnosis of moderate to severe atopic dermatitis AND ONE of the following:
      1. Patient’s medication history indicates use of TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication OR
      2. Patient has an intolerance or hypersensitivity to TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication OR
      3. Patient has an FDA labeled contraindication to TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:**



**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Use of ONE preferred TNF (Cyltezo, Enbrel, or Humira) is required for diagnoses of ankylosing spondylitis, rheumatoid arthritis, or psoriatic arthritis

Use of ONE preferred TNF (Cyltezo or Humira) is required for diagnoses of ulcerative colitis or Crohn's disease

Use of TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) are required for diagnosis of moderate to severe atopic dermatitis

NO preferred TNF agents are required for diagnosis of non-radiographic Axial Spondyloarthritis

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Rituxan

**Drug Name(s)**

Rituxan

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
2. ALL of the following:
  - A. ONE of the following:
    - i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:
      - a. Patient’s medication history indicates use of preferred biologic immunomodulator agent(s) OR
      - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
      - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
    - ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND
  - B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND
  - C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:

- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- B. Prescriber states the patient is currently being treated with the requested agent OR
- C. ALL of the following:
  - i. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
  - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
  - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

**Prior Authorization Group Description:**

Biologic Immunomodulators PA - Rituxan Hycela

**Drug Name(s)**

Rituxan Hycela

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND
    - ii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
    - iii. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following
    - i. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
    - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND

- iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
- iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

There are no preferred agents required for Rituxan Hycela

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Ruxience

**Drug Name(s)**

Ruxience

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
2. ALL of the following:
  - A. ONE of the following:
    - i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:
      - a. Patient’s medication history indicates use of preferred biologic immunomodulator agent(s) OR
      - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
      - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
    - ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND
  - B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND
  - C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:

- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- B. Prescriber states the patient is currently being treated with the requested agent OR
- C. ALL of the following:
  - i. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
  - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
  - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

**Prior Authorization Group Description:**

Biologic Immunomodulators PA – Stelara

**Drug Name(s)**

Stelara

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
  - D. Patient's diagnosis does NOT require a conventional prerequisite agent OR
  - E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
  - F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
  - G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, moderate ulcerative colitis, or Crohn's disease



NO prerequisites are required for diagnosis of severe ulcerative colitis

Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine

Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, mercaptopurine

Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, mercaptopurine

**Prior Authorization Group Description:**

Biologic Immunomodulators PA - Truxima

**Drug Name(s)**

Truxima

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
2. ALL of the following:
  - A. ONE of the following:
    - i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:
      - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
      - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
      - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
    - ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND
  - B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND
  - C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:

- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- B. Prescriber states the patient is currently being treated with the requested agent OR
- C. ALL of the following:
  - i. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
  - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
  - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
  - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Cyltezo, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

**Prior Authorization Group Description:**

Biologic Immunomodulators PA - Xeljanz Solution

**Drug Name(s)**

Xeljanz Solution

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. Patient's medication history indicates use of preferred TNF agent(s) OR
    - ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
    - iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of ONE preferred TNF (Cyltezo, Enbrel, or Humira) is required for diagnosis of juvenile idiopathic arthritis

**Prior Authorization Group Description:**

Biologic Immunomodulators PA - Xeljanz Tablet

**Drug Name(s)**

Xeljanz Tablet

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. Patient's medication history indicates use of preferred TNF agent(s) OR
    - ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
    - iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of ONE preferred TNF (Cyltezo, Enbrel, or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, or ankylosing spondylitis

Use of ONE preferred TNF (Cyltezo or Humira) is required for diagnosis of ulcerative colitis

**Prior Authorization Group Description:**

Biologic Immunomodulators PA - Xeljanz XR

**Drug Name(s)**

Xeljanz Xr

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. Patient's medication history indicates use of preferred TNF agent(s) OR
    - ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
    - iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Use of ONE preferred TNF (Cyltezo, Enbrel, or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, or ankylosing spondylitis

Use of ONE preferred TNF (Cyltezo or Humira) is required for diagnosis of ulcerative colitis

**Prior Authorization Group Description:**

Bivigam/Flebogamma/Gammaplex/Octagam/Privigen PA

**Drug Name(s)**

Gammaplex

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ONE of the following:

**1. Patient has ONE of the following diagnoses:**

- A. Primary immunodeficiency [e.g., congenital agammaglobulinemia, common variable immunodeficiency (CVID), severe combined immunodeficiency, Wiskott-Aldrich Syndrome, X-linked agammaglobulinemia (XLA), humoral immunodeficiency, IgG subclass deficiency with or without IgA deficiency] OR
- B. B-cell chronic lymphocytic leukemia OR multiple myeloma AND ONE of the following:
  - i. Patient has a history of infections OR
  - ii. Patient has evidence of specific antibody deficiency OR
  - iii. Patient has hypogammaglobulinemia OR
- C. Idiopathic thrombocytopenia purpura AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone), or immunosuppressants (e.g., azathioprine)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
- D. Dermatomyositis AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
- E. Polymyositis AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
- F. Severe rheumatoid arthritis AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., tumor necrosis factor antagonists (e.g., Humira), DMARDS (e.g., methotrexate)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

Criteria continues: see Other Criteria

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 6 months for indications in Other Criteria, 12 months for all others

**Other Criteria:**

G. Myasthenia gravis (MG) AND ONE of the following:

- i. Patient is in acute myasthenic crisis OR
- ii. Patient has severe refractory MG (e.g., major functional disability/weakness) AND ONE of the following:
  - a) Patient has failed ONE immunomodulator therapy (i.e., corticosteroid, pyridostigmine, or azathioprine) OR
  - b) Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE immunomodulator therapy OR

H. Multiple sclerosis (MS) AND BOTH of the following:

- i. Patient has a diagnosis of relapsing remitting MS (RRMS) AND
- ii. Patient has had an insufficient response, documented failure, or FDA labeled contraindication to TWO MS agents (e.g., Avonex, Betaseron, Copaxone, dimethyl fumarate, glatiramer, Glatopa, Plegridy, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:

- i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

J. Refractory pemphigus vulgaris AND ONE of the following:

- i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR

2. ONE of the following:

- A. Patient has another FDA labeled indication for the requested agent OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome

Drug is also subject to Part B versus Part D review.



**Prior Authorization Group Description:**

Budesonide Oral ER PA – Uceris

**Drug Name(s)**

Budesonide Er

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Bydureon PA

**Drug Name(s)**

Bydureon Bcise

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Requested agent will be used for weight loss alone

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of type 2 diabetes mellitus AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. BOTH of the following:
    - i. ONE of the following:
      1. Patient's medication history includes use of an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR
      2. Patient had an ineffective treatment response to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      3. Patient has an intolerance or hypersensitivity to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      4. Patient has an FDA labeled contraindication to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Carglumic PA

**Drug Name(s)**

Carglumic Acid

**Indications:**

All FDA-Approved Indications, Some Medically-Accepted Indications.

**Off-Label Uses:**

Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of ONE of the following:
  - a. Acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) OR
  - b. Chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) OR
  - c. Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)AND
2. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, nephrologist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Chenodal PA

**Drug Name(s)**

Chenodal

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of radiolucent stones in a well-opacifying gallbladder AND
2. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Chorionic Gonadotropin PA

**Drug Name(s)**

Chorionic Gonadotropin

Pregnyl

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Requested agent will be used to promote fertility AND requested agent will be used to treat erectile dysfunction AND FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of prepubertal cryptorchidism not due to anatomic obstruction OR

B. Patient's sex is male, with a diagnosis of hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency) AND BOTH of the following:

i. Patient has a measured current or pretreatment total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory's lower limit of the normal range AND

ii. Patient has measured luteinizing hormone (LH) AND follicle-stimulating hormone (FSH) levels that are at (low-normal) or below the testing laboratory's normal range OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Cinacalcet PA

**Drug Name(s)**

Cinacalcet Hydrochloride

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has ONE of the following:

- A. A diagnosis of hypercalcemia due to parathyroid carcinoma OR
- B. A diagnosis of primary hyperparathyroidism (HPT) AND BOTH of the following:
  - i. Patient has a pretreatment serum calcium level that is above the testing laboratory's upper limit of normal AND
  - ii. Patient is unable to undergo parathyroidectomy OR
- C. Another indication that is FDA approved or supported in CMS approved compendia for the requested agent not otherwise excluded from Part D [i.e., secondary hyperparathyroidism due to end-stage renal disease (ESRD) on dialysis]

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Colony Stimulating Factors PA – Fulphila

**Drug Name(s)**

Fulphila

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Colony Stimulating Factors PA – Granix

**Drug Name(s)**

Granix

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**



**Prior Authorization Group Description:**

Colony Stimulating Factors PA – Leukine

**Drug Name(s)**

Leukine

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Colony Stimulating Factors PA – Nivestym

**Drug Name(s)**

Nivestym

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Colony Stimulating Factors PA – Udenyca

**Drug Name(s)**

Udenyca

Udenyca Onbody

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Colony Stimulating Factors PA – Ziextenzo

**Drug Name(s)**

Ziextenzo

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Corlanor PA

**Drug Name(s)**

Corlanor

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has stable, symptomatic chronic heart failure (e.g., NYHA Class II, III, IV: ACCF/AHA Class C, D)  
AND

2. ONE of following:

a. ALL of the following:

- i. The requested agent is for a pediatric patient, 6 months of age or over AND
- ii. Patient has heart failure due to dilated cardiomyopathy (DCM) AND
- iii. Patient is in sinus rhythm with an elevated heart rate OR

b. ALL of the following:

- i. The requested agent is for an adult patient AND
- ii. Patient has a baseline OR current left ventricular ejection fraction of 35% or less AND
- iii. Patient is in sinus rhythm with a resting heart rate of 70 beats or greater per minute prior to initiating therapy with the requested agent AND
- iv. ONE of the following:
  - 1. Patient is on a maximally tolerated dose of beta blocker (e.g., bisoprolol, carvedilol, metoprolol) OR
  - 2. Patient has an intolerance, FDA labeled contraindications, or hypersensitivity to a beta blocker

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Cresemba PA

**Drug Name(s)**

Cresemba

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of invasive aspergillosis OR
- B. Patient has a diagnosis of invasive mucormycosis OR
- C. Patient has another indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:

- A. Patient has a diagnosis of invasive aspergillosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR
- B. Patient has a diagnosis of invasive mucormycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR
- C. BOTH of the following:
  - i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
  - ii. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Crysvita PA

**Drug Name(s)**

Crysvita

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

**1. ONE of the following:****A. BOTH of the following:**

i. Patient has a diagnosis of X-linked hypophosphatemia (XLH) as confirmed by ONE of the following:

a. Genetic testing OR

b. Elevated levels of intact fibroblast growth factor 23 (FGF23) OR

c. Prescriber has provided information indicating the patient has a positive family history of XLH AND

ii. ONE of the following:

a. Patient's epiphyseal plate has not fused OR

b. Patient's epiphyseal plate has fused AND the patient is experiencing symptoms of XLH (e.g., bone pain, fractures, limited mobility) OR

B. Patient has a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND BOTH of the following:

i. The requested agent is being used to treat FGF23 related hypophosphatemia AND

ii. The tumor cannot be curatively surgically resected or localized AND

**2. The requested dose is within FDA labeled dosing for the requested indication**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

**2. ONE of the following:**

A. Patient has a diagnosis of X-linked hypophosphatemia (XLH) OR

B. Patient has a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND

3. Patient has had clinical benefit with the requested agent (e.g., enhanced height velocity, improvement in lower extremity bowing and associated abnormalities, radiographic evidence of epiphyseal healing, improvement in bone pain, enhanced mobility, improvement in osteomalacia, improvement in fracture healing) AND

4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent for the requested indication

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Cystaran PA

**Drug Name(s)**

Cystaran

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., ophthalmologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Cystinosis Agents PA – Cystagon

**Drug Name(s)**

Cystagon

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of nephropathic cystinosis AND
2. Prescriber has performed a baseline white blood cell (WBC) cystine level test AND
3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of nephropathic cystinosis AND
3. Patient has had clinical benefit with the requested agent (e.g., decrease in WBC cystine levels from baseline) AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Dalfampridine PA

**Drug Name(s)**

Dalfampridine Er

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of multiple sclerosis (MS) AND
2. ONE of the following:
  - A. The requested agent will be used in combination with a disease modifying agent [e.g., Aubagio, Avonex, Bafiertam, Betaseron, dimethyl fumarate (e.g., Tecfidera), Extavia, fingolimod, glatiramer (e.g., Copaxone, Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia] OR
  - B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying agent OR
  - C. Prescriber has provided information indicating that a disease modifying agent is not clinically appropriate for the patient

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of multiple sclerosis (MS) AND
3. ONE of the following:
  - A. The requested agent will be used in combination with a disease modifying agent [e.g., Aubagio, Avonex, Bafiertam, Betaseron, dimethyl fumarate (e.g., Tecfidera), Extavia, fingolimod, glatiramer (e.g., Copaxone, Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, Vumerity, Zeposia] OR
  - B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying agent OR
  - C. Prescriber has provided information indicating that a disease modifying agent is not clinically appropriate for the patient AND
4. Patient has had improvements or stabilization from baseline in timed walking speed (timed 25-foot walk)

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Initial approval will be for 3 months, renewal approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Droxidopa PA

**Drug Name(s)**

Droxidopa

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND
2. Prescriber has performed baseline blood pressure readings while the patient is sitting or supine (lying face up), AND also within three minutes of standing from a supine position AND
3. Patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing AND
4. Patient has persistent and consistent symptoms of neurogenic orthostatic hypotension (nOH) caused by ONE of the following:
  - A. Primary autonomic failure [Parkinson's disease (PD), multiple system atrophy, or pure autonomic failure] OR
  - B. Dopamine beta-hydroxylase deficiency OR
  - C. Non-diabetic autonomic neuropathy AND
5. Prescriber has assessed the severity of the patient's baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND
6. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND
3. Patient has had improvements or stabilization with the requested agent as indicated by improvement in severity from baseline symptoms of ONE of the following:
  - A. Dizziness
  - B. Lightheadedness
  - C. Feeling faint
  - D. Feeling like the patient may black out AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be 1 month for initial, 3 months for renewal

**Other Criteria:**

**Prior Authorization Group Description:**

Dupixent PA

**Drug Name(s)**

Dupixent

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. ONE of the following:

A. Patient has a diagnosis of moderate-to-severe atopic dermatitis AND ALL of the following:

i. ONE of the following:

a. Patient has tried and failed a topical steroid (e.g., triamcinolone) OR

b. Patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to a topical steroid AND

ii. For patients 2 years of age or over, ONE of the following:

a. Patient has tried and failed a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR

b. Patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to a topical calcineurin inhibitor AND

iii. Patient will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Adbry, Cibinqo, Opzelura, Rinvoq) OR

B. Patient has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND BOTH of the following:

i. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent AND

ii. Patient will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasentra, Nucala) for the requested indication OR

C. Patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND the following:

i. BOTH of the following:

a. ONE of the following:

1. Patient has tried and had an inadequate response to an oral systemic corticosteroid AND an intranasal corticosteroid (e.g., fluticasone) OR

2. Patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to an oral systemic corticosteroid AND an intranasal corticosteroid AND

Initial criteria continues: see Other Criteria

**Age Restriction:**

For diagnosis of moderate-to-severe atopic dermatitis, patient is 6 months of age or over. For diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma, patient is 6 years of age or over. For diagnosis of CRSwNP, patient is 18 years of age or over. For diagnosis of EoE, patient is 1 year of age or over. For diagnosis of PN, patient is 18 years of age or over.

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, dermatologist, immunologist, gastroenterologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

- b. Patient will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR
  - D. Patient has a diagnosis of eosinophilic esophagitis (EoE) confirmed by esophageal biopsy OR
  - E. Patient has a diagnosis of prurigo nodularis (PN) AND
2. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
  - A. Patient has a diagnosis of moderate-to-severe atopic dermatitis AND the following:
    - i. Patient will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Adbry, Cibinqo, Opzelura, Rinvoq) OR
  - B. Patient has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND BOTH of the following:
    - i. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
    - ii. Patient will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenna, Nucala) for the requested indication OR
  - C. Patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND the following:
    - i. Patient will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR
  - D. Patient has a diagnosis of eosinophilic esophagitis (EoE) OR
  - E. Patient has a diagnosis of prurigo nodularis (PN) AND
3. Patient has had clinical benefit with the requested agent AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Prior Authorization Group Description:**

Elmiron PA

**Drug Name(s)**

Elmiron

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. The requested agent will be used for the relief of bladder pain or discomfort associated with interstitial cystitis AND
2. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. The requested agent will be used for the relief of bladder pain or discomfort associated with interstitial cystitis AND
3. Patient has had clinical benefit with the requested agent (e.g., decreased bladder pain, decreased frequency or urgency of urination) AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be 6 months for initial, 12 months for renewal

**Other Criteria:**

**Prior Authorization Group Description:**

Emgality PA

**Drug Name(s)**

Emgality

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:
  - A. Patient has a diagnosis of migraine AND ALL of the following:
    - i. The requested agent is being used for migraine prophylaxis AND
    - ii. Patient has 4 migraine headaches or more per month AND
    - iii. ONE of the following:
      - a. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
      - b. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agent OR
      - c. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent AND
    - iv. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis OR
  - B. Patient has a diagnosis of episodic cluster headache AND BOTH of the following:
    - i. Patient has had at least 5 cluster headache attacks AND
    - ii. Patient has had at least two cluster periods lasting 7 days to one year and separated by pain-free remission periods of 3 months or more

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
  - A. ALL of the following:
    - i. Patient has a diagnosis of migraine AND
    - ii. The requested agent is being used for migraine prophylaxis AND
    - iii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis OR
  - B. Patient has a diagnosis of episodic cluster headache AND
3. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months



**Other Criteria:**

**Prior Authorization Group Description:**

Emsam PA

**Drug Name(s)**

Emsam

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. ONE of the following:
  - A. Patient has a diagnosis of major depressive disorder (MDD) OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. BOTH of the following:
    - i. ONE of the following:
      - a. BOTH of the following:
        - i. Patient has a diagnosis of major depressive disorder (MDD) AND
        - ii. ONE of the following:
          1. Patient has tried and had an inadequate response to at least two different oral antidepressants (e.g., SSRIs, SNRIs, mirtazapine, bupropion) OR
          2. Patient has an intolerance or hypersensitivity to at least two different oral antidepressants (e.g., SSRIs, SNRIs, mirtazapine, bupropion) OR
          3. Patient has an FDA labeled contraindication to at least two different oral antidepressants (e.g., SSRIs, SNRIs, mirtazapine, bupropion) OR
        - b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
      - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:

- A. Patient has a diagnosis of major depressive disorder (MDD) OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:
- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days
  - OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. BOTH of the following:
    - i. Patient has had clinical benefit with the requested agent AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Prior Authorization Group Description:**

Endari PA

**Drug Name(s)**

Endari

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of sickle cell disease AND
2. Patient is using the requested agent to reduce the acute complications of sickle cell disease AND
3. ONE of the following:
  - A. Patient has tried and had an inadequate response to maximally tolerated dose of hydroxyurea OR
  - B. Patient has an intolerance or hypersensitivity to hydroxyurea OR
  - C. Patient has an FDA labeled contraindication to hydroxyurea AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Epclusa PA

**Drug Name(s)**

Epclusa

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. ONE of the following:

A. Patient has a diagnosis of hepatitis C confirmed by serological markers OR

B. Patient is a hepatitis C virus (HCV) - uninfected solid organ transplant recipient AND BOTH of the following:

i. Patient received an HCV - viremic donor organ AND

ii. The requested agent is being used for prophylaxis AND

2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND

3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND

4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

**Other Criteria:**

**Prior Authorization Group Description:**

Epidiolex PA

**Drug Name(s)**

Epidiolex

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of seizures associated with ONE of the following:

- A. Lennox-Gastaut syndrome OR
- B. Dravet syndrome OR
- C. Tuberous sclerosis complex AND

2. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Erythropoietin Stimulating Agents PA – Aranesp

**Drug Name(s)**

Aranesp Albumin Free

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. The requested agent is being prescribed for ONE of the following:

A. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:

- i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND
- ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
- iii. The intent of chemotherapy is non-curative OR

B. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:

- i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND
- ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
- iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR

C. Anemia due to myelodysplastic syndrome AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR

D. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

2. Patient's transferrin saturation and serum ferritin have been evaluated

Drug is also subject to Part B versus Part D review.

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

6 months for chemotherapy, 12 months for other indications

**Other Criteria:**

**Prior Authorization Group Description:**

Erythropoietin Stimulating Agents PA - Epogen/Procrit

**Drug Name(s)**

Epogen

Procrit

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. The requested agent is being prescribed for ONE of the following:

- A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but 13 g/dL or less OR
- B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:
  - i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND
  - ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
  - iii. The intent of chemotherapy is non-curative OR
- C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:
  - i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND
  - ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
  - iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR
- D. Anemia due to myelodysplastic syndrome AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR
- E. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks)  
OR

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**



1 month for surgery (reduce transfusion possibility), 6 months for chemo, 12 months for other

**Other Criteria:**

F. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

2. Patient's transferrin saturation and serum ferritin have been evaluated

Drug is also subject to Part B versus Part D review.

**Prior Authorization Group Description:**

Erythropoietin Stimulating Agents PA – Retacrit

**Drug Name(s)**

Retacrit

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. The requested agent is being prescribed for ONE of the following:

A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but 13 g/dL or less OR

B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:

i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND

iii. The intent of chemotherapy is non-curative OR

C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:

i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks)

AND

ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND

iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR

D. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks)

OR

E. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

2. Patient's transferrin saturation and serum ferritin have been evaluated

Drug is also subject to Part B versus Part D review.

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

1 month for surgery (reduce transfusion possibility), 6 months for chemo, 12 months for other

**Other Criteria:**

**Prior Authorization Group Description:**

Fasenra PA

**Drug Name(s)**

Fasenra

Fasenra Pen

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of severe asthma with an eosinophilic phenotype AND
2. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
3. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Nucala) for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
5. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Nucala) for the requested indication AND
6. The requested dose is within the FDA labeled dosing for the requested indication

**Age Restriction:**

Patient is 12 years of age or over

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Fentanyl Oral PA - Fentanyl lozenge

**Drug Name(s)**

Fentanyl Citrate Oral Transmucosal

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. ONE of the following:

a. Patient has a documented diagnosis (i.e., medical records) of chronic cancer pain due to an active malignancy AND the following:

i. There is evidence of a claim that the patient is currently being treated with a long-acting opioid with the requested agent within the past 90 days OR

b. Patient has a diagnosis that is supported in CMS approved compendia for the requested agent AND

2. Patient will NOT be using the requested agent in combination with any other oral or nasal fentanyl agent

**Age Restriction:**

Patient is 16 years of age or over

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Fintepla PA

**Drug Name(s)**

Fintepla

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of seizures associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS) AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. An echocardiogram assessment will be obtained before and during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension AND
    - ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
    - iii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Gammagard/Gammaked/Gamunex-C PA

**Drug Name(s)**

Gammagard Liquid

Gammagard S/D Iga Less Than 1Mcg/ML

Gamunex-C

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ONE of the following:

1. Patient has ONE of the following diagnoses:

- A. Primary immunodeficiency [e.g., congenital agammaglobulinemia, common variable immunodeficiency (CVID), severe combined immunodeficiency, Wiskott-Aldrich Syndrome, X-linked agammaglobulinemia (XLA), humoral immunodeficiency, IgG subclass deficiency with or without IgA deficiency] OR
- B. B-cell chronic lymphocytic leukemia OR multiple myeloma AND ONE of the following:
  - i. Patient has a history of infections OR
  - ii. Patient has evidence of specific antibody deficiency OR
  - iii. Patient has hypogammaglobulinemia OR
- C. Idiopathic thrombocytopenia purpura AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone), or immunosuppressants (e.g., azathioprine)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
- D. Dermatomyositis AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
- E. Polymyositis AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
- F. Severe rheumatoid arthritis AND ONE of the following:
  - i. Patient has failed ONE conventional therapy [e.g., tumor necrosis factor antagonists (e.g., Humira), DMARDS (e.g., methotrexate)] OR
  - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

Criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 6 months for indications in Other Criteria, 12 months for all others

**Other Criteria:**

- G. Myasthenia gravis (MG) AND ONE of the following:
    - i. Patient is in acute myasthenic crisis OR
    - ii. Patient has severe refractory MG (e.g., major functional disability/weakness) AND ONE of the following:
      - a) Patient has failed ONE immunomodulator therapy (i.e., corticosteroid, pyridostigmine, or azathioprine) OR
      - b) Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE immunomodulator therapy OR
  - H. Multiple sclerosis (MS) AND BOTH of the following:
    - i. Patient has a diagnosis of relapsing remitting MS (RRMS) AND
    - ii. Patient has had an insufficient response, documented failure, or FDA labeled contraindication to TWO MS agents (e.g., Avonex, Betaseron, Copaxone, dimethyl fumarate, glatiramer, Glatopa, Plegridy, Vumerity) OR
  - I. Acquired von Willebrand hemophilia AND ONE of the following:
    - i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR
    - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
  - J. Refractory pemphigus vulgaris AND ONE of the following:
    - i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR
    - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR
2. ONE of the following:
- A. Patient has another FDA labeled indication for the requested agent OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome

Drug is also subject to Part B versus Part D review.



**Prior Authorization Group Description:**

Gattex PA

**Drug Name(s)**

Gattex

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of short bowel syndrome (SBS) AND
2. Patient is dependent on parenteral nutrition OR intravenous (PN/IV) fluids AND
3. ONE of the following:
  - A. Patient is aged 1 year to 17 years AND BOTH of the following:
    - i. A fecal occult blood test has been performed within 6 months prior to initiating treatment with the requested agent AND
    - ii. ONE of the following:
      - a. There was no unexplained blood in the stool OR
      - b. There was unexplained blood in the stool AND a colonoscopy or a sigmoidoscopy was performed OR
  - B. Patient is 18 years of age or over AND BOTH of the following:
    - i. Patient has had a colonoscopy within 6 months prior to initiating treatment with the requested agent AND
    - ii. If polyps were present at this colonoscopy, the polyps were removed AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of short bowel syndrome (SBS) AND
3. Patient has had a reduction from baseline in parenteral nutrition OR intravenous (PN/IV) fluids AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be 6 months for initial, 12 months for renewal

**Other Criteria:**

**Prior Authorization Group Description:**

Gaucher Enzyme Replacement PA – Cerezyme

**Drug Name(s)**

Cerezyme

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following:
  - A. A baseline glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
  - B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline measurements of hemoglobin, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
  - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
  - B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR
  - C. Hepatomegaly OR
  - D. Splenomegaly OR
  - E. Growth failure (i.e., growth velocity below the standard mean for age) OR
  - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvement and/or stabilization from baseline in at least ONE of the following:
  - A. Hemoglobin (Hb) level OR
  - B. Platelet count OR
  - C. Liver volume OR
  - D. Spleen volume OR
  - E. Growth velocity OR
  - F. Bone pain or disease

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Gaucher Enzyme Replacement PA – Eleyso

**Drug Name(s)**

Eleyso

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following:
  - A. A baseline glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
  - B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline measurements of hemoglobin, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
  - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
  - B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR
  - C. Hepatomegaly OR
  - D. Splenomegaly OR
  - E. Growth failure (i.e., growth velocity below the standard mean for age) OR
  - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvement and/or stabilization from baseline in at least ONE of the following:
  - A. Hemoglobin (Hb) level OR
  - B. Platelet count OR
  - C. Liver volume OR
  - D. Spleen volume OR
  - E. Growth velocity OR
  - F. Bone pain or disease

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Gaucher Enzyme Replacement PA – Vpriv

**Drug Name(s)**

Vpriv

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following:
  - A. A baseline glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
  - B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline measurements of hemoglobin, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
  - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
  - B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR
  - C. Hepatomegaly OR
  - D. Splenomegaly OR
  - E. Growth failure (i.e., growth velocity below the standard mean for age) OR
  - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvement and/or stabilization from baseline in at least ONE of the following:
  - A. Hemoglobin (Hb) level OR
  - B. Platelet count OR
  - C. Liver volume OR
  - D. Spleen volume OR
  - E. Growth velocity OR
  - F. Bone pain or disease

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Growth Hormone PA – Omnitrope

**Drug Name(s)**

Omnitrope

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

For Children – Criteria for initial approval require the following:

**1. ONE of the following:**

- a. Patient has a diagnosis of Turner Syndrome OR
- b. Patient has a diagnosis of Prader-Willi Syndrome OR
- c. Patient has a diagnosis of panhypopituitarism AND BOTH of the following:
  - i. Deficiencies in 3 or more pituitary axes AND
  - ii. Measured serum IGF-1 (insulin-like growth factor-1) levels are below the age and sex-appropriate reference range when off GH therapy OR
- d. Patient has a diagnosis of growth hormone deficiency (GHD) or short stature AND BOTH of the following:
  - i. Patient has ONE of the following:
    - a) Height more than 2 standard deviations (SD) below the mean for age and sex OR
    - b) Height more than 1.5 SD below the midparental height OR
    - c) A decrease in height SD of more than 0.5 over one year in children at least 2 years of age OR
    - d) Height velocity more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years AND
  - ii. Failure of at least 2 growth hormone (GH) stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) OR
- e. Patient has a diagnosis of small for gestational age (SGA) AND ALL of the following:
  - i. Patient is at least 2 years of age AND
  - ii. Documented birth weight and/or length that is 2 or more SD below the mean for gestational age AND
  - iii. At 24 months of age, the patient fails to manifest catch-up growth evidenced by a height that remains 2 or more SD below the mean for age and sex

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

For Children – Criteria for renewal approval require ALL of the following:



1. Patient has been previously approved for the preferred agent through the plan's Prior Authorization criteria AND
2. Patient has been diagnosed with ONE of the following:
  - a. Growth Hormone Deficiency, Short Stature OR
  - b. Panhypopituitarism OR
  - c. Prader-Willi Syndrome OR
  - d. Small for Gestational Age (SGA) OR
  - e. Turner Syndrome AND
3. ALL of the following:
  - a. Patient does NOT have closed epiphyses AND
  - b. Patient is being monitored for adverse effects of therapy with the requested agent AND
  - c. Patient's height has increased or height velocity has improved since initiation or last approval of the requested agent

For Adults – Criteria for initial approval require the following:

1. Patient has been diagnosed with ONE of the following:
  - a. Childhood growth hormone deficiency (GHD) with genetic or organic origin AND ONE of the following:
    - i. Low IGF-1 (insulin-like growth factor-1) level without GH replacement therapy OR
    - ii. Failure of at least one growth hormone (GH) stimulation test as an adult (e.g., peak GH value of 5 mcg/L or lower after stimulation, or otherwise considered abnormal as determined by testing lab) OR
  - b. Acquired adult GHD secondary to structural lesions or trauma AND ONE of the following:
    - i. Patient has a diagnosis of panhypopituitarism AND BOTH of the following:
      - a) Deficiencies in 3 or more pituitary axes AND
      - b) Low IGF-1 level without GH replacement therapy OR
    - ii. Patient has failed at least one growth hormone (GH) stimulation test as an adult OR
  - c. Idiopathic GHD (adult or childhood onset) AND the patient has failed at least two growth hormone (GH) stimulation tests as an adult

For Adults – Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the preferred agent through the plan's Prior Authorization criteria AND
2. Patient has been diagnosed with ONE of the following:
  - a. Childhood growth hormone deficiency (GHD) with genetic or organic origin OR
  - b. Acquired adult GHD secondary to structural lesions or trauma OR
  - c. Idiopathic GHD (adult or childhood onset) AND
3. Patient is being monitored for adverse effects of therapy with the requested agent AND
4. Patient's IGF-1 level has been evaluated to confirm the appropriateness of the current dose AND
5. Patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life)

**Prior Authorization Group Description:**

HAE PA – Cinryze

**Drug Name(s)**

Cinryze

**Indications:**

All FDA-Approved Indications, Some Medically-Accepted Indications.

**Off-Label Uses:**

Acute HAE attacks

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed via two confirmatory tests of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
  - a. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type I)]: decreased quantities of C4 and C1-INH (antigenic and functional level) OR
  - b. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type II)]: decreased quantities of C4 and C1-INH function (C1-INH protein level may be normal) OR
  - c. Hereditary angioedema (HAE) with normal C1INH [HAE-nI-C1INH (Type III)]: Normal levels of C4 and C1-INH [antigenic and functional level (at baseline and during an attack)] AND ONE of the following:
    - i. BOTH of the following:
      1. Family history of angioedema AND
      2. ALL other causes of angioedema have been ruled out OR
    - ii. Patient demonstrates a Factor XII mutation, angiotensin-converting enzyme 1 (ACE1) mutation, plasminogen (PLG) mutation, kininogen1 mutation, heparan sulfate 3-O-sulfotransferase 6 gene mutation, or myoferlin gene mutation that is associated with the disease AND
2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. ONE of the following:
  - a. The requested agent will be used to treat acute HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks OR
  - b. The requested agent will be used for prophylaxis against HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria

AND

2. Patient has a diagnosis of hereditary angioedema (HAE) AND ONE of the following:

a. The requested agent will be used to treat acute HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks OR

b. The requested agent will be used for prophylaxis against HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks AND

3. Patient has had a decrease in the frequency or severity of acute attacks or has had stabilization of disease from use of the requested agent

**Prior Authorization Group Description:**

HAE PA – Haegarda

**Drug Name(s)**

Haegarda

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed via two confirmatory tests of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
  - a. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type I)]: decreased quantities of C4 and C1-INH (antigenic and functional level) OR
  - b. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type II)]: decreased quantities of C4 and C1-INH function (C1-INH protein level may be normal) OR
  - c. Hereditary angioedema (HAE) with normal C1INH [HAE-ni-C1INH (Type III)]: Normal levels of C4 and C1-INH [antigenic and functional level (at baseline and during an attack)] AND ONE of the following:
    - i. BOTH of the following:
      1. Family history of angioedema AND
      2. ALL other causes of angioedema have been ruled out OR
    - ii. Patient demonstrates a Factor XII mutation, angiotensin-converting enzyme 1 (ACE1) mutation, plasminogen (PLG) mutation, kininogen1 mutation, heparan sulfate 3-O-sulfotransferase 6 gene mutation, or myoferlin gene mutation that is associated with the disease AND
2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. The requested agent will be used for prophylaxis against HAE attacks AND
4. Patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of hereditary angioedema (HAE) AND
3. The requested agent is being used for prophylaxis against HAE attacks AND
4. Patient has had a decrease in the frequency or severity of acute attacks or has had stabilization of disease from use of the requested agent AND

5. Patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks

**Prior Authorization Group Description:**

HAE PA – Icatibant

**Drug Name(s)**

Icatibant Acetate

Sajazir

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed via two confirmatory tests of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
  - a. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type I)]: decreased quantities of C4 and C1-INH (antigenic and functional level) OR
  - b. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type II)]: decreased quantities of C4 and C1-INH function (C1-INH protein level may be normal) OR
  - c. Hereditary angioedema (HAE) with normal C1INH [HAE-nI-C1INH (Type III)]: Normal levels of C4 and C1-INH [antigenic and functional level (at baseline and during an attack)] AND ONE of the following:
    - i. BOTH of the following:
      1. Family history of angioedema AND
      2. ALL other causes of angioedema have been ruled out OR
    - ii. Patient demonstrates a Factor XII mutation, angiotensin-converting enzyme (ACE) mutation, plasminogen (PLG) mutation, kininogen1 mutation, heparan sulfate 3-O-sulfotransferase 6 gene mutation, or myoferlin gene mutation that is associated with the disease AND
2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. The requested agent will be used to treat acute HAE attacks AND
4. Patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of hereditary angioedema (HAE) AND
3. The requested agent will be used to treat acute HAE attacks AND

4. Patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks AND
5. Patient has had a decrease in the frequency or severity of acute attacks or stabilization of disease from use of the requested agent

**Prior Authorization Group Description:**

Harvoni PA

**Drug Name(s)**

Harvoni

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND
2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND
3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

**Other Criteria:**



**Prior Authorization Group Description:**

High Risk Medication PA - All Starts

**Drug Name(s)**

Clemastine Fumarate

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

PA does NOT apply to patients less than 65 years of age.

Criteria for approval require ALL of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested high-risk medication AND
2. Prescriber has indicated that the benefits of the requested high-risk medication outweigh the risks for the patient AND
3. Prescriber has indicated that the risks and potential side effects of the requested high-risk medication have been discussed with the patient

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Ilaris PA

**Drug Name(s)**

Ilaris

**Indications:**

All FDA-Approved Indications, Some Medically-Accepted Indications.

**Off-Label Uses:**

Acute gouty arthritis

**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of:

## 1. ONE of the following:

- A. Patient (pt) has been diagnosed with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) OR
- B. Pt has been diagnosed with Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) OR
- C. Pt has been diagnosed with Familial Mediterranean Fever (FMF) AND ONE of the following:
  - i. Pt has tried and had an inadequate response to colchicine OR
  - ii. Pt has an intolerance or hypersensitivity to colchicine OR
  - iii. Pt has an FDA labeled contraindication to colchicine OR
- D. Pt has been diagnosed with Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) OR
- E. Pt has been diagnosed with active Systemic Juvenile Idiopathic Arthritis (SJIA) AND BOTH of the following:
  - i. Pt has documented active systemic features (e.g., ongoing fever, evanescent erythematous rash, generalized lymphadenopathy, 1 or more joints with active arthritis, hepatomegaly, splenomegaly, serositis) AND
  - ii. ONE of the following:
    - a. Pt has tried and had an inadequate response to at least ONE prerequisite agent (e.g., glucocorticosteroids, prescription oral NSAIDs, methotrexate, leflunomide) OR
    - b. Pt has an intolerance or hypersensitivity to at least ONE prerequisite agent OR
    - c. Pt has an FDA labeled contraindication to at least ONE prerequisite agent OR
- F. Pt has a diagnosis of adult onset Still's disease OR
- G. Pt has been diagnosed with acute gouty arthritis AND ONE of the following:
  - i. Pt has tried and had an inadequate response to at least TWO conventional first-line agents (e.g., prescription oral NSAIDs, colchicine, systemic corticosteroids) OR
  - ii. Pt has an intolerance or hypersensitivity to at least TWO conventional first-line agents OR
  - iii. Pt has an FDA labeled contraindication to at least TWO conventional first-line agents AND

## 2. Pt will NOT be using the requested agent in combination with another biologic agent

**Age Restriction:**

For diagnosis of CAPS including FCAS or MWS, patient is 4 years of age or over

For diagnosis of SJIA, patient is 2 years of age or over

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Injectable Oncology PA

**Drug Name(s)**

Abraxane  
Adcetris  
Aliqopa  
Alymsys  
Avastin  
Beleodaq  
Besponsa  
Blenrep  
Blincyto  
Bortezomib  
Cycramza  
Danyelza  
Darzalex  
Darzalex Faspro  
Doxorubicin Hydrochloride Liposomal  
Empliciti  
Enhertu  
Erbix  
Foloty  
Fulvestrant  
Gazyva  
Halaven  
Herceptin  
Herceptin Hylecta  
Herzuma  
Jevtana  
Kadcyla  
Kanjinti  
Kyprolis  
Lumoxiti  
Margenza  
Monjuvi  
Mvasi  
Mylotarg

Nelarabine  
Ogivri  
Onivyde  
Ontruzant  
Padcev  
Pemetrexed  
Perjeta  
Phesgo  
Polivy  
Portrazza  
Poteligeo  
Romidepsin  
Rybrevant  
Sarclisa  
Synribo  
Trazimera  
Trodely  
Unituxin  
Vectibix  
Vegzelma  
Vyxeos  
Yondelis  
Zaltrap  
Zepzelca  
Zirabev  
Zynlonta

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:

- i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
- ii. ONE of the following:
  - a. The requested agent is FDA labeled or supported by CMS approved compendia as first-line therapy for the requested indication OR
  - b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested indication OR
  - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
  - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
- iii. Patient does NOT have any FDA labeled contraindications to the requested agent AND
- iv. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

May also be subject to Part B versus Part D review.

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Iron Chelating Agents PA – Exjade

**Drug Name(s)**

Deferasirox (Exjade)

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. ONE of the following:

A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND ONE of the following:

- i. A liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR
- ii. A serum ferritin greater than 300 mcg/L OR
- iii. MRI confirmation of iron deposition OR

B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND

2. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:

A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome OR

B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND

3. Patient has had clinical benefit with the requested agent AND

4. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent for the requested indication

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Iron Chelating Agents PA – Jadenu

**Drug Name(s)**

Deferasirox (Jadenu)

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

## 1. ONE of the following:

A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND ONE of the following:

- i. A liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR
- ii. A serum ferritin greater than 300 mcg/L OR
- iii. MRI confirmation of iron deposition OR

B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND

## 2. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication

Criteria for renewal approval require ALL of the following:

## 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

## 2. ONE of the following:

A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome OR

B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND

## 3. Patient has had clinical benefit with the requested agent AND

## 4. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent for the requested indication

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Kalydeco PA

**Drug Name(s)**

Kalydeco

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cystic fibrosis AND
2. ONE of the following:
  - A. Patient has ONE of the CFTR gene mutations or a mutation in the CFTR gene that is responsive based on in vitro data, as indicated in the FDA label, confirmed by genetic testing OR
  - B. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND
3. Patient is NOT homozygous for the F508del mutation AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cystic fibrosis AND
3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Kerendia PA

**Drug Name(s)**

Kerendia

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Korlym PA

**Drug Name(s)**

Korlym

Mifepristone

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of Cushing's syndrome AND
2. ONE of the following:
  - A. Patient has type 2 diabetes mellitus OR
  - B. Patient has glucose intolerance as defined by a 2-hour glucose tolerance test plasma glucose value of 140-199 mg/dL AND
3. ONE of the following:
  - A. Patient has failed surgical resection OR
  - B. Patient is NOT a candidate for surgical resection

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Cushing's syndrome AND
3. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Leuprolide PA

**Drug Name(s)**

Eligard

Leuprolide Acetate

Lupron Depot (1-Month)

Lupron Depot (3-Month)

Lupron Depot (4-Month)

Lupron Depot (6-Month)

Lupron Depot-Ped (1-Month)

Lupron Depot-Ped (3-Month)

Lupron Depot-Ped (6-Month)

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. BOTH of the following:
    - i. Patient is NOT currently being treated with the requested agent AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND
3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Lidocaine Topical PA - Lidocaine Gel/Jelly

**Drug Name(s)**

Glydo

Lidocaine Hcl Gel

Lidocaine Hcl Jelly

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. The requested agent will be used for ONE of the following:

- A. Surface anesthesia and lubrication for urethral procedure OR
- B. Topical treatment for pain of urethritis OR
- C. Surface anesthesia and lubrication for endotracheal intubation (oral and nasal) OR
- D. Another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Lidocaine Topical PA - Lidocaine Ointment

**Drug Name(s)**

Lidocaine Ointment

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. The requested agent will be used for ONE of the following:

- A. Anesthesia of accessible mucous membranes of the oropharynx OR
- B. Anesthetic lubricant for intubation OR
- C. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR
- D. Another indication that is supported in CMS approved compendia for the requested agent

AND ONE of the following:

- i. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR
- ii. Patient has an intolerance or hypersensitivity to a conventional therapy OR
- iii. Patient has an FDA labeled contraindication to a conventional therapy

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Lidocaine Topical PA - Lidocaine Patch

**Drug Name(s)**

Lidocan

Lidocan III

Lidocaine Patch

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has ONE of the following diagnoses:

- A. Pain associated with postherpetic neuralgia (PHN) OR
  - B. Pain associated with diabetic neuropathy OR
  - C. Neuropathic pain associated with cancer, or cancer treatment OR
  - D. Another diagnosis that is supported in CMS approved compendia for the requested agent
- AND

2. ONE of the following:

- A. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR
- B. Patient has an intolerance or hypersensitivity to a conventional therapy OR
- C. Patient has an FDA labeled contraindication to a conventional therapy

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Lidocaine Topical PA - Lidocaine Solution

**Drug Name(s)**

Lidocaine Solution

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. The requested agent will be used for ONE of the following:
  - A. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities OR
  - B. Topical anesthesia of accessible mucous membranes of proximal portions of the digestive tract OR
  - C. Another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Lidocaine Topical PA - Lidocaine/prilocaine Cream

**Drug Name(s)**

Lidocaine/Prilocaine

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. The requested agent will be used for ONE of the following:
  - A. Local analgesia on normal intact skin OR
  - B. Topical anesthetic for dermal procedures OR
  - C. Adjunctive anesthesia prior to local anesthetic infiltration in adult male genital skin OR
  - D. Anesthesia for minor procedures on female external genitalia OR
  - E. Another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Linezolid PA

**Drug Name(s)**

Linezolid

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND ONE of the following:
  - a. The requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient OR
  - b. Patient has a documented infection due to vancomycin-resistant *Enterococcus faecium* OR
  - c. Patient has a diagnosis of pneumonia caused by *Staphylococcus aureus* or *Streptococcus pneumoniae* AND ONE of the following:
    - i. Patient has a documented infection that is resistant to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole, OR that is resistant to vancomycin OR
    - ii. Patient has an intolerance or hypersensitivity to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR
    - iii. Patient has an FDA labeled contraindication to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR
    - iv. Patient has an intolerance or hypersensitivity to vancomycin OR
    - v. Patient has an FDA labeled contraindication to vancomycin OR
  - d. Patient has a documented skin and skin structure infection, including diabetic foot infections, caused by *Staphylococcus aureus*, *Streptococcus pyogenes*, or *Streptococcus agalactiae* AND ONE of the following:
    - i. Patient has a documented infection that is resistant to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole, OR that is resistant to vancomycin at the site of infection OR
    - ii. Patient has an intolerance or hypersensitivity to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR
    - iii. Patient has an FDA labeled contraindication to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR

Criteria continues: see Other Criteria

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 3 months

**Other Criteria:**

- iv. Patient has an intolerance or hypersensitivity to vancomycin OR

- v. Patient has an FDA labeled contraindication to vancomycin AND
- 2. Patient will NOT be using the requested agent in combination with Sivextro (tedizolid) for the same infection AND
- 3. The requested dose is within FDA labeled dosing for the requested indication

**Prior Authorization Group Description:**

Memantine ER PA

**Drug Name(s)**

Memantine Hydrochloride Er

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

PA does NOT apply to patients greater than or equal to 30 years of age

Criteria for approval require the following:

1. Patient is younger than 30 years of age AND ONE of the following:
  - A. Patient has a diagnosis of moderate to severe dementia of the Alzheimer's type OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Memantine PA

**Drug Name(s)**

Memantine Hcl Titration Pak

Memantine Hydrochloride

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

PA does NOT apply to patients greater than or equal to 30 years of age

Criteria for approval require the following:

1. Patient is younger than 30 years of age AND ONE of the following:
  - A. Patient has a diagnosis of moderate to severe dementia of the Alzheimer's type OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Migranal PA

**Drug Name(s)**

Dihydroergotamine Mesylate Spray

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. The requested agent will be used for the treatment of acute migraine with or without aura AND
2. ONE of the following:
  - A. Patient has tried and had an inadequate response to TWO triptan agents with differing active ingredients (e.g., sumatriptan, rizatriptan) OR
  - B. Patient has an intolerance or hypersensitivity to TWO triptan agents with differing active ingredients OR
  - C. Patient has an FDA labeled contraindication to TWO triptan agents with differing active ingredients AND
3. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, acute CGRP)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. The requested agent will be used for the treatment of acute migraine with or without aura AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, acute CGRP)

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Modafinil PA

**Drug Name(s)**

Modafinil

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another target agent (i.e., armodafinil)

**Age Restriction:**

Patient is 17 years of age or over

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

MS PA – Avonex

**Drug Name(s)**

Avonex

Avonex Pen

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

MS PA – Betaseron

**Drug Name(s)**

Betaseron

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

MS PA - Dimethyl Fumarate

**Drug Name(s)**

Dimethyl Fumarate

Dimethyl Fumarate Starterpack

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

MS PA – Glatiramer

**Drug Name(s)**

Copaxone

Glatiramer Acetate

Glatopa

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

MS PA – Plegridy

**Drug Name(s)**

Plegridy

Plegridy Starter Pack

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

MS PA – Rebif

**Drug Name(s)**

Rebif

Rebif Rebidose

Rebif Titration Pack

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

MS PA – Tysabri

**Drug Name(s)**

Tysabri

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. Patient has ONE of the following diagnoses:
    - i. Relapsing form of Multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease AND ONE of the following:
      - a. Prescriber states the patient has highly active disease OR
      - b. ONE of the following:
        1. Patient has tried and had an inadequate response to TWO preferred agents (Avonex, Betaseron, Copaxone, dimethyl fumarate, glatiramer, Glatopa, Plegridy, Vumerity) OR
        2. Patient has an intolerance or hypersensitivity to TWO preferred agents (Avonex, Betaseron, Copaxone, dimethyl fumarate, glatiramer, Glatopa, Plegridy, Vumerity) OR
        3. Patient has an FDA labeled contraindication to TWO preferred agents (Avonex, Betaseron, Copaxone, dimethyl fumarate, glatiramer, Glatopa, Plegridy, Vumerity) OR

Initial criteria continues: see Other Criteria

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months for MS, for CD 16 weeks for initial and 12 months renewal

**Other Criteria:**

- ii. Moderately to severely active Crohn's disease (CD) AND BOTH of the following:
  - a. ONE of the following:
    1. Patient has tried and had an inadequate response to ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate) OR

2. Patient has an intolerance or hypersensitivity to ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate) OR

3. Patient has an FDA labeled contraindication to ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate) AND

b. ONE of the following:

1. Patient has tried and had an inadequate response to ONE preferred biologic agent (Humira or Stelara) for the treatment of CD OR

2. Patient has an intolerance or hypersensitivity to ONE preferred biologic agent (Humira or Stelara) OR

3. Patient has an FDA labeled contraindication to ONE preferred biologic agent (Humira or Stelara) AND

3. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication for the requested agent AND

3. Patient has had clinical benefit with the requested agent AND

4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Prior Authorization Group Description:**

MS PA – Vumerity

**Drug Name(s)**

Vumerity

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Myalept PA

**Drug Name(s)**

Myalept

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has leptin deficiency associated with a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND
2. Prescriber has provided the patient's baseline levels for HbA1C, triglycerides, and fasting insulin, measured prior to beginning therapy with the requested agent AND
3. Patient also has at least ONE of the complications related to lipodystrophy: diabetes mellitus, hypertriglyceridemia (200 mg/dL or higher), and/or high fasting insulin (30 $\mu$ U/mL or higher) AND
4. Patient has tried and had an inadequate response to maximum tolerable dosing of a conventional agent for the additional diagnosis AND
5. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has leptin deficiency associated with a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND
3. Patient has had improvement or stabilization with the requested agent as indicated by change from baseline level of at least ONE of the following:
  - A. HbA1C
  - B. Triglycerides
  - C. Fasting insulin AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Conventional agent examples include:

Hypertriglyceridemia: statins, fenofibrates, Omega-3-Acid Ethyl Esters (generic Lovaza)

Diabetes/high fasting insulin: insulin, sulfonylurea/sulfonylurea combination, metformin/metformin combination

**Prior Authorization Group Description:**

Natpara PA

**Drug Name(s)**

Natpara

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

Increased baseline risk for osteosarcoma (e.g., Paget's disease of bone, unexplained elevations of alkaline phosphatase, hereditary disorders predisposing to osteosarcoma, history of external beam or implant radiation therapy involving the skeleton, pediatric and young adult patients with open epiphyses)

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of hypocalcemia associated with hypoparathyroidism AND
2. Patient does NOT have a baseline vitamin D level below the testing laboratory's lower limit of normal AND
3. Patient's baseline serum calcium level (albumin-corrected) is above 7.5 mg/dL AND
4. Patient will NOT be using the requested agent in combination with alendronate for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of hypocalcemia associated with hypoparathyroidism AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with alendronate for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Nuedexta PA

**Drug Name(s)**

Nuedexta

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. ONE of the following:

A. Patient has a diagnosis of pseudobulbar affect OR

B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

2. Patient will NOT be using the requested agent in combination with a monoamine oxidase inhibitor (MAOI) [e.g., Marplan (isocarboxazid), Nardil (phenelzine), and Parnate (tranylcypromine)]

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Nuplazid PA

**Drug Name(s)**

Nuplazid

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Nurtec PA

**Drug Name(s)**

Nurtec

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of migraine AND
2. ONE of the following:
  - A. The requested agent is being used for the treatment of acute migraine with or without aura AND BOTH of the following:
    - i. ONE of the following:
      - a. Patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent OR
      - b. Patient has an intolerance, or hypersensitivity to a triptan OR
      - c. Patient has an FDA labeled contraindication to a triptan AND
    - ii. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP) OR
  - B. The requested agent is being used for migraine prophylaxis AND ALL of the following:
    - i. Patient has 4 migraine headaches or more per month AND
    - ii. ONE of the following:
      - a. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
      - b. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agent OR
      - c. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent AND
    - iii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 Months

**Other Criteria:**

Criteria for renewal require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. ONE of the following:

- A. The requested agent is being used for the treatment of acute migraine with or without aura AND BOTH of the following:
  - i. Patient has had clinical benefit with the requested agent AND
  - ii. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP) OR
- B. The requested agent is being used for migraine prophylaxis AND BOTH of the following:
  - i. Patient has had clinical benefit with the requested agent AND
  - ii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

**Prior Authorization Group Description:**

Ocaliva PA

**Drug Name(s)**

Ocaliva

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of primary biliary cholangitis (PBC) confirmed by at least TWO of the following:
  - A. There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation
  - B. Presence of antimitochondrial antibody (AMA): a titer greater than 1:80 OR a level that is above the testing laboratory's upper limit of the normal range
  - C. If the AMA is negative or present only in low titer (less than or equal to 1:80), presence of other PBC-specific autoantibodies, including sp100 or gp210
  - D. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND
2. ONE of the following:
  - A. Patient does NOT have cirrhosis OR
  - B. Patient has compensated cirrhosis with NO evidence of portal hypertension AND
3. Prescriber has measured the patient's alkaline phosphatase (ALP) level AND total bilirubin level AND
4. ONE of the following:
  - A. BOTH of the following:
    - i. Patient has tried and had an inadequate response to ursodiol AND
    - ii. The requested agent will be used in combination with ursodiol OR
  - B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of primary biliary cholangitis (PBC) AND
3. ONE of the following:
  - A. Patient does NOT have cirrhosis OR
  - B. Patient has compensated cirrhosis with NO evidence of portal hypertension AND
4. ONE of the following:
  - A. The requested agent will be used in combination with ursodiol OR
  - B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol AND

5. Patient has had improvements or stabilization with the requested agent as indicated by BOTH of the following:

- A. Decrease in alkaline phosphatase (ALP) level from baseline AND
- B. Total bilirubin is less than or equal to the upper limit of normal (ULN)



**Prior Authorization Group Description:**

Ofev PA

**Drug Name(s)**

Ofev

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:
  - A. BOTH of the following:
    - i. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
    - ii. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD) OR
  - B. BOTH of the following:
    - i. Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND
    - ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans OR
  - C. BOTH of the following:
    - i. Patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND
    - ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of ONE of the following:
  - A. Idiopathic pulmonary fibrosis (IPF) OR
  - B. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) OR
  - C. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND
3. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Bavencio

**Drug Name(s)**

Bavencio

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
    - ii. ONE of the following:
      - a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR
      - b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR
      - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
      - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
    - iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Imfinzi

**Drug Name(s)**

Imfinzi

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR

b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR

c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Jemperli

**Drug Name(s)**

Jemperli

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
    - ii. ONE of the following:
      - a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR
      - b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR
      - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
      - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
    - iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Keytruda

**Drug Name(s)**

Keytruda

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR

b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR

c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Libtayo

**Drug Name(s)**

Libtayo

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR

b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR

c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Opdivo

**Drug Name(s)**

Opdivo

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
    - ii. ONE of the following:
      - a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR
      - b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR
      - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
      - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
    - iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Tecentriq

**Drug Name(s)**

Tecentriq

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
    - ii. ONE of the following:
      - a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR
      - b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR
      - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
      - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
    - iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Oncology Immunotherapy PA – Yervoy

**Drug Name(s)**

Yervoy

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
    - ii. ONE of the following:
      - a. The requested agent is FDA labeled or supported in CMS approved compendia as first-line therapy for the requested indication OR
      - b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested agent OR
      - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
      - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
    - iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Opioids ER PA - Fentanyl Patch

**Drug Name(s)**

Fentanyl

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
- B. Patient has a diagnosis of pain due to sickle cell disease OR
- C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
  - i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - iii. ALL of the following:
    - a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
      - 1. Diagnosis AND
      - 2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND
    - b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
    - c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
    - d. ONE of the following:
      - 1. Patient's medication history includes use of an immediate-acting opioid OR
      - 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR
      - 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND
    - e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND
    - f. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Opioids ER PA – Hydrocodone

**Drug Name(s)**

Hydrocodone Bitartrate Er

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
- B. Patient has a diagnosis of pain due to sickle cell disease OR
- C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
  - i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - iii. ALL of the following:
    - a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
      - 1. Diagnosis AND
      - 2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND
    - b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
    - c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
    - d. ONE of the following:
      - 1. Patient's medication history includes use of an immediate-acting opioid OR
      - 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR
      - 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND
    - e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND
    - f. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Opioids ER PA – Tapentadol

**Drug Name(s)**

Nucynta Er

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
- B. Patient has a diagnosis of pain due to sickle cell disease OR
- C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
  - i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - iii. ALL of the following:
    - a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
      - 1. Diagnosis AND
      - 2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND
    - b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
    - c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
    - d. ONE of the following:
      - 1. Patient's medication history includes use of an immediate-acting opioid OR
      - 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR
      - 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND
    - e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND
    - f. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Opioids ER PA – Tramadol

**Drug Name(s)**

Tramadol Hcl Er

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
- B. Patient has a diagnosis of pain due to sickle cell disease OR
- C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
  - i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - iii. ALL of the following:
    - a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
      - 1. Diagnosis AND
      - 2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND
    - b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
    - c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
    - d. ONE of the following:
      - 1. Patient's medication history includes use of an immediate-acting opioid OR
      - 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR
      - 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND
    - e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND
    - f. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months



**Other Criteria:**

**Prior Authorization Group Description:**

Oral Immunotherapy Agents PA – Oralair

**Drug Name(s)**

Oralair

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of allergic rhinitis, with or without conjunctivitis AND
2. Patient's diagnosis is confirmed with ONE of the following:
  - A. Positive skin test to ONE of the pollen extracts included in the requested agent OR
  - B. IgE specific antibodies to ONE of the extracts included in the requested agent: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass AND
3. ONE of the following:
  - A. Patient has tried and had an inadequate response to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
  - B. Patient has an intolerance or hypersensitivity to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
  - C. Patient has an FDA labeled contraindication to TWO standard allergy medications, one of which was an intranasal corticosteroid AND
4. Patient will NOT be using the requested agent in combination with a subcutaneous injectable immunotherapy agent AND
5. The requested agent will be started, or has already been started, 3 to 4 months before the expected onset of the applicable pollen season AND
6. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
7. Patient has been prescribed epinephrine auto-injector for at home emergency use

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Standard allergy medications:

Oral antihistamines, oral corticosteroids, intranasal corticosteroids, intranasal antihistamines, or leukotriene inhibitors

**Prior Authorization Group Description:**

Orkambi PA

**Drug Name(s)**

Orkambi

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cystic fibrosis AND
2. ONE of the following:
  - A. Patient has the presence of the F508del mutation on both alleles (homozygous) of the CFTR gene confirmed by genetic testing OR
  - B. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND
3. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cystic fibrosis AND
3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Otezla PA

**Drug Name(s)**

Otezla

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. BOTH of the following:
  - A. Patient has ONE of the following diagnoses:
    - i. Plaque psoriasis OR
    - ii. Active psoriatic arthritis AND
  - B. ONE of the following:
    - i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
    - ii. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
    - iii. Patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication OR
    - iv. Patient has tried and had an inadequate response to at least ONE conventional prerequisite agent for the requested indication OR
    - v. Patient has an intolerance or hypersensitivity to at least ONE conventional prerequisite agent for the requested indication OR
    - vi. Patient has an FDA labeled contraindication to at least ONE conventional prerequisite agent for the requested indication OR
2. Patient has a diagnosis of oral ulcers associated with Behcet's disease (BD)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of plaque psoriasis, active psoriatic arthritis, or oral ulcers associated with Behcet's disease (BD) AND
3. Patient has had clinical benefit with the requested agent (slowing of disease progression or decrease in symptom severity and/or frequency)

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Formulary conventional agent required for diagnoses of plaque psoriasis or active psoriatic arthritis

Formulary conventional agents for plaque psoriasis include cyclosporine, methotrexate, tazarotene, topical calcitriol, or topical corticosteroids

Formulary conventional agents for active psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine

NO prerequisites are required for a diagnosis of oral ulcers associated with Behcet's disease (BD)

**Prior Authorization Group Description:**

Ozempic PA

**Drug Name(s)**

Ozempic

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

Requested agent will be used for weight loss alone

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of type 2 diabetes mellitus AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. BOTH of the following:
    - i. ONE of the following:
      1. Patient's medication history includes use of an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR
      2. Patient had an ineffective treatment response to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      3. Patient has an intolerance or hypersensitivity to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      4. Patient has an FDA labeled contraindication to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      5. BOTH of the following:
        - a. Patient has a diagnosis of established cardiovascular disease [e.g., myocardial infarction, stroke, any revascularization procedure, transient ischemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease] AND
        - b. The requested agent will be used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Palynziq PA

**Drug Name(s)**

Palynziq

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of phenylketonuria (PKU) AND
2. Patient has a baseline blood Phe level greater than 600 micromol/L (10 mg/dL) AND
3. Patient will NOT be using the requested agent in combination with sapropterin for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of phenylketonuria (PKU) AND
3. ONE of the following:
  - a. Patient's blood Phe levels are being maintained within the acceptable range OR
  - b. Patient has had a decrease in blood Phe level from baseline AND
4. Patient will NOT be using the requested agent in combination with sapropterin for the requested indication AND
5. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic or genetic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Initial approval will be for 9 months, renewal approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Panretin PA

**Drug Name(s)**

Panretin

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. ONE of the following:

- A. Patient has a diagnosis of cutaneous lesions associated with AIDS-related Kaposi's sarcoma (KS) OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

- A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- B. Prescriber states the patient is currently being treated with the requested agent OR
- C. ALL of the following:
  - i. ONE of the following:
    - 1. BOTH of the following:
      - a. Patient has a diagnosis of cutaneous lesions associated with AIDS-related Kaposi's sarcoma (KS) AND
      - b. Patient does NOT require systemic anti-Kaposi's sarcoma therapy OR
    - 2. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
  - ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, dermatologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
  - iii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Pegylated Interferon PA

**Drug Name(s)**

Pegasys

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of chronic hepatitis B AND BOTH of the following:

- i. The chronic hepatitis B infection has been confirmed by serological markers AND
- ii. Patient has NOT been administered the requested agent for more than 48 weeks for the treatment of chronic hepatitis B OR

B. BOTH of the following:

- i. Patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND
- ii. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months for all other diagnoses. For hep B, hep C see Other Criteria

**Other Criteria:**

No prior peginterferon alfa use, approve 48 weeks for hepatitis B infection. Prior peginterferon alfa use, approve remainder of 48 weeks of total therapy for hepatitis B infection

Duration of therapy for hepatitis C: Based on FDA approved labeling or AASLD/IDSA guideline supported

**Prior Authorization Group Description:**

Pirfenidone PA

**Drug Name(s)**

Pirfenidone

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
2. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
3. Patient has had clinical benefit with the requested agent

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Posaconazole PA

**Drug Name(s)**

Noxafil Pak

Posaconazole Inj

Posaconazole Dr

Posaconazole Susp

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following:

- i. Patient has tried and had an inadequate response to fluconazole or an alternative antifungal agent OR
- ii. Patient has an intolerance or hypersensitivity to fluconazole or an alternative antifungal agent OR
- iii. Patient has an FDA labeled contraindication to fluconazole or an alternative antifungal agent OR

B. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida AND patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR

C. Patient has a diagnosis of invasive Aspergillus AND ONE of the following:

- i. Patient has tried and had an inadequate response to an alternative antifungal agent OR
- ii. Patient has an intolerance or hypersensitivity to an alternative antifungal agent OR
- iii. Patient has an FDA labeled contraindication to an alternative antifungal agent OR

D. Patient has another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

One month for oropharyngeal candidiasis, 6 months for all other indications

**Other Criteria:**

Criteria for renewal approval require BOTH of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:

A. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida and patient continues to be severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR

B. Patient has a diagnosis of invasive Aspergillus AND patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR

C. BOTH of the following:

i. Patient has a diagnosis of oropharyngeal candidiasis AND

ii. Patient has had clinical benefit with the requested agent OR

D. BOTH of the following:

i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Prolia PA

**Drug Name(s)**

Prolia

**Indications:**

All FDA-Approved Indications, Some Medically-Accepted Indications.

**Off-Label Uses:**

Osteopenia (osteoporosis prophylaxis)

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of:

1. ONE of:

A. Patient's (pt) sex is male or the pt is postmenopausal with a diagnosis of osteoporosis AND BOTH of:

i. Pt's diagnosis was confirmed by ONE of:

1. A fragility fracture in the hip or spine OR
2. A T-score of -2.5 or lower OR
3. A T-score of -1.0 to -2.5 AND ONE of:
  - a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
  - b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR
  - c. A FRAX 10-year probability of hip fracture of 3% or greater AND

ii. ONE of:

1. Pt is at a very high fracture risk as defined by ONE of:
  - a. Pt had a recent fracture (within the past 12 months) OR
  - b. Pt had fractures while on FDA approved osteoporosis therapy OR
  - c. Pt has had multiple fractures OR
  - d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
  - e. Pt has a very low T-score (less than -3.0) OR
  - f. Pt is at high risk for falls or has a history of injurious falls OR
  - g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR
2. ONE of:
  - a. Pt's medication history includes use of a bisphosphonate OR
  - b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR

B. Pt is requesting the agent for osteopenia (osteoporosis prophylaxis) AND ALL of:

i. ONE of:

1. Pt's sex is male and the pt is 50 years of age or over OR
2. Pt is postmenopausal AND

- ii. Pt has a T-score between -1.0 to -2.50 AND
- iii. ONE of:
  - a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
  - b. 10-year probability of a hip fracture 3% and greater per FRAX OR
  - c. 10-year probability of a major OP-related fracture 20% and greater per FRAX AND
- iv. ONE of:
  - a. Pt's medication history includes use of a bisphosphonate OR

Criteria continues: See Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

- b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR
- C. Pt's sex is a female with a diagnosis of breast cancer who is receiving aromatase inhibitor therapy AND ONE of:
  - i. Pt's medication history includes use of a bisphosphonate OR
  - ii. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR
- D. Pt's sex is male with a diagnosis of prostate cancer receiving androgen deprivation therapy (ADT) AND ONE of:
  - i. Pt's medication history includes use of a bisphosphonate OR
  - ii. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR
- E. Pt has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of:
  - i. Pt is either initiating or continuing systemic glucocorticoids in a daily dose equivalent to 7.5 mg or greater of prednisone AND
  - ii. Pt is expected to remain on glucocorticoids for at least 6 months AND
  - iii. Pt's diagnosis was confirmed by ONE of:
    - 1. A fragility fracture in the hip or spine OR
    - 2. A T-score of -2.5 or lower OR
    - 3. A T-score of -1.0 to -2.5 AND ONE of the following:
      - a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
      - b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR
      - c. A FRAX 10-year probability of hip fracture of 3% or greater AND
  - iv. ONE of:
    - 1. Pt is at a very high fracture risk as defined by ONE of the following:
      - a. Pt had a recent fracture (within the past 12 months) OR
      - b. Pt had fractures while on FDA approved osteoporosis therapy OR

- c. Pt has had multiple fractures OR
- d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
- e. Pt has a very low T-score (less than -3.0) OR
- f. Pt is at high risk for falls or has a history of injurious falls OR
- g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR

2. ONE of:

- a. Pt's medication history includes use of a bisphosphonate OR
- b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate AND

2. ONE of:

- A. Pt has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
- B. Pt has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
- C. Prescriber has indicated that the pt is not at risk for hypocalcemia (not including risk associated with the requested agent) AND

3. Pt will NOT be using the requested agent in combination with a bisphosphonate, another form of denosumab (e.g., Xgeva), romosozumab-aqqg, or parathyroid hormone analog (e.g., abaloparatide, teriparatide) for the requested indication AND

4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Prior Authorization Group Description:**

Promacta PA

**Drug Name(s)**

Promacta

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient (pt) has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
  - A. Pt has tried and had an insufficient response to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
  - B. Pt has an intolerance or hypersensitivity to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
  - C. Pt has an FDA labeled contraindication to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
  - D. Pt has had an insufficient response to a splenectomy OR
2. Pt has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:
  - A. Pt's platelet count is less than  $75 \times 10^9/L$  AND the intent is to increase platelet counts sufficiently to initiate pegylated interferon therapy OR
  - B. Pt is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia OR
3. Pt has a diagnosis of severe aplastic anemia (SAA) AND ALL of the following:
  - A. Pt has at least 2 of the following blood criteria:
    - i. Neutrophils less than  $0.5 \times 10^9/L$  OR
    - ii. Platelets less than  $30 \times 10^9/L$  OR
    - iii. Reticulocyte count less than  $60 \times 10^9/L$  AND
  - B. Pt has at least 1 of the following marrow criteria:
    - i. Severe hypocellularity is less than 25% OR
    - ii. Moderate hypocellularity is 25-50% with hematopoietic cells representing less than 30% of residual cells AND
  - C. ONE of the following:
    - i. Pt has tried and had an insufficient response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy OR
    - ii. BOTH of the following:
      1. Pt will be using the requested agent as first-line treatment (i.e., has not been treated with ATG and/or cyclosporine) AND
      2. Pt will use the requested agent in combination with standard immunosuppressive therapy (i.e., ATG AND cyclosporine) OR
4. Pt has another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Initial: 6 months for ITP. Renewal: 12 months for ITP. Other indications, see Other Criteria.

**Other Criteria:**



Criteria for renewal approval require BOTH of the following:

1. Pt has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
  - A. Pt has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
    - i. Pt's platelet count is  $50 \times 10^9/L$  or greater OR
    - ii. Pt's platelet count has increased sufficiently to avoid clinically significant bleeding OR
  - B. Pt has a diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following:
    - i. ONE of the following:
      1. Pt will be initiating hepatitis C therapy with pegylated interferon and ribavirin OR
      2. Pt will be maintaining hepatitis C therapy with pegylated interferon and ribavirin at the same time as the requested agent AND
    - ii. ONE of the following:
      1. Pt's platelet count is  $90 \times 10^9/L$  or greater OR
      2. Pt's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C OR
  - C. Pt has a diagnosis of severe aplastic anemia (SAA) AND the pt has had clinical benefit with the requested agent OR
  - D. Pt has another indication that is supported in CMS approved compendia and the pt has had clinical benefit with the requested agent

Initial: 48 weeks for hepatitis C associated thrombocytopenia, 6 months for first-line therapy in severe aplastic anemia, 16 weeks for SAA, 12 months for All other indications

Renewal: 48 weeks for hepatitis C associated thrombocytopenia, 12 months for SAA, 12 months for All other indications

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Adempas

**Drug Name(s)**

Adempas

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4, as determined by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography AND ALL of the following:

i. ONE of the following:

- a. Patient is NOT a candidate for surgery OR
- b. Patient has had pulmonary endarterectomy AND has persistent or recurrent disease AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units OR

C. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

- v. ONE of the following:
  - a. The requested agent will be utilized as monotherapy OR
  - b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:
    - 1. Patient has unacceptable or deteriorating clinical status despite established pharmacotherapy AND
    - 2. The requested agent is in a different therapeutic class OR
  - c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:
    - 1. ONE of the following:
      - i. A prostanoid has been started as one of the agents in the triple therapy OR
      - ii. Patient has an intolerance or hypersensitivity to a prostanoid OR
      - iii. Patient has an FDA labeled contraindication to a prostanoid AND
    - 2. Patient has unacceptable or deteriorating clinical status despite established pharmacotherapy AND
    - 3. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:

- 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
- 2. Patient has an FDA labeled indication for the requested agent AND
- 3. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Ambrisentan

**Drug Name(s)**

Ambrisentan

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be used in combination with a phosphodiesterase 5 (PDE5) inhibitor for dual therapy ONLY OR

c. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), [except for dual therapy requests for a phosphodiesterase 5 (PDE 5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication for the requested agent AND

3. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Bosentan

**Drug Name(s)**

Bosentan

Tracleer

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Elevated liver enzymes accompanied by signs or symptoms of liver dysfunction/injury or a bilirubin level of 2 times the ULN (upper limit of normal) or greater AND FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR

b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1, as determined by right heart catheterization, AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be used in combination with a phosphodiesterase 5 (PDE5) inhibitor for dual therapy ONLY OR

c. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), [except for dual therapy requests for a phosphodiesterase 5 inhibitor (PDE5) plus an endothelin receptor antagonist (ERA)], AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

3. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Opsumit

**Drug Name(s)**

Opsumit

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be used in combination with a phosphodiesterase 5 (PDE5) inhibitor for dual therapy ONLY OR

c. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), [except for dual therapy requests for a phosphodiesterase 5 (PDE 5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months



**Other Criteria:**

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication for the requested agent AND

3. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Sildenafil

**Drug Name(s)**

Sildenafil

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Concurrently taking another phosphodiesterase 5 (PDE 5) inhibitor with the requested agent AND FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR

b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be used in combination with an endothelin receptor antagonist (ERA) for dual therapy ONLY OR

c. The requested agent will be utilized for add-on therapy to existing monotherapy, [except for dual requests for a phosphodiesterase 5 (PDE5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

3. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Tadalafil

**Drug Name(s)**

Alyq

Tadalafil 20Mg Tablet

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Concurrently taking another phosphodiesterase 5 (PDE 5) inhibitor with the requested agent AND FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR

b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be used in combination with an endothelin receptor antagonist (ERA) for dual therapy ONLY OR

c. The requested agent will be utilized for add-on therapy to existing monotherapy, [except for dual requests for a phosphodiesterase 5 (PDE5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

3. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Upravi

**Drug Name(s)**

Upravi

Upravi Titration Pack

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Pulmonary Hypertension PA – Ventavis

**Drug Name(s)**

Ventavis

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

**1. ONE of the following:****A. BOTH of the following:****i. ONE of the following:**

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND

**ii. Patient has an FDA labeled indication for the requested agent OR****B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:****i. Patient's World Health Organization (WHO) functional class is II or greater AND****ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND****iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND****iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND****v. ONE of the following:****a. The requested agent will be utilized as monotherapy OR****b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:****1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND****2. The requested agent is in a different therapeutic class OR****c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:****1. Patient is WHO functional class III or IV AND****2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND****3. All three agents in the triple therapy are from a different therapeutic class****Age Restriction:****Prescriber Restrictions:****Coverage Duration:**



Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Drug is also subject to Part B versus Part D review.

**Prior Authorization Group Description:**

Pyrimethamine PA

**Drug Name(s)**

Pyrimethamine

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 6 months

**Other Criteria:**

**Prior Authorization Group Description:**

Regranex PA

**Drug Name(s)**

Regranex

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

a. BOTH of the following:

i. Patient has a diagnosis of lower extremity diabetic neuropathic ulcer(s) that extends into the subcutaneous tissue or beyond AND

ii. The ulcer(s) intended for treatment has an adequate blood supply OR

b. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Relistor Inj PA

**Drug Name(s)**

Relistor Injection

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. ONE of the following diagnoses:
  - A. Patient has opioid-induced constipation (OIC) with advanced illness or pain caused by active cancer and is receiving palliative care OR
  - B. Patient has opioid induced constipation (OIC) and chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND
2. Patient has chronic use of an opioid agent in the past 90 days AND
3. ONE of the following:
  - A. Patient has tried and had an inadequate response to lactulose OR
  - B. Patient has an intolerance or hypersensitivity to lactulose OR
  - C. Patient has an FDA labeled contraindication to lactulose

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Relistor Tablet PA

**Drug Name(s)**

Relistor Tablet

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has opioid induced constipation (OIC) and chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND
2. Patient has chronic use of an opioid agent in the past 90 days AND
3. ONE of the following:
  - A. Patient has tried and had an inadequate response to lactulose OR
  - B. Patient has an intolerance or hypersensitivity to lactulose OR
  - C. Patient has an FDA labeled contraindication to lactulose

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Repatha PA

**Drug Name(s)**

Repatha

Repatha Pushtronex System

Repatha Sureclick

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has ONE of the following:

- A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following:
  - i. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or 1/LDLRAP1 gene OR
  - ii. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) OR
  - iii. Patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma) OR
  - iv. Patient has “definite” or “possible” familial hypercholesterolemia as defined by the Simon Broome criteria OR
  - v. Patient has a Dutch Lipid Clinic Network criteria score of greater than 5 OR
  - vi. Patient has a treated low-density lipoprotein cholesterol (LDL-C) level 100 mg/dL or greater after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy OR
- B. A diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ONE of the following:
  - i. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or LDLRAP1 gene OR
  - ii. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C 300 mg/dL or greater (7.76 mmol/L or greater) OR
  - iii. Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) OR
- C. A diagnosis of established cardiovascular disease [angina pectoris, coronary heart disease, myocardial infarction, transient ischemic attacks, cerebrovascular disease (CeVD) or peripheral vascular disease (PVD) or after coronary revascularization or carotid endarterectomy] AND the requested agent will be used to reduce the risk of myocardial infarction, stroke, and coronary revascularization OR
- D. A diagnosis of primary hyperlipidemia (not associated with HeFH, HoFH, or established cardiovascular disease) OR

Initial criteria continues: see Other Criteria

**Age Restriction:****Prescriber Restrictions:**

The agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

- E. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
- 3. ONE of the following:
  - A. Patient has tried and had an inadequate response to a high-intensity statin (i.e., rosuvastatin 20-40 mg or atorvastatin 40-80 mg) OR
  - B. Patient has an intolerance to TWO different statins OR
  - C. Patient has an FDA labeled contraindication to a statin AND
- 4. Patient will NOT be using the requested agent in combination with another PCSK9 agent

Criteria for renewal approval require ALL of the following:

- 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
- 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
- 3. Patient has had clinical benefit with the requested agent AND
- 4. Patient will NOT be using the requested agent in combination with another PCSK9 agent

**Prior Authorization Group Description:**

Roflumilast PA

**Drug Name(s)**

Roflumilast

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. Patient has tried and had an inadequate response to an agent from two of the following categories:
    - i. long-acting beta-2 agonist (LABA) [e.g., salmeterol]
    - ii. long-acting muscarinic antagonist (LAMA) [e.g., umeclidinium]
    - iii. inhaled corticosteroid (ICS) [e.g., fluticasone] OR
  - B. Patient has an intolerance or hypersensitivity to an agent from two of the following categories:
    - i. long-acting beta-2 agonist (LABA) [e.g., salmeterol]
    - ii. long-acting muscarinic antagonist (LAMA) [e.g., umeclidinium]
    - iii. inhaled corticosteroid (ICS) [e.g., fluticasone] OR
  - C. Patient has an FDA labeled contraindication to an agent from two of the following categories:
    - i. long-acting beta-2 agonist (LABA) [e.g., salmeterol]
    - ii. long-acting muscarinic antagonist (LAMA) [e.g., umeclidinium]
    - iii. inhaled corticosteroid (ICS) [e.g., fluticasone]

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Rybelsus PA

**Drug Name(s)**

Rybelsus

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

Requested agent will be used for weight loss alone

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of type 2 diabetes mellitus AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. BOTH of the following:
    - i. ONE of the following:
      1. Patient's medication history includes use of an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR
      2. Patient had an ineffective treatment response to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      3. Patient has an intolerance or hypersensitivity to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      4. Patient has an FDA labeled contraindication to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Samsca PA

**Drug Name(s)**

Tolvaptan

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the request agent AND Any underlying liver disease, including cirrhosis

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. The requested agent was initiated (or re-initiated) in the hospital AND
2. Prior to initiating the requested agent, the patient has or had a diagnosis of clinically significant hypovolemic or euvolemic hyponatremia defined by ONE of the following:
  - A. Serum sodium is less than 125 mEq/L OR
  - B. Serum sodium is 125 mEq/L or greater AND patient has symptomatic hyponatremia that has resisted correction with fluid restriction AND
3. Medications known to cause hyponatremia have been evaluated and discontinued when appropriate AND
4. Patient has NOT already received 30 days of therapy with the requested agent following the most recent hospitalization for initiation of therapy AND
5. The requested dose is within the FDA labeled dosing for the requested indication (Recommended starting dose is 15 mg once daily. Dosage may be increased at intervals greater than or equal to 24 hours to 30 mg once daily, and to a maximum of 60 mg once daily as needed to raise serum sodium. Do not administer for more than 30 days to minimize the risk of liver injury.)

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 30 days

**Other Criteria:**

**Prior Authorization Group Description:**

Sapropterin PA

**Drug Name(s)**

Javygtor

Sapropterin Dihydrochloride

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of phenylketonuria (PKU) AND
2. Prescriber has submitted a baseline blood Phe level measured prior to initiation of therapy with the requested agent, which is above the recommended levels indicated for the patient's age range or condition AND
3. Patient will NOT be using the requested agent in combination with Palynziq (pegvaliase-pqpz) for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of phenylketonuria (PKU) AND
3. ONE of the following:
  - a. Patient's blood Phe levels are being maintained within the acceptable range OR
  - b. Patient has had a decrease in blood Phe level from baseline AND
4. Patient will NOT be using the requested agent in combination with Palynziq (pegvaliase-pqpz) for the requested indication AND
5. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic or genetic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Initial: 2 months if dose is 5 to less than 20 mg/kg/day, 1 month if 20 mg/kg/day Renewal: 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Self - Administered Oncology PA

**Drug Name(s)**

Abiraterone Acetate  
Akeega  
Alecensa  
Alunbrig  
Augtyro  
Ayvakit  
Balversa  
Besremi  
Bexarotene Cap  
Bosulif  
Braftovi  
Brukinsa  
Cabometyx  
Calquence  
Caprelsa  
Cometriq  
Copiktra  
Cotellic  
Daurismo  
Erivedge  
Erleada  
Erlotinib Hydrochloride  
Everolimus  
Exkivity  
Farydak  
Fotivda  
Fruzaqla  
Gavreto  
Gefitinib  
Gilotrif  
Ibrance  
Iclusig  
Idhifa  
Imatinib Mesylate  
Imbruvica  
Inlyta  
Inqovi  
Inrebic  
Iwilfin  
Jakafi  
Jaypirca

Kisqali  
Kisqali Femara 200 Dose  
Kisqali Femara 400 Dose  
Kisqali Femara 600 Dose  
Koselugo  
Krazati  
Lapatinib Ditosylate  
Lenalidomide  
Lenvima 10 Mg Daily Dose  
Lenvima 12Mg Daily Dose  
Lenvima 14 Mg Daily Dose  
Lenvima 18 Mg Daily Dose  
Lenvima 20 Mg Daily Dose  
Lenvima 24 Mg Daily Dose  
Lenvima 4 Mg Daily Dose  
Lenvima 8 Mg Daily Dose  
Lonsurf  
Lorbrena  
Lumakras  
Lynparza  
Lytgobi  
Matulane  
Mekinist  
Mektovi  
Nerlynx  
Ninlaro  
Nubeqa  
Odomzo  
Ogsiveo  
Ojjaara  
Onureg  
Orgovyx  
Orserdu  
Pazopanib  
Pemazyre  
Piqray 200Mg Daily Dose  
Piqray 250Mg Daily Dose  
Piqray 300Mg Daily Dose  
Pomalyst  
Qinlock  
Retevmo  
Revlimid  
Rezlidhia  
Rozlytrek

Rubraca  
Rydapt  
Scemblix  
Sorafenib  
Sprycel  
Stivarga  
Sunitinib Malate  
Tabrecta  
Tafinlar  
Tagrisso  
Talzenna  
Tasigna  
Tazverik  
Tepmetko  
Thalomid  
Tibsovo  
Tretinoin 10Mg Cap  
Truqap  
Tukysa  
Turalio  
Vanflyta  
Venclexta  
Venclexta Starting Pack  
Verzenio  
Vitrakvi  
Vizimpro  
Vonjo  
Votrient  
Welireg  
Xalkori  
Xospata  
Xpovio  
Xpovio 100 Mg Once Weekly  
Xpovio 40 Mg Once Weekly  
Xpovio 40 Mg Twice Weekly  
Xpovio 60 Mg Once Weekly  
Xpovio 60 Mg Twice Weekly  
Xpovio 80 Mg Once Weekly  
Xpovio 80 Mg Twice Weekly  
Xtandi  
Zejula  
Zelboraf  
Zolinza  
Zydelig

Zykadia

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. ALL of the following:
    - i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND
    - iii. ONE of the following:
      - a. The requested agent is FDA labeled or supported by compendia as a first-line therapy for the requested indication OR
      - b. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated as first-line therapy for the requested indication OR
      - c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
      - d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
    - iv. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines AND

Criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

- v. ONE of the following:
  - a. The requested agent is not Bosulif or Tasigna OR
  - b. The requested agent is Bosulif or Tasigna AND ONE of the following:
    1. Patient's medication history indicates use of imatinib OR Sprycel for the requested indication (if applicable) OR
    2. Patient has an intolerance or hypersensitivity to imatinib OR Sprycel OR
    3. Patient has an FDA labeled contraindication to imatinib OR Sprycel OR

4. CMS approved compendia does not support the use of imatinib OR Sprycel for the requested indication OR
  5. Prescriber has provided information in support of use of Bosulif or Tasigna over imatinib OR Sprycel for the requested indication AND
- vi. ONE of the following:
- a. The requested agent is not Calquence OR
  - b. The requested agent is Calquence AND ONE of the following:
    1. Patient's medication history indicates use of Brukinsa OR Imbruvica for the requested indication (if applicable) OR
    2. Patient has an intolerance or hypersensitivity to Brukinsa OR Imbruvica OR
    3. Patient has an FDA labeled contraindication to Brukinsa OR Imbruvica OR
    4. CMS approved compendia do not support the use of Brukinsa OR Imbruvica for the requested indication OR
    5. Prescriber has provided information in support of use of Calquence over Brukinsa OR Imbruvica for the requested indication



**Prior Authorization Group Description:**

Signifor LAR PA

**Drug Name(s)**

Signifor Lar

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Severe hepatic impairment (i.e., Child Pugh C)

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of acromegaly AND ONE of the following:

i. Patient had an inadequate response to surgery as indicated by growth hormone and serum IGF-1 levels that are above the reference ranges for the patient's gender and age  
OR

ii. Patient is NOT a candidate for surgery OR

B. Patient has a diagnosis of Cushing's disease (CD) AND ONE of the following:

i. Patient had an inadequate response to pituitary surgical resection OR

ii. Patient is NOT a candidate for pituitary surgical resection OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:

A. Patient has a diagnosis of acromegaly AND ONE of the following:

i. Patient has growth hormone and serum IGF-1 levels that are within normal limits for patient's gender and age reference range OR

ii. Patient has had clinical improvement (e.g., reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) OR

B. Patient has a diagnosis of Cushing's disease (CD) AND BOTH of the following:

i. Patient has a urinary free cortisol level less than or equal to the upper limit of normal  
AND

ii. Patient has had improvement in at least ONE of the following clinical signs and symptoms:

1. Fasting plasma glucose OR

2. Hemoglobin A1c OR

3. Hypertension OR

4. Weight OR

C. BOTH of the following:

i. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Initial: Acromegaly - 6 months, CD - 7 months, All other diagnoses - 12 months, Renewal: 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Signifor PA

**Drug Name(s)**

Signifor

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Severe hepatic impairment (i.e., Child Pugh C)

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of Cushing's disease (CD) AND ONE of the following:

i. Patient had an inadequate response to pituitary surgical resection OR

ii. Patient is NOT a candidate for pituitary surgical resection OR

B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:

A. Patient has a diagnosis of Cushing's disease (CD) AND BOTH of the following:

i. Patient has a urinary free cortisol level less than or equal to the upper limit of normal AND

ii. Patient has had improvement in at least ONE of the following clinical signs and symptoms:

1. Fasting plasma glucose OR

2. Hemoglobin A1c OR

3. Hypertension OR

4. Weight OR

B. BOTH of the following:

i. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient has had clinical benefit with the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Initial approval: 6 months for CD, 12 months for all other diagnoses, Renewal approval: 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Sivextro PA

**Drug Name(s)**

Sivextro

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has ONE of the following:

A. BOTH of the following:

i. A documented acute bacterial skin and skin structure infection (ABSSSI) defined as a bacterial infection of the skin with a lesion size area of at least 75 cm<sup>2</sup> (lesion size measured by the area of redness, edema, or induration) AND

ii. The infection is due to *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus*, *Streptococcus intermedius*, *Streptococcus constellatus*, or *Enterococcus faecalis* OR

B. Another indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

A. The requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient OR

B. The requested agent is NOT prescribed by an infectious disease specialist or the prescriber has NOT consulted with an infectious disease specialist on treatment of this patient AND ONE of the following:

i. There is documentation of resistance to TWO of the following: beta-lactams, macrolides, clindamycin, tetracycline, or co-trimoxazole at the site of infection OR

ii. Patient has an intolerance or hypersensitivity to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR

iii. Patient has an FDA labeled contraindication to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR

iv. There is documentation of resistance to vancomycin at the site of infection OR

v. Patient has an intolerance or hypersensitivity to vancomycin OR

vi. Patient has an FDA labeled contraindication to vancomycin AND

3. Patient will NOT be using the requested agent in combination with linezolid for the same infection AND

4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be 6 days for ABSSSI or 30 days for all other indications

**Other Criteria:**

**Prior Authorization Group Description:**

Sodium Oxybate PA

**Drug Name(s)**

Xyrem

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of narcolepsy with cataplexy OR
- B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following:

- i. ONE of the following:

- a. Patient is under 18 years of age OR

- b. ONE of the following:

- 1. Patient has tried and had an inadequate response to modafinil or armodafinil OR
      - 2. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR
      - 3. Patient has an FDA labeled contraindication to modafinil or armodafinil AND

- ii. ONE of the following:

- a. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR
    - b. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR
    - c. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate) OR

- C. Patient has another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

Patient is 7 years of age or over

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Somatostatin Analogs PA – Lanreotide

**Drug Name(s)**

Somatuline Depot

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

## 1. ONE of the following:

A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:

- i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- ii. Prescriber states the patient is currently being treated with the requested agent OR

## B. ONE of the following:

i. Patient has a diagnosis of acromegaly AND ONE of the following:

- a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR
- b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR
- c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR

ii. Patient has a diagnosis of gastroenteropancreatic neuroendocrine tumors AND BOTH of the following:

- a. The tumors are well or moderately differentiated AND
- b. ONE of the following:
  1. The tumors are unresectable, locally advanced OR
  2. Patient has metastatic disease OR

iii. Patient has a diagnosis of carcinoid syndrome OR

iv. Patient has another indication that is supported in CMS approved compendia for the requested agent AND

## 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be 6 months for initial, 12 months for renewal

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

## 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. BOTH of the following:
    - i. ONE of the following:
      1. Patient has a diagnosis of acromegaly OR
      2. Patient has a diagnosis of metastatic OR unresectable, locally advanced, well or moderately differentiated gastroenteropancreatic neuroendocrine tumors OR
      3. Patient has a diagnosis of carcinoid syndrome OR
      4. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
    - ii. Patient has had clinical benefit with the requested agent AND
4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication



**Prior Authorization Group Description:**

Somatostatin Analogs PA – Octreotide

**Drug Name(s)**

Octreotide Acetate

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. ONE of the following:

A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:

- i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- ii. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR

B. ONE of the following:

i. Patient has a diagnosis of acromegaly AND ONE of the following:

- a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR
- b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR
- c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR

ii. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR

iii. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR

iv. Patient has a diagnosis of dumping syndrome AND ONE of the following:

- a. Patient has tried and had an inadequate response to acarbose OR
- b. Patient has an intolerance or hypersensitivity to acarbose OR
- c. Patient has an FDA labeled contraindication to acarbose OR

v. Patient has another indication that is supported in CMS approved compendia for the requested agent AND

2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be 6 months for initial, 12 months for renewal

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:

A. Patient has a diagnosis of acromegaly OR

B. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR

C. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR

D. Patient has a diagnosis of dumping syndrome OR

E. Patient has another indication that is supported in CMS approved compendia for the requested agent

AND

3. Patient has had clinical benefit with the requested agent AND

4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Prior Authorization Group Description:**

Somatostatin Analogs PA – Somavert

**Drug Name(s)**

Somavert

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of acromegaly AND ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. BOTH of the following:
    - i. ONE of the following:
      - a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR
      - b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR
      - c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by serum IGF-1 levels that are above the reference range AND
    - ii. ONE of the following:
      - a. Patient has tried and had an inadequate response to octreotide or Somatuline Depot (lanreotide) OR
      - b. Patient has an intolerance or hypersensitivity to octreotide or Somatuline Depot (lanreotide) OR
      - c. Patient has an FDA labeled contraindication to octreotide or Somatuline Depot (lanreotide) AND
2. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of acromegaly AND
3. Patient has had clinical benefit with the requested agent AND
4. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be 6 months for initial, 12 months for renewal

**Other Criteria:**

**Prior Authorization Group Description:**

Sovaldi PA

**Drug Name(s)**

Sovaldi

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND
2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND
3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND
5. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Eplclusa and Harvoni for supported genotypes OR
  - D. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Eplclusa and Harvoni for supported genotypes

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

**Other Criteria:**

**Prior Authorization Group Description:**

Spravato PA

**Drug Name(s)**

Spravato 56Mg Dose

Spravato 84Mg Dose

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. BOTH of the following:
  - a. ONE of the following:
    - i. Patient has a diagnosis of treatment-resistant depression (TRD) OR
    - ii. Patient has a diagnosis of major depressive disorder (MDD) with acute suicidal ideation or behavior AND
  - b. The requested agent will be used in combination with an oral antidepressant AND
2. ONE of the following:
  - a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - b. Prescriber states the patient is currently being treated with the requested agent OR
  - c. ALL of the following:
    - i. ONE of the following:
      1. BOTH of the following:
        - a. Patient has a diagnosis of treatment-resistant depression (TRD) AND
        - b. Patient has tried and had an inadequate response to at least two different oral antidepressants (e.g., SSRIs, SNRIs) OR
      2. Patient has a diagnosis of major depressive disorder (MDD) with acute suicidal ideation or behavior AND
    - ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
    - iii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Strensiq PA

**Drug Name(s)**

Strensiq

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has ONE of the following diagnoses:
  - A. Perinatal or infantile-onset hypophosphatasia OR
  - B. Juvenile-onset hypophosphatasia AND
2. Patient has documentation (i.e., medical records) of clinical manifestations to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., vitamin B6-dependent seizures, skeletal abnormalities such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, “failure to thrive”) AND
3. Patient has documentation (i.e., medical records) of radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, alveolar bone loss, craniosynostosis, fractures) AND
4. Patient has documentation (i.e., medical records) of confirmed mutation(s) in the ALPL gene that encodes the tissue non-specific isoenzyme of alkaline phosphatase (TNSALP) AND
5. Patient has documentation (i.e., medical records) of a measured total serum alkaline phosphatase (ALP) level that is below the normal lab reference range for age and sex AND
6. Patient has documentation (i.e., medical records) of ONE of the following:
  - A. Elevated urine concentration of phosphoethanolamine (PEA) OR
  - B. Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR
  - C. Elevated urinary inorganic pyrophosphate (PPi) AND
7. The requested dose is within FDA labeled dosing (based on the patient’s weight) for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist or geneticist with expertise in metabolic bone diseases) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND
2. Patient has ONE of the following diagnoses:
  - A. Perinatal or infantile-onset hypophosphatasia OR

- B. Juvenile-onset hypophosphatasia AND
3. There is documentation (i.e., medical records) that the patient has had a decrease from baseline (before treatment with the requested agent) in at least ONE of the following levels:
    - a. Urine concentration of phosphoethanolamine (PEA) OR
    - b. Serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR
    - c. Urinary inorganic pyrophosphate (PPI) AND
  4. Patient has documentation (i.e., medical records) of clinical improvement and/or stabilization with the requested agent (e.g., improvement in respiratory status, growth, pain, radiographic findings, other symptoms associated with the disease) AND
  5. The requested dose is within FDA labeled dosing (based on the patient's weight) for the requested indication

**Prior Authorization Group Description:**

Substrate Reduction Therapy PA – Miglustat

**Drug Name(s)**

Miglustat

Yargesa

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following:
  - A. A baseline glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
  - B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline measurements of hemoglobin level, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
  - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
  - B. Thrombocytopenia (defined as platelet count of less than 100,000 per microliter) OR
  - C. Hepatomegaly OR
  - D. Splenomegaly OR
  - E. Growth failure (i.e., growth velocity is below the standard mean for age) OR
  - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvements or stabilization with the requested agent as indicated by ONE of the following:
  - A. Spleen volume OR
  - B. Hemoglobin level OR
  - C. Liver volume OR
  - D. Platelet count OR
  - E. Growth OR
  - F. Bone pain or crisis

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient's diagnosis



**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Symdeko PA

**Drug Name(s)**

Symdeko

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cystic fibrosis AND
2. ONE of the following:
  - A. Patient has the presence of the F508del mutation on both alleles (homozygous) of the CFTR gene confirmed by genetic testing OR
  - B. Patient has ONE of the CFTR gene mutations or a mutation in the CFTR gene that is responsive based on in vitro data, as indicated in the FDA label, confirmed by genetic testing OR
  - C. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND
3. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cystic fibrosis AND
3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Tasimelteon Capsule PA

**Drug Name(s)**

Tasimelteon

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

- i. Patient has a diagnosis of Non-24-hour sleep-wake disorder AND
- ii. Patient is totally blind (i.e., no light perception) OR

B. BOTH of the following:

- i. Patient has a diagnosis of Smith-Magenis Syndrome (SMS) confirmed by the presence of ONE of the following genetic mutations:
  - A. A heterozygous deletion of 17p11.2 OR
  - B. A heterozygous pathogenic variant involving RAI1 AND
- ii. The requested agent is being used to treat nighttime sleep disturbances associated with SMS

**Age Restriction:**

For diagnosis of Non-24-hour sleep-wake disorder, patient is 18 years of age or over. For diagnosis of Smith-Magenis Syndrome (SMS), patient is 16 years of age or over.

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, sleep specialist, psychiatrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Teriparatide PA

**Drug Name(s)**

Forteo

Teriparatide

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has ONE of the following diagnoses:
  - A. Postmenopausal with osteoporosis OR
  - B. Patient's sex is male with primary or hypogonadal osteoporosis OR
  - C. Osteoporosis with sustained systemic glucocorticoid therapy AND
2. Patient's diagnosis was confirmed by ONE of the following:
  - A. A fragility fracture in the hip or spine OR
  - B. A T-score of -2.5 or lower OR
  - C. A T-score of -1.0 to -2.5 AND ONE of the following:
    - i. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
    - ii. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR
    - iii. A FRAX 10-year probability of hip fracture of 3% or greater AND
3. ONE of the following:
  - A. Patient is at a very high fracture risk as defined by ONE of the following:
    - i. Patient had a recent fracture (within the past 12 months) OR
    - ii. Patient had fractures while on FDA approved osteoporosis therapy OR
    - iii. Patient has had multiple fractures OR
    - iv. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
    - v. Patient has a very low T-score (less than -3.0) OR
    - vi. Patient is at high risk for falls or has a history of injurious falls OR
    - vii. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR
  - B. ONE of the following:
    - i. Patient has tried and had an inadequate response to a bisphosphonate OR
    - ii. Patient has an intolerance or hypersensitivity to a bisphosphonate OR
    - iii. Patient has an FDA labeled contraindication to a bisphosphonate AND
4. Patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., abaloparatide) for the requested indication AND

Criteria continues: see Other Criteria

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

No prior teriparatide and/or Tymlos use approve 2 years, Prior use - see Other Criteria

**Other Criteria:**

5. The requested dose is within FDA labeled dosing for the requested indication AND

6. ONE of the following:

A. Patient has never received treatment with teriparatide or Tymlos (abaloparatide) OR

B. Patient has been previously treated with teriparatide or Tymlos (abaloparatide) AND ONE of the following:

i. The total cumulative duration of treatment with teriparatide and Tymlos (abaloparatide) has NOT exceeded 2 years OR

ii. Patient has received 2 years or more of treatment with teriparatide, and remains at or has returned to having a high risk for fracture

Prior teriparatide and/or Tymlos use approve remainder of 2 years of total cumulative therapy. Approve 1 year if patient has received 2 years or more teriparatide

**Prior Authorization Group Description:**

Tetrabenazine PA

**Drug Name(s)**

Tetrabenazine

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. ONE of the following:
  - A. Patient has a diagnosis of chorea associated with Huntington’s disease OR
  - B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. Patient does NOT have a current diagnosis of depression OR
  - B. Patient has a current diagnosis of depression and is being treated for depression AND
3. ONE of the following:
  - A. Patient does NOT have a diagnosis of suicidal ideation and/or behavior OR
  - B. Patient has a diagnosis of suicidal ideation and/or behavior and must NOT be actively suicidal AND
4. Patient will NOT be using the requested agent in combination with a monoamine oxidase inhibitor (MAOI) AND
5. Patient will NOT be using the requested agent in combination with reserpine

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Tobramycin neb PA

**Drug Name(s)**

Tobramycin Neb

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of cystic fibrosis AND
2. Documentation has been provided that indicates the patient has a *Pseudomonas aeruginosa* respiratory infection AND
3. ONE of the following:
  - a. Patient is NOT currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled aztreonam, inhaled tobramycin) OR
  - b. Patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled aztreonam, inhaled tobramycin) AND ONE of the following:
    - i. Prescriber has confirmed that the other inhaled antibiotic will be discontinued, and that therapy will be continued only with the requested agent OR
    - ii. Prescriber has provided information in support of another inhaled antibiotic therapy used concurrently with or alternating with (i.e., continuous alternating therapy) the requested agent

Drug is also subject to Part B versus Part D review.

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Topical Retinoids PA – Tazarotene

**Drug Name(s)**

Tazarotene

Tazorac

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Requested agent will be used for cosmetic purposes

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

- a. Patient has an FDA labeled indication for the requested agent OR
- b. Patient has an indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Trelstar PA

**Drug Name(s)**

Trelstar Mixject

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent OR
  - C. BOTH of the following:
    - i. Patient is NOT currently being treated with the requested agent AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND
3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Trientine PA

**Drug Name(s)**

Trientine Hydrochloride

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of Wilson's disease confirmed by ONE of the following:
  - A. Confirmation of genetic mutation of the ATP7B gene OR
  - B. Patient has TWO or more of the following:
    - i. Presence of hepatic abnormality (e.g., acute liver failure, cirrhosis, fatty liver)
    - ii. Presence of Kayser-Fleischer rings
    - iii. Serum ceruloplasmin level less than 20 mg/dL
    - iv. Basal urinary copper excretion greater than 40 mcg/24 hours or the testing laboratory's upper limit of normal
    - v. Hepatic parenchymal copper content greater than 40 mcg/g dry weight
    - vi. Presence of neurological symptoms (e.g., dystonia, hypertonia, rigidity with tremors, dysarthria, muscle spasms, dysphasia, polyneuropathy, dysautonomia) AND
2. ONE of the following:
  - A. Patient has tried and had an inadequate response to penicillamine OR
  - B. Patient has an intolerance or hypersensitivity to penicillamine OR
  - C. Patient has an FDA labeled contraindication to penicillamine

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Wilson's disease AND
3. Patient has had clinical benefit with the requested agent as evidenced by ONE of the following:
  - A. Improvement and/or stabilization in hepatic abnormality OR
  - B. Reduction in Kayser-Fleischer rings OR
  - C. Improvement and/or stabilization in neurological symptoms (e.g., dystonia, hypertonia, rigidity with tremors, dysarthria, muscle spasms, dysphasia, polyneuropathy, dysautonomia) OR
  - D. Basal urinary copper excretion greater than 200 mcg/24 hours

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Trikafta PA

**Drug Name(s)**

Trikafta

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cystic fibrosis AND
2. ONE of the following:
  - A. Patient has the presence of the F508del mutation in at least ONE allele (heterozygous OR homozygous) of the CFTR gene confirmed by genetic testing OR
  - B. Patient has ONE of the CFTR gene mutations or a mutation in the CFTR gene that is responsive based on in vitro data, as indicated in the FDA label, confirmed by genetic testing OR
  - C. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND
3. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cystic fibrosis AND
3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Trulicity PA

**Drug Name(s)**

Trulicity

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

Requested agent will be used for weight loss alone

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of type 2 diabetes mellitus AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. BOTH of the following:
    - i. ONE of the following:
      1. Patient's medication history includes use of an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR
      2. Patient had an ineffective treatment response to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      3. Patient has an intolerance or hypersensitivity to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      4. Patient has an FDA labeled contraindication to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      5. BOTH of the following:
        - a. Patient has a diagnosis of established cardiovascular disease [e.g., myocardial infarction, stroke, any revascularization procedure, transient ischemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease] AND
        - b. The requested agent will be used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Tymlos PA

**Drug Name(s)**

Tymlos

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient (pt) has ONE of the following:
  - A. Postmenopausal with osteoporosis OR
  - B. Pt's sex is male with osteoporosis AND
2. BOTH of the following:
  - A. Pt's diagnosis was confirmed by ONE of the following:
    - i. A fragility fracture in the hip or spine OR
    - ii. A T-score of -2.5 or lower OR
    - iii. A T-score of -1.0 to -2.5 AND ONE of the following:
      - a. A fragility fracture of proximal humerus, pelvis, or distal forearm OR
      - b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR
      - c. A FRAX 10-year probability of hip fracture of 3% or greater AND
  - B. ONE of the following:
    - i. Pt is at a very high fracture risk as defined by ONE of the following:
      - a. Pt had a recent fracture (within the past 12 months) OR
      - b. Pt had fractures while on FDA approved osteoporosis therapy OR
      - c. Pt has had multiple fractures OR
      - d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
      - e. Pt has a very low T-score (less than -3.0) OR
      - f. Pt is at high risk for falls or has a history of injurious falls OR
      - g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR
    - ii. ONE of the following:
      - a. Pt has tried and had an inadequate response to a bisphosphonate OR
      - b. Pt has an intolerance or hypersensitivity to a bisphosphonate OR
      - c. Pt has an FDA labeled contraindication to a bisphosphonate AND
3. Pt will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication AND
5. The total cumulative duration of treatment with teriparatide and Tymlos (abaloparatide) has not exceeded 2 years

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

No prior Tymlos and/or teriparatide use approve 2 years, Prior use - see Other Criteria

**Other Criteria:**

Prior Tymlos and/or teriparatide use approve remainder of 2 years of total cumulative therapy

**Prior Authorization Group Description:**

Ubrelvy PA

**Drug Name(s)**

Ubrelvy

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
2. The requested agent is being used for the treatment of acute migraine with or without aura AND
3. ONE of the following:
  - A. Patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent OR
  - B. Patient has an intolerance, or hypersensitivity to a triptan OR
  - C. Patient has an FDA labeled contraindication to a triptan AND
4. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for the treatment of acute migraine with or without aura AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP)

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Urea Cycle Disorders PA - Sodium Phenylbutyrate

**Drug Name(s)**

Sodium Phenylbutyrate

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of ONE of the following:
  - a. Urea cycle disorder with neonatal-onset involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase OR
  - b. Urea cycle disorder with late-onset and history of hyperammonemic encephalopathy involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase AND
2. The requested dose is within FDA labeled dosing for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Vemlidy PA

**Drug Name(s)**

Vemlidy

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has an FDA labeled indication for the requested agent

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Viberzi PA

**Drug Name(s)**

Viberzi

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

**Age Restriction:**

**Prescriber Restrictions:**

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Victoza PA

**Drug Name(s)**

Victoza

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

Requested agent will be used for weight loss alone

**Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of type 2 diabetes mellitus AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. BOTH of the following:
    - i. ONE of the following:
      1. Patient's medication history includes use of an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR
      2. Patient had an ineffective treatment response to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      3. Patient has an intolerance or hypersensitivity to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      4. Patient has an FDA labeled contraindication to an oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR
      5. BOTH of the following:
        - a. Patient has a diagnosis of established cardiovascular disease [e.g., myocardial infarction, stroke, any revascularization procedure, transient ischemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease] AND
        - b. The requested agent will be used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND
    - ii. Patient does NOT have any FDA labeled contraindications to the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Voriconazole PA

**Drug Name(s)**

Voriconazole

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of invasive *Aspergillus* OR
- B. Patient has a serious infection caused by *Scedosporium apiospermum* or *Fusarium* species OR
- C. Patient has a diagnosis of esophageal candidiasis or candidemia in nonneutropenic patient

AND ONE of the following:

- i. Patient has tried and had an inadequate response to fluconazole or an alternative antifungal agent OR
  - ii. Patient has an intolerance or hypersensitivity to fluconazole or an alternative antifungal agent OR
  - iii. Patient has an FDA labeled contraindication to fluconazole or an alternative antifungal agent OR
- D. Patient has a diagnosis of blastomycosis AND ONE of the following:
- i. Patient has tried and had an inadequate response to itraconazole OR
  - ii. Patient has an intolerance or hypersensitivity to itraconazole OR
  - iii. Patient has an FDA labeled contraindication to itraconazole OR
- E. The requested agent is being prescribed for prophylaxis of invasive *Aspergillus* or *Candida* AND patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR
- F. Patient has another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

One month for esophageal candidiasis, 6 months for all other indications

**Other Criteria:**

Criteria for renewal approval require BOTH of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:

- A. Patient has a diagnosis of invasive Aspergillus, a serious infection caused by *Scedosporium apiospermum* or *Fusarium* species, esophageal candidiasis, candidemia in nonneutropenic patient, or blastomycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR
- B. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or *Candida* and patient continues to be severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR
- C. BOTH of the following:
- i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
  - ii. Patient has had clinical benefit with the requested agent

**Prior Authorization Group Description:**

Vosevi PA

**Drug Name(s)**

Vosevi

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND
2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND
3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND
5. If genotype 1, the patient's subtype has been identified and provided

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

**Other Criteria:**

**Prior Authorization Group Description:**

Vyndamax PA

**Drug Name(s)**

Vyndamax

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Vyndaqel PA

**Drug Name(s)**

Vyndaqel

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

**Age Restriction:**

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**



**Prior Authorization Group Description:**

Xermelo PA

**Drug Name(s)**

Xermelo

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of carcinoid syndrome diarrhea AND
2. Patient has tried and had an inadequate response to treatment with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) AND
3. The requested agent will be used in combination with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide])

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of carcinoid syndrome diarrhea AND
3. Patient has had clinical benefit with the requested agent (e.g., reduction in the average number of daily bowel movements) AND
4. The requested agent will be used in combination with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide])

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Xgeva PA

**Drug Name(s)**

Xgeva

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

**1. ONE of the following:****A. Patient has a diagnosis of multiple myeloma AND BOTH of the following:**

i. The requested agent will be used for the prevention of skeletal-related events AND

**ii. ONE of the following:**

1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR

**B. Patient has a diagnosis of prostate cancer AND ALL of the following:**

i. The requested agent will be used for the prevention of skeletal-related events AND

ii. Patient has bone metastases AND

**iii. ONE of the following:**

1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR

Criteria continues: see Other Criteria

**Age Restriction:****Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

C. Patient has a solid tumor cancer diagnosis (e.g., thyroid, non-small cell lung, kidney cancer, or breast cancer) AND ALL of the following:

i. The requested agent will be used for the prevention of skeletal-related events AND

ii. Patient has bone metastases AND

- iii. ONE of the following:
  - 1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
  - 2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
  - 3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR
- D. Patient has a diagnosis of giant cell tumor of bone AND ONE of the following:
  - i. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
  - ii. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
  - iii. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR
- E. Patient has a diagnosis of hypercalcemia of malignancy AND
- 2. Patient will NOT be using the requested agent in combination with Prolia (denosumab) AND
- 3. The requested dose is within FDA labeled dosing for the requested indication

**Prior Authorization Group Description:**

Xifaxan PA

**Drug Name(s)**

Xifaxan

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. Patient has ONE of the following:

- a. A diagnosis of irritable bowel syndrome with diarrhea (IBS-D) OR
- b. A diagnosis of hepatic encephalopathy [reduction in risk of overt hepatic encephalopathy (HE) recurrence] OR
- c. BOTH of the following:
  - i. A diagnosis of traveler's diarrhea (TD) AND
  - ii. The traveler's diarrhea is caused by noninvasive strains of Escherichia coli

**Age Restriction:**

For diagnosis of traveler's diarrhea (TD), patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Xolair PA

**Drug Name(s)**

Xolair

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. ONE of the following:

A. Patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following:

i. ONE of the following:

a. Patient is 6 to less than 12 years of age AND BOTH of the following:

I. Patient's pretreatment IgE level is 30 IU/mL to 1300 IU/mL AND

II. Patient's weight is 20 kg to 150 kg OR

b. Patient is 12 years of age or over AND BOTH of the following:

I. Patient's pretreatment IgE level is 30 IU/mL to 700 IU/mL AND

II. Patient's weight is 30 kg to 150 kg AND

iii. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test (RAST) to a perennial aeroallergen AND

iv. ONE of the following:

a. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent OR

b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an asthma control therapy OR

B. Patient has a diagnosis of chronic idiopathic urticaria AND BOTH of the following:

i. Patient has had over 6 weeks of hives and itching AND

ii. ONE of the following:

a. Patient has tried and had an inadequate response to maximum tolerable H1 antihistamine therapy OR

b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to H1 antihistamine therapy OR

C. Patient has a diagnosis of nasal polyps AND BOTH of the following:

i. ONE of the following:

a. Patient has tried and had an inadequate response to an intranasal corticosteroid OR

b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid AND

ii. ONE of the following:

a. The requested agent will be used in combination with an intranasal corticosteroid OR

- b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid AND

Initial criteria continues: see Other Criteria

**Age Restriction:**

For diagnosis of moderate to severe persistent asthma, patient is 6 years of age or over. For diagnosis of chronic idiopathic urticaria, patient is 12 years of age or over. For diagnosis of nasal polyps, patient is 18 years of age or over.

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be 6 months for initial, 12 months for renewal

**Other Criteria:**

- 2. Patient will NOT be using the requested agent in combination with Dupixent or an injectable Interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasentra, Nucala) for the requested indication AND
- 3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

- 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
- 2. ONE of the following:
  - A. Patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following:
    - i. Patient's weight is within the FDA indicated range for their age (i.e., 20 kg to 150 kg for patients age 6 to less than 12 years and 30 kg to 150 kg for patients 12 years of age or over) AND
    - ii. Patient has had clinical benefit with the requested agent AND
    - iii. ONE of the following:
      - a. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent OR
      - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an asthma control therapy OR
  - B. Patient has a diagnosis of chronic idiopathic urticaria AND the following:
    - a. Patient has had clinical benefit with the requested agent OR
  - C. Patient has a diagnosis of nasal polyps AND the following:
    - a. Patient has had clinical benefit with the requested agent AND
- 3. Patient will NOT be using the requested agent in combination with Dupixent or an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasentra, Nucala) for the requested indication AND
- 4. The requested dose is within FDA labeled dosing for the requested indication

**Prior Authorization Group Description:**

Xywav PA

**Drug Name(s)**

Xywav

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of narcolepsy with cataplexy OR

B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following:

i. ONE of the following:

a. Patient is under 18 years of age OR

b. ONE of the following:

1. Patient has tried and had an inadequate response to modafinil or armodafinil OR

2. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR

3. Patient has an FDA labeled contraindication to modafinil or armodafinil AND

ii. ONE of the following:

a. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR

b. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR

c. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate) OR

C. Patient has a diagnosis of idiopathic hypersomnia OR

D. Patient has another indication that is supported in CMS approved compendia for the requested agent

**Age Restriction:**

For diagnosis of narcolepsy with cataplexy, patient is 7 years of age or over. For diagnosis of narcolepsy with excessive daytime sleepiness, patient is 7 years of age or over. For diagnosis of idiopathic hypersomnia, patient is 18 years of age or over.

**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**

**Prior Authorization Group Description:**

Zepatier PA

**Drug Name(s)**

Zepatier

**Indications:**

All Medically-Accepted Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND
2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND
3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND
5. If genotype 1, the patient's subtype has been identified and provided AND
6. If genotype 1a, the prescriber has tested the patient for the presence of virus with NS5A resistance-associated polymorphisms AND
7. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR
  - C. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
  - D. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa and Harvoni for supported genotypes

**Age Restriction:****Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

**Other Criteria:**



**Prior Authorization Group Description:**

Zokinvy PA

**Drug Name(s)**

Zokinvy

**Indications:**

All FDA-Approved Indications.

**Off-Label Uses:****Exclusion Criteria:**

FDA labeled contraindications to the requested agent

**Required Medical Information:**

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

- i. Patient has a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS) AND
- ii. Genetic testing has confirmed a pathogenic variant in the LMNA gene that results in production of progerin OR

B. Patient has a diagnosis of processing-deficient progeroid laminopathy AND ONE of the following:

- i. Genetic testing has confirmed heterozygous LMNA mutation with progerin-like protein accumulation OR
- ii. Genetic testing has confirmed homozygous or compound heterozygous ZMPSTE24 mutations

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has a diagnosis of ONE of the following:

- A. Hutchinson-Gilford progeria syndrome (HGPS) OR
- B. Processing-deficient progeroid laminopathies with either: heterozygous LMNA mutation with progerin-like protein accumulation OR homozygous or compound heterozygous ZMPSTE24 mutations AND

3. Patient has had clinical benefit with the requested agent

**Age Restriction:**

Patient is within the FDA labeled age for the requested agent

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Coverage Duration:**

Approval will be for 12 months

**Other Criteria:**