MEMORIAL HERMANN
Health Plan
Medicare Advantage Plans

# 2026 Memorial Hermann Health Plan Medicare Advantage (HMO) and HMO D-SNP Formulary Prior Authorization Criteria

# 2026 PRIOR AUTHORIZATION CRITERIA

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**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 or more migraine headache days per month AND
4. 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:**
Alcohol Swabs PA
**Drug Name(s)**
Alcohol Swabs
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
This program will be implemented as a dynamic PA.
Criteria for approval require BOTH of the following:
1. The requested medical supply product will be used in the delivery of insulin to the body AND
2. Patient's medication history includes use of insulin within the past 180 days
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
Alosetron PA
**Drug Name(s)**
Alosetron Hcl
**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 Injectable PA - testosterone cypionate
**Drug Name(s)**
Depo-Testosterone
Testosterone Cypionate
**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's sex is male with 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/m2 OR
            c. At least 5% total body cell mass (BCM) loss within 6 months OR
            d. BCM less than 35% of total body weight and BMI less than 27 kg/m2 AND
        ii. All other causes of weight loss have been ruled out OR
    B. Patient's sex is female with metastatic/inoperable breast cancer OR
    C. Patient's sex is male with primary or secondary (hypogonadotropic) hypogonadism OR
    D. Patient's sex is male and is an adolescent with delayed puberty AND
2. If the patient's sex is a 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 the testing laboratory's normal range 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 the testing laboratory's normal range 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 Injectable PA - testosterone enanthate
**Drug Name(s)**
Testosterone Enanthate
**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's sex is male with 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/m2 OR
            c. At least 5% total body cell mass (BCM) loss within 6 months OR
            d. BCM less than 35% of total body weight and BMI less than 27 kg/m2 AND
        ii. All other causes of weight loss have been ruled out OR
    B. Patient's sex is female with metastatic/inoperable breast cancer OR
    C. Patient's sex is male with primary or secondary (hypogonadotropic) hypogonadism OR
    D. Patient's sex is male and is an adolescent with delayed puberty AND
2. If the patient's sex is a 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 the testing laboratory's normal range 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 the testing laboratory's normal range 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
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Antipsychotics PA
**Drug Name(s)**
Aripiprazole
Aripiprazole Odt
Asenapine Maleate Sl
Chlorpromazine Hcl
Clozapine
Clozapine Odt
Fanapt
Fanapt Pack A
Fanapt Pack C
Fluphenazine Decanoate
Fluphenazine Hcl
Haloperidol
Haloperidol Decanoate
Haloperidol Lactate
Loxapine
Lurasidone Hcl
Lybalvi
Molindone Hcl
Olanzapine
Olanzapine Odt
Opipza
Paliperidone Er
Perphenazine
Pimozide
Quetiapine Fumarate
Quetiapine Fumarate Er
Rexulti
Risperidone
Risperidone Odt
Secuado
Thioridazine Hcl
Thiothixene
Trifluoperazine Hcl
Versacloz
Ziprasidone Mesylate
**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 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:**
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:**
Arikayce PA
**Drug Name(s)**
Arikayce
**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 Mycobacterium avium complex (MAC) lung disease AND
2. Patient has not achieved negative sputum cultures despite at least 6 consecutive months of treatment with standard combination antibiotic therapy for MAC lung disease [e.g., standard combination may include a macrolide (clarithromycin, azithromycin), a rifamycin (rifampin, rifabutin), and ethambutol] AND
3. Patient will continue treatment with a combination antibiotic therapy for MAC lung disease with the requested agent [e.g., combination may include a macrolide (clarithromycin, azithromycin), a rifamycin (rifampin, rifabutin), and ethambutol]

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 Mycobacterium avium complex (MAC) lung disease AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will continue treatment with a combination antibiotic therapy for MAC lung disease with the requested agent [e.g., combination may include a macrolide (clarithromycin, azithromycin), a rifamycin (rifampin, rifabutin), and ethambutol]
**Age Restriction:**
**Prescriber Restrictions:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist) 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:**
Armodafinil PA
**Drug Name(s)**
Armodafinil
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Atopic Dermatitis PA – Eucrisa
**Drug Name(s)**
Eucrisa
**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 atopic dermatitis AND
2. 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
**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:**
Attruby PA
**Drug Name(s)**
Attruby
**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 variant transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The diagnosis has been confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing (TTR genotyping)] AND
3. The requested agent will be used to reduce cardiovascular death and cardiovascular-related hospitalization AND
4. Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure AND
5. Patient has clinical manifestations of cardiomyopathy (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) AND
6. Patient will NOT be using the requested agent in combination with Amvuttra or a 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 variant transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular death and cardiovascular-related hospitalization AND
4. Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure AND
5. Patient has had clinical benefit with the requested agent AND
6. Patient will NOT be using the requested agent in combination with Amvuttra or a 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:**
Austedo PA
**Drug Name(s)**
Austedo
Austedo Xr
Austedo Xr Patient Titration Kit
**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 chorea associated with Huntington's disease AND BOTH of the following:
        i. ONE of the following:
            1. Patient does NOT have a current diagnosis of depression OR
            2. Patient has a current diagnosis of depression and is being treated for depression AND
        ii. ONE of the following:
            1. Patient does NOT have a diagnosis of passive suicidal ideation and/or behavior OR
            2. Patient has a diagnosis of passive suicidal ideation and/or behavior and must NOT be actively suicidal OR
    B. Patient has a diagnosis of tardive dyskinesia AND ONE of the following:
        i. Prescriber has reduced the dose of or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) OR
        ii. Prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate AND
2. Patient will NOT be using the requested agent in combination with a monoamine oxidase inhibitor (MAOI) AND
3. 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:**
Benign Prostatic Hyperplasia PA – Tadalafil
**Drug Name(s)**
Tadalafil 2.5Mg, 5Mg
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
Requested agent will be used to treat erectile dysfunction ONLY AND FDA labeled contraindications to the requested agent
**Required Medical Information:**
Criteria for approval require BOTH of the following:
1. Patient has a diagnosis of benign prostatic hyperplasia (BPH) AND
2. Patient has tried and had an insufficient response, intolerance or hypersensitivity, or FDA labeled contraindication to TWO alpha blocker agents (e.g., terazosin, doxazosin, tamsulosin)
**Age Restriction:**
**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:**
Pending CMS Review

**Prior Authorization Group Description:**
Benzodiazepines PA – Clobazam
**Drug Name(s)**
Clobazam
**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 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 – Clorazepate
**Drug Name(s)**
Clorazepate Dipotassium
**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 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 has 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. Alcohol withdrawal OR
            d. 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:**
PA does NOT apply to patients less than 65 years of age.
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 – Lorazepam
**Drug Name(s)**
Lorazepam
Lorazepam Intensol
**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 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. 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
            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 – Sympazan
**Drug Name(s)**
Sympazan
**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 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. 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. 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. 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 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 – Actemra
**Drug Name(s)**
Actemra
Actemra Actpen
**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 (Hadlima, Rinvoq tablets, Rinvoq solution, or Simlandi) is required for diagnosis of polyarticular juvenile idiopathic arthritis

Use of TWO preferred agents (Hadlima, Rinvoq tablets, or Simlandi) is required for diagnosis of rheumatoid arthritis

Use of ONE preferred agent (Rinvoq tablets) is required for diagnosis of giant cell arteritis

NO preferred agent is required for diagnoses of systemic sclerosis-associated interstitial lung disease (SSc-ILD), cytokine release syndrome, or systemic juvenile idiopathic arthritis

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Cosentyx
**Drug Name(s)**
Cosentyx
Cosentyx Sensoready Pen
Cosentyx Unoready
**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 diagnosis of plaque psoriasis

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

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

**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. 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 ONE preferred agent (Hadlima or Simlandi) is required for diagnoses of ankylosing spondylitis, psoriatic arthritis, adult plaque psoriasis, polyarticular juvenile idiopathic arthritis, or rheumatoid arthritis

NO preferred agent is required for diagnoses of juvenile psoriatic arthritis or pediatric plaque psoriasis

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Entyvio SC
**Drug Name(s)**
Entyvio Pen
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Hadlima
**Drug Name(s)**
Hadlima
Hadlima Pushtouch
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**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 (Hadlima, Rinvoq tablets, Rinvoq solution, or Simlandi) is required for diagnosis of juvenile idiopathic arthritis

Use of TWO preferred agents (Hadlima, Rinvoq tablets, or Simlandi) is required for diagnosis of rheumatoid arthritis

For patients 18 years of age or over, use of TWO preferred agents (Cosentyx, Hadlima, Otezla, Rinvoq tablets, Rinvoq solution, Simlandi, Skyrizi, Stelara, Steqeyma, or Tremfya) is required for diagnosis of psoriatic arthritis

For patients between 6 and less than 18 years of age, use of ONE preferred agent (Cosentyx) is required for diagnosis of psoriatic arthritis

For patients between 2 and less than 6 years of age, NO preferred agent 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 – Pyzchiva
**Drug Name(s)**
Pyzchiva
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Rinvoq Solution
**Drug Name(s)**
Rinvoq Lq
**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) OR
        iv. The request is for an FDA labeled indication that is not covered by 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 (Hadlima or Simlandi) is required for diagnoses of adult psoriatic arthritis or juvenile idiopathic arthritis

NO preferred TNF agent is required for diagnosis of pediatric psoriatic arthritis

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Rinvoq Tablet
**Drug Name(s)**
Rinvoq Tablet
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Selarsdi
**Drug Name(s)**
Selarsdi
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA - Simlandi
**Drug Name(s)**
Simlandi
**Indications:**
All FDA-Approved Indications
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Skyrizi
**Drug Name(s)**
Skyrizi
Skyrizi Pen
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Stelara
**Drug Name(s)**
Stelara
Ustekinumab
**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 plaque psoriasis or Crohn's disease

NO prerequisites are required for diagnoses of psoriatic arthritis, moderate ulcerative colitis, or severe ulcerative colitis

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

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Steqeyma
**Drug Name(s)**
Steqeyma
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Biologic Immunomodulators PA – Tremfya
**Drug Name(s)**
Tremfya
**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 plaque psoriasis or Crohn's disease

NO prerequisites are required for diagnoses of psoriatic arthritis, moderate ulcerative colitis, or severe ulcerative colitis

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

**Prior Authorization Group Description:**
Biologic Immunomodulators PA - Tyenne
**Drug Name(s)**
Tyenne
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 (Hadlima, Rinvoq tablets, Rinvoq solution, or Simlandi) is required for diagnosis of polyarticular juvenile idiopathic arthritis

Use of TWO preferred agents (Hadlima, Rinvoq tablets, or Simlandi) is required for diagnosis of rheumatoid arthritis

Use of ONE preferred agent (Rinvoq tablets) is required for diagnosis of giant cell arteritis

NO preferred agent is required for diagnoses of cytokine release syndrome or systemic juvenile idiopathic arthritis

**Prior Authorization Group Description:**
Budesonide Oral ER PA – Entocort
**Drug Name(s)**
Budesonide Dr (Entocort)
**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:**
Budesonide Oral ER PA – Uceris
**Drug Name(s)**
Budesonide Er (Uceris)
**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:**
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:**
Cayston PA
**Drug Name(s)**
Cayston
**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 tobramycin) OR
    b. Patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., 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
**Age Restriction:**
**Prescriber Restrictions:**
**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 ONLY 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 Hcl
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**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:**
Cobenfy PA
**Drug Name(s)**
Cobenfy
Cobenfy Starter Pack
**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 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 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Prescriber has assessed the patient's liver enzymes and bilirubin prior to starting therapy with the requested agent AND
        ii. Prescriber has assessed the patient's heart rate prior to starting therapy with the requested agent AND
        iii. ONE of the following:
            a. Patient has tried and had an inadequate response to TWO antipsychotic agents (e.g., aripiprazole, haloperidol, loxapine, olanzapine, quetiapine, risperidone) for the requested indication OR
            b. Patient has an intolerance or hypersensitivity to TWO antipsychotic agents (e.g., aripiprazole, haloperidol, loxapine, olanzapine, quetiapine, risperidone) OR
            c. Patient has an FDA labeled contraindication to TWO antipsychotic agents (e.g., aripiprazole, haloperidol, loxapine, olanzapine, quetiapine, risperidone) AND
        iv. 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. Patient has an FDA labeled indication 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. Prescriber has assessed the patient's liver enzymes and bilirubin as clinically indicated during treatment with the requested agent AND

ii. Prescriber has assessed the patient's heart rate as clinically indicated during treatment with the requested agent AND

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

iv. Patient has had clinical benefit with the requested agent

**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:**
Corlanor PA
**Drug Name(s)**
Corlanor
Ivabradine Hcl
**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. ONE of following:
    A. ALL of the following:
        i. Patient has stable, symptomatic heart failure (e.g., NYHA Class II, III, IV: ACCF/AHA Class C, D) due to dilated cardiomyopathy (DCM) AND
        ii. The requested agent is for a pediatric patient, 6 months of age or over AND
        iii. Patient is in sinus rhythm with an elevated heart rate OR
    B. ALL of the following:
        i. Patient has stable, symptomatic chronic heart failure (e.g., NYHA Class II, III, IV: ACCF/AHA Class C, D) AND
        ii. The requested agent is for an adult patient AND
        iii. Patient has a baseline OR current left ventricular ejection fraction of 35% or less AND
        iv. 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
        v. ONE of the following:
            a. Patient is on a maximally tolerated dose of beta blocker (e.g., bisoprolol, carvedilol, metoprolol) OR
            b. 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 or invasive mucormycosis and patient has continued indicators of active disease (e.g.) biomarkers in serum assay, microbiologic culture, radiographic evidence) OR
    B. 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:**
Pending CMS Review

**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:**
Pending CMS Review

**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 or more migraine headache days per month 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 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 BOTH 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., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), mirtazapine, bupropion) OR
                    2. Patient has an intolerance or hypersensitivity to at least two different oral antidepressants (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), mirtazapine, bupropion) OR
                    3. Patient has an FDA labeled contraindication to at least two different oral antidepressants (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (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:**
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 - Epogen/Procrit
**Drug Name(s)**
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 less than or equal to 13 g/dL 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 (there must be a minimum of 2 additional months of planned 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 less than or equal to 13 g/dL 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 (there must be a minimum of 2 additional months of planned 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:**
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 BOTH of the following:
        i. Prescriber has provided the patient's type of cancer AND
        ii. 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 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:**
Flucytosine PA
**Drug Name(s)**
Flucytosine
**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 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. The requested agent will be used in combination with amphotericin B OR
    B. Prescriber has provided information in support of therapy without concurrent amphotericin B for the requested indication 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:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis
**Coverage Duration:**
Approval will be for 10 weeks
**Other Criteria:**

**Prior Authorization Group Description:**
Focalin PA
**Drug Name(s)**
Dexmethylphenidate Hcl (Focalin)
**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:**
Gammagard/Gammaked/Gamunex-C PA
**Drug Name(s)**
Gammagard Liquid
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., mycophenolate)] 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., Enbrel), 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, dimethyl fumarate, fingolimod, glatiramer, Glatopa, Kesimpta, Plegridy, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:
i. Patient has failed ONE conventional therapy (e.g., desmopressin, von Willebrand factor replacement therapy, corticosteroids, 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:**
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 (prior to therapy for the requested indication) 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 glucocerebrosidase (GBA) gene with two disease-causing alleles AND
2. 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 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 Gaucher disease type 1 (GD1) 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:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, hepatologist, 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 – Elelyso
**Drug Name(s)**
Elelyso
**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 (prior to therapy for the requested indication) 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 glucocerebrosidase (GBA) gene with two disease-causing alleles AND
2. 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 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 Gaucher disease type 1 (GD1) 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:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, hepatologist, 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 (prior to therapy for the requested indication) 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 glucocerebrosidase (GBA) gene with two disease-causing alleles AND
2. 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 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 Gaucher disease type 1 (GD1) 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:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, hematologist, hepatologist, 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:**
Gauze Pads PA
**Drug Name(s)**
Gauze Pads
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
This program will be implemented as a dynamic PA.
Criteria for approval require BOTH of the following:
1. The requested medical supply product will be used in the delivery of insulin to the body AND
2. Patient's medication history includes use of insulin within the past 180 days
**Age Restriction:**
**Prescriber Restrictions:**
**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 – 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-nl-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, angiopoietin-1 (ANGPT1) 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-nl-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, angiopoietin-1 (ANGPT1) 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:**
High Risk Medication PA - All Starts
**Drug Name(s)**
Cyproheptadine Hcl
Dicyclomine Hcl
Diphenoxylate/Atropine
Hydroxyzine Hcl
Promethazine Hcl
Scopolamine
**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:**
Imiquimod PA
**Drug Name(s)**
Imiquimod Cream 5%
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Criteria for approval require the following:
1. Patient has ONE of the following diagnoses:
    A. Actinic keratosis OR
    B. Superficial basal cell carcinoma OR
    C. External genital and/or perianal warts/condyloma acuminata OR
    D. Squamous cell carcinoma OR
    E. Basal cell carcinoma OR
    F. Another indication that is supported in CMS approved compendia for the requested agent
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
4 months for Actinic keratosis, other diagnoses - see Other Criteria
**Other Criteria:**
2 months for Superficial basal cell carcinoma, Squamous cell carcinoma, or Basal cell carcinoma

4 months for External genital and/or perianal warts/condyloma acuminata

12 months for All other diagnoses

**Prior Authorization Group Description:**
Inbrija PA
**Drug Name(s)**
Inbrija
**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. The requested agent will be used for intermittent treatment of OFF episodes in patients with Parkinson's disease AND
2. The requested agent will be used in combination with carbidopa/levodopa
**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:**
Ingrezza PA
**Drug Name(s)**
Ingrezza
**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 chorea associated with Huntington's disease AND BOTH of the following:
        i. ONE of the following:
            1. Patient does NOT have a current diagnosis of depression OR
            2. Patient has a current diagnosis of depression and is being treated for depression AND
        ii. ONE of the following:
            1. Patient does NOT have a diagnosis of passive suicidal ideation and/or behavior OR
            2. Patient has a diagnosis of passive suicidal ideation and/or behavior and must NOT be actively suicidal OR
    B. Patient has a diagnosis of tardive dyskinesia AND ONE of the following:
        i. Prescriber has reduced the dose of or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) OR
        ii. Prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
Injectable Oncology PA
**Drug Name(s)**
Firmagon
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Insulin Pen Needle PA
**Drug Name(s)**
Insulin Pen Needle
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
This program will be implemented as a dynamic PA.
Criteria for approval require BOTH of the following:
1. The requested medical supply product will be used in the delivery of insulin to the body AND
2. Patient's medication history includes use of insulin within the past 180 days
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
Insulin Syringe_Needle PA
**Drug Name(s)**
Insulin Syringe/Needle
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
This program will be implemented as a dynamic PA.
Criteria for approval require BOTH of the following:
1. The requested medical supply product will be used in the delivery of insulin to the body AND
2. Patient's medication history includes use of insulin within the past 180 days
**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:**
Isotretinoin PA
**Drug Name(s)**
Accutane
Amnesteem
Claravis
Isotretinoin
Zenatane
**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. Patient has an FDA labeled indication or 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
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be 6 months for initial, 12 months for renewal
**Other Criteria:**

**Prior Authorization Group Description:**
Ivermectin Tablet PA
**Drug Name(s)**
Ivermectin Tablet
**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 4 months
**Other Criteria:**

**Prior Authorization Group Description:**
Jubbonti PA
**Drug Name(s)**
Jubbonti
**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:**
Pending CMS Review

**Prior Authorization Group Description:**
Jynarque PA
**Drug Name(s)**
Jynarque
Tolvaptan (Jynarque)
**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 autosomal dominant polycystic kidney disease (ADPKD) confirmed by ONE of the following:
    A. Ultrasound OR
    B. MRI or CT scan OR
    C. Genetic testing AND
2. Patient is at risk of rapid disease progression 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 autosomal dominant polycystic kidney disease (ADPKD) 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:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., 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:**
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:**
Leuprolide PA
**Drug Name(s)**
Eligard
Leuprolide Acetate
Lupron Depot
Lupron Depot-Ped
**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. 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
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
L-glutamine PA
**Drug Name(s)**
L-glutamine
**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 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

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 sickle cell disease AND
3. Patient is using the requested agent to reduce the acute complications of sickle cell disease AND
4. Patient has had clinical benefit with 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:**
Lidocaine Topical PA - Lidocaine Patch
**Drug Name(s)**
Lidocaine Patch
Lidocan
Tridacaine 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
**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:**
Mavyret PA
**Drug Name(s)**
Mavyret
**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:**
Memantine PA
**Drug Name(s)**
Memantine Hcl Titration Pak
Memantine Hcl
**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:**
Methylin PA
**Drug Name(s)**
Methylphenidate Hcl (Methylin)
**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:**
Methylphenidate ER Tablet PA
**Drug Name(s)**
Methylphenidate Hcl Er 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 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:**
Miebo PA
**Drug Name(s)**
Miebo
**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:**
Mifepristone PA
**Drug Name(s)**
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 had an inadequate response to 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:**
Migranal PA
**Drug Name(s)**
Dihydroergotamine Mesylate Spray
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Pending CMS Review

**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:**
Mounjaro PA
**Drug Name(s)**
Mounjaro
**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 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 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR
    C. ALL of the following:
        i. Patient does NOT have any FDA labeled contraindications to the requested agent AND
        ii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND
        iii. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor
**Age Restriction:**
**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 – Fingolimod
**Drug Name(s)**
Fingolimod Hcl
**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. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication AND
3. Prescriber has performed an electrocardiogram within 6 months prior to initiating treatment

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)**
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 – Kesimpta
**Drug Name(s)**
Kesimpta
**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 – 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:**
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 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
**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., 5HT-1F, ergotamine, acute CGRP) OR
    B. The requested agent is being used for migraine prophylaxis AND BOTH of the following:
        i. Patient has 4 or more migraine headache days per month AND
        ii. 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. 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., 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
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months

**Other Criteria:**

**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:**
Omnipod PA
**Drug Name(s)**
Omnipod Kit
Omnipod Pods
**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 diabetes mellitus AND
2. Patient is on an insulin regimen of 3 or more injections per day AND
3. ONE of the following:
    A. Patient is testing glucose levels 4 or more times per day OR
    B. Patient is using a continuous glucose monitor (CGM)

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 diabetes mellitus AND
3. Patient has had clinical benefit with the requested agent (e.g., stable or improved glycemic control)
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
Ophthalmic Immunomodulators PA – Xiidra
**Drug Name(s)**
Xiidra
**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:**
Opioids ER PA - Fentanyl Patch
**Drug Name(s)**
Fentanyl Patch
**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 cancer-related pain 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 completed a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis 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 – Morphine
**Drug Name(s)**
Morphine Sulfate 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 cancer-related pain 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 completed a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis 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 cancer-related pain 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 completed a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis 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:**
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 the following:
1. ONE of the following:
    A. BOTH of the following:
        i. Patient has ONE of the following diagnoses:
            1. Plaque psoriasis OR
            2. Active psoriatic arthritis AND
        ii. ONE of the following:
            1. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
            2. 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
            3. Patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication OR
            4. Patient has tried and had an inadequate response to at least ONE conventional prerequisite agent for the requested indication OR
            5. Patient has an intolerance or hypersensitivity to at least ONE conventional prerequisite agent for the requested indication OR
            6. Patient has an FDA labeled contraindication to at least ONE conventional prerequisite agent for the requested indication OR
    B. 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 ONE of the following diagnoses:
    A. Plaque psoriasis OR
    B. Active psoriatic arthritis OR
    C. 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 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 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR
    C. ALL of the following:
        i. Patient does NOT have any FDA labeled contraindications to the requested agent AND
        ii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND
        iii. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

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

**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)**
Posaconazole
Posaconazole Dr
**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:**
Approval will be 1 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., biomarkers in serum assay, microbiologic cultures, radiographic evidence) 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:
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 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 -2.5) OR
f. Pt is at high risk for falls or has a history of injurious falls OR
g. Pt has a high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 20%, hip fracture greater than 3%) 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 lower limit of the testing laboratory's normal range OR
B. Pt has a pretreatment or current calcium level that is below the lower limit 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, 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)**
Eltrombopag
**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 (pt) has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
        i. Pt has tried and had an insufficient response to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
        ii. Pt has an intolerance or hypersensitivity to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
        iii. Pt has an FDA labeled contraindication to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
        iv. Pt has had an insufficient response to a splenectomy OR
    B. Pt has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:
        i. Pt's platelet count is less than 75 x 10^9/L AND the intent is to increase platelet counts sufficiently to initiate interferon therapy OR
        ii. Pt is on concomitant therapy with interferon therapy AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia OR
    C. Pt has a diagnosis of severe aplastic anemia (SAA) AND ALL of the following:
        i. Pt has at least 2 of the following blood criteria:
            1. Neutrophils less than 0.5 X 10^9/L OR
            2. Platelets less than 30 X 10^9/L OR
            3. Reticulocyte count less than 60 X 10^9/L AND
        ii. Pt has at least 1 of the following marrow criteria:
            1. Severe hypocellularity is less than 25% OR
            2. Moderate hypocellularity is 25-50% with hematopoietic cells representing less than 30% of residual cells AND
        iii. ONE of the following:
            1. Pt has tried and had an insufficient response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy OR
            2. BOTH of the following:
                a. Pt will be using the requested agent as first-line treatment (i.e., has not been treated with ATG and/or cyclosporine) AND
                b. Pt will use the requested agent in combination with standard immunosuppressive therapy (i.e., ATG AND cyclosporine) OR

Initial criteria continues: see Other Criteria
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**

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

**Other Criteria:**

D. Pt 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

Criteria for renewal approval require ALL 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 x 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 interferon therapy OR

2. Pt will be maintaining hepatitis C therapy with interferon therapy at the same time as the requested agent AND

ii. ONE of the following:

1. Pt's platelet count is 90 x 10^9/L or greater OR

2. Pt's platelet count has increased sufficiently to initiate or maintain interferon 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 AND

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

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 2 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 2 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 BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established 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

**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 2 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 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 OR

e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following:

1. Patient is classified as WHO functional class IV or has been assessed as high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) AND
2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid

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 2 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 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 OR

e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following:

1. Patient is classified as WHO functional class IV or has been assessed as high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) AND
2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid 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 – Orenitram
**Drug Name(s)**
Orenitram
Orenitram Titration Kit
**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 2 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 or has been assessed as intermediate to high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) 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

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 as part of triple therapy in a treatment naive patient AND BOTH of the following:

1. Patient is classified as WHO functional class IV or has been assessed as high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) AND
2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid OR

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

1. Patient is WHO functional class III or IV or has been assessed as intermediate to high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) AND
2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All four agents in the quadruple 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 Citrate
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
Concurrently taking another phosphodiesterase 5 (PDE5) 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 2 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 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 OR

e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following:

1. Patient is classified as WHO functional class IV or has been assessed as high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) AND
2. The three agents being utilized consist of ERA plus PDE5i plus prostanoid 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)**
Tadalafil Tablet 20Mg
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
Concurrently taking another phosphodiesterase 5 (PDE5) 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 2 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 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 OR

e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following:

1. Patient is classified as WHO functional class IV or has been assessed as high risk using another PAH risk stratification tool (e.g., 6-minute walking distance, natriuretic peptide) AND
2. The three agents being utilized consist of ERA plus PDE5i plus prostanoid 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 – Winrevair
**Drug Name(s)**
Winrevair
**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 2 Wood units AND
        v. ALL of the following:
            a. The requested agent will be utilized for add-on therapy AND
            b. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
            c. All agents in the 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:**
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:**
Pyrukynd PA
**Drug Name(s)**
Pyrukynd
Pyrukynd Taper Pack
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Criteria for initial approval require the following:
1. Patient has a diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD) AND ALL of the following:
    A. ONE of the following:
        i. Genetic testing showing a pathogenic PKLR gene mutation OR
        ii. Patient does NOT have two known pathogenic mutations in the PKLR gene, AND patient has a decrease in pyruvate kinase enzyme activity AND
    B. Patient is NOT homozygous for the c.1436G to A (p.R479H) variant AND
    C. Patient has at least 2 variant alleles in the PKLR gene, of which at least 1 is a missense variant AND
    D. Patient does NOT have two non-missense 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 hemolytic anemia with pyruvate kinase deficiency (PKD) 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., hematologist) 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:**
Quinine PA
**Drug Name(s)**
Quinine Sulfate
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**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. ONE of the following:
            a. Patient is 18 years of age or older AND has a pretreatment LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) OR
            b. Patient is between the ages of 10 and less than 18 years of age AND has a pretreatment LDL-C greater than 155 mg/dL (greater than 4.0 mmol/L) OR
        iii. Clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, corneal arcus, tuberous xanthomas, or xanthelasma) OR
        iv. "Definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria OR
        v. A Dutch Lipid Clinic Network criteria score of greater than 5 OR
        vi. A treated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 100 mg/dL 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 bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the LDLR, Apo-B, PCSK9, or LDLRAP1 genes or greater than or equal to 2 such variants at different loci OR
        ii. History of untreated LDL-C greater than 400 mg/dL (greater than 10 mmol/L) AND ONE of the following:
            a. Cutaneous or tendon xanthomas before 10 years of age OR
            b. Untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia (HeFH) in both parents (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) OR

Initial criteria continues: see Other Criteria
**Age Restriction:**
**Prescriber Restrictions:**

**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

C. BOTH of the following:

i. A diagnosis of established cardiovascular disease [acute coronary syndrome (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), peripheral artery disease (PAD) including aortic aneurysm] AND

ii. The requested agent will be used to reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) OR

D. A diagnosis of primary hyperlipidemia (not associated with HeFH, HoFH, or established cardiovascular disease) OR

E. Patient has another indication 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 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

3. 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:**
Revcovi PA
**Drug Name(s)**
Revcovi
**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 adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by ONE of the following:
    A. Molecular genetic confirmation of mutations in both alleles of the ADA1 gene OR
    B. Deficiency or absence of ADA in lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus OR
    C. Positive screening by T cell receptor excision circles (TRECs) OR
    D. Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates over the testing laboratory's upper limit of the normal range 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 adenosine deaminase severe combined immune deficiency (ADA-SCID) 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:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, hematologist, immunologist, oncologist) 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:**
Rezdiffra PA
**Drug Name(s)**
Rezdiffra
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
Decompensated cirrhosis AND Moderate to severe hepatic impairment (Child-Pugh Class B or C)
**Required Medical Information:**
Criteria for initial approval require BOTH of the following:
1. Patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis AND
2. Patient has stage F2 or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent):
    A. A FIB-4 score consistent with stage F2 or F3 fibrosis adjusted for age AND
    B. ONE of the following:
        i. A liver biopsy OR
        ii. ONE of the following:
            1. Vibration-controlled transient elastography (VCTE, e.g., Fibroscan) OR
            2. Enhanced liver fibrosis (ELF) OR
            3. Magnetic resonance elastography (MRE)

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 noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis 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., hepatologist, gastroenterologist) 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:**
Ritalin PA
**Drug Name(s)**
Methylphenidate Hcl (Ritalin)
**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:**
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:**
Pending CMS Review

**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 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 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR
    C. ALL of the following:
        i. Patient does NOT have any FDA labeled contraindications to the requested agent AND
        ii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND
        iii. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
Sapropterin PA
**Drug Name(s)**
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
Abirtega
Akeega
Alecensa
Alunbrig
Augtyro
Avmapki Fakzynja Co-Pack
Ayvakit
Balversa
Besremi
Bexarotene Capsules
Bosulif
Braftovi
Brukinsa
Cabometyx
Calquence
Caprelsa
Cometriq
Copiktra
Cotellic
Danziten
Dasatinib
Daurismo
Erivedge
Erleada
Erlotinib Hcl
Everolimus
Fotivda
Fruzaqla
Gavreto
Gefitinib
Gilotrif
Gomekli
Hernexeos
Ibrance
Ibtrozi
Iclusig
Idhifa
Imatinib Mesylate
Imbruvica
Imkeldi

Inlyta
Inqovi
Inrebic
Itovebi
Iwilfin
Jakafi
Jaypirca
Kisqali
Kisqali Femara
Koselugo
Krazati
Lapatinib Ditosylate
Lazcluze
Lenalidomide
Lenvima
Lonsurf
Lorbrena
Lumakras
Lynparza
Lytgobi
Matulane
Mekinist
Mektovi
Modeyso
Nerlynx
Nilotinib
Ninlaro
Nubeqa
Odomzo
Ogsiveo
Ojemda
Ojjaara
Onureg
Orgovyx
Orserdu
Pazopanib Hcl
Pemazyre
Piqray
Pomalyst
Qinlock
Retevmo
Revuforj
Rezlidhia
Romvimza

Rozlytrek
Rubraca
Rydapt
Scemblix
Sorafenib
Stivarga
Sunitinib Malate
Tabrecta
Tafinlar
Tagrisso
Talzenna
Tazverik
Tepmetko
Thalomid
Tibsovo
Torpenz
Tretinoin Capsule
Truqap
Tukysa
Turalio
Vanflyta
Venclexta
Venclexta Starting Pack
Verzenio
Vitrakvi
Vizimpro
Vonjo
Voranigo
Welireg
Xalkori
Xospata
Xpovio
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 CMS approved compendia as a 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
        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
            b. The requested agent is Bosulif AND ONE of the following:
                1. Patient's medication history indicates use of imatinib OR dasatinib for the requested indication (if applicable) OR
                2. Patient has an intolerance or hypersensitivity to imatinib OR dasatinib OR
                3. Patient has an FDA labeled contraindication to imatinib OR dasatinib OR
                4. CMS approved compendia does not support the use of imatinib OR dasatinib for the requested indication OR
                5. Prescriber has provided information in support of use of Bosulif over imatinib OR dasatinib for the requested indication AND
        vi. ONE of the following:
            a. The requested agent is not Ibrance OR

b. The requested agent is Ibrance AND ONE of the following:

1. Patient's medication history indicates use of Kisqali, Kisqali/Femara, OR Verzenio for the requested indication (if applicable) OR
2. Patient has an intolerance or hypersensitivity to Kisqali, Kisqali/Femara, OR Verzenio OR
3. Patient has an FDA labeled contraindication to Kisqali, Kisqali/Femara, OR Verzenio OR
4. CMS approved compendia does not support the use of Kisqali, Kisqali/Femara, OR Verzenio for the requested indication OR
5. Prescriber has provided information in support of use of Ibrance over Kisqali, Kisqali/Femara, OR Verzenio for the requested indication AND

vii. ONE of the following:

a. The requested agent is not Ojjaara OR Inrebic OR

b. The requested agent is Ojjaara OR Inrebic AND ONE of the following:

1. Patient's medication history indicates use of Jakafi for the requested indication (if applicable) OR
2. Patient has an intolerance or hypersensitivity to Jakafi OR
3. Patient has an FDA labeled contraindication to Jakafi OR
4. CMS approved compendia does not support the use of Jakafi for the requested indication OR
5. Prescriber has provided information in support of use of Ojjaara OR Inrebic over Jakafi for the requested indication

**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:**
Pending CMS Review

**Prior Authorization Group Description:**
Sivextro PA
**Drug Name(s)**
Sivextro
**Indications:**
All Medically-Accepted Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Sodium Oxybate PA
**Drug Name(s)**
Sodium Oxybate
**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 narcolepsy with cataplexy OR
    B. BOTH of the following:
        i. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND
        ii. ONE of the following:
            a. Patient is between the ages of 7 and less than 18 years OR
            b. BOTH of the following:
                1. Patient is 18 years of age or over AND
                2. ONE of the following:
                    a) Patient has tried and had an inadequate response to modafinil or armodafinil OR
                    b) Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR
                    c) Patient has an FDA labeled contraindication to modafinil or armodafinil OR
    C. Patient has another 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. 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 OR
    C. 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
**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.
**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:**
Pending CMS Review

**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, Some Medically-Accepted Indications.
**Off-Label Uses:**
Niemann-Pick disease type C (NPC)
**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 Gaucher disease type 1 (GD1) confirmed by ONE of the following:
            a. A baseline (prior to therapy for the requested indication) 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 the glucocerebrosidase (GBA) gene with two disease-causing alleles AND
        ii. 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 OR
    B. ALL of the following:
        i. Patient has a diagnosis of Niemann-Pick disease type C (NPC) as confirmed by genetic analysis mutation in the NPC1 or NPC2 genes AND
        ii. The requested agent will be used for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) AND
        iii. The requested agent will be used in combination with Miplyffa (arimoclomol)
**Age Restriction:**
**Prescriber Restrictions:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, gastroenterologist, geneticist, hematologist, hepatologist, neurologist, 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:**

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 Gaucher disease type 1 (GD1) OR
    B. ALL of the following:
        i. Patient has a diagnosis of Niemann-Pick disease type C (NPC) AND
        ii. The requested agent will be used for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) AND
        iii. The requested agent will be used in combination with Miplyffa (arimoclomol) AND
3. Patient has had clinical benefit with the requested agent

**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)**
Bonsity
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:
    A. Postmenopausal 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 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 -2.5) OR
        vi. Patient is at high risk for falls or has a history of injurious falls OR
        vii. Patient has a high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 20%, hip fracture greater than 3%) 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, or a combination of teriparatide and Tymlos (abaloparatide), 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 or a combination of teriparatide and Tymlos (abaloparatide)

**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) OR
    b. Patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled aztreonam) 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 Diclofenac 3% Gel PA
**Drug Name(s)**
Diclofenac Sodium Gel 3%
**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 actinic keratosis (AK)
**Age Restriction:**
**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 3 months
**Other Criteria:**

**Prior Authorization Group Description:**
Topical NSAID PA – Pennsaid
**Drug Name(s)**
Diclofenac Sodium (Pennsaid)
**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 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:**
3 months for acute pain, 12 months for all other diagnoses
**Other Criteria:**

**Prior Authorization Group Description:**
Topical Retinoids PA – Tazarotene
**Drug Name(s)**
Tazarotene
**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:**
Topical Retinoids PA – Tretinoin
**Drug Name(s)**
Tretinoin Cream, Gel
**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 Hcl
**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 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 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR
    C. ALL of the following:
        i. Patient does NOT have any FDA labeled contraindications to the requested agent AND
        ii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND
        iii. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

**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 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:**
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:**
Valchlor PA
**Drug Name(s)**
Valchlor
**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. BOTH of the following:
        i. ONE of the following:
            a. BOTH of the following:
                1. Patient has a diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma AND
                2. Patient's medication history indicates use of at least ONE prior skin-directed therapy (e.g., topical corticosteroid) OR
            b. 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

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. 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
**Age Restriction:**

**Prescriber Restrictions:**
**Coverage Duration:**
Approval will be for 12 months
**Other Criteria:**

**Prior Authorization Group Description:**
Veozah PA
**Drug Name(s)**
Veozah
**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:**
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. BOTH of the following:
        i. ONE of the following:
            1. Patient has a diagnosis of esophageal candidiasis OR
            2. Patient has a diagnosis of candidemia in nonneutropenic patient OR
            3. Patient has a diagnosis of other deep tissue Candida infections AND
        ii. ONE of the following:
            1. Patient has tried and had an inadequate response to fluconazole or an alternative antifungal agent OR
            2. Patient has an intolerance or hypersensitivity to fluconazole or an alternative antifungal agent OR
            3. 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:**
Approval will be 1 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, other deep tissue Candida infections, or blastomycosis and patient has continued indicators of active disease (e.g., biomarkers in serum assay, microbiologic cultures, radiographic evidence) 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:**
Vowst PA
**Drug Name(s)**
Vowst
**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 prevent the recurrence of Clostridioides difficile infection (CDI) AND
2. Patient has had a confirmed diagnosis of recurrent CDI as defined by greater than or equal to 3 episodes of CDI in a 12 month period AND
3. Patient has completed a standard of care antibiotic regimen (e.g., vancomycin, fidaxomicin) for recurrent CDI at least 2 to 4 days before initiating treatment with the requested agent AND
4. Patient will NOT be using the requested agent in combination with any antibiotic regimen for any 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., infectious disease, gastroenterologist) 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:**
Wyost PA
**Drug Name(s)**
Wyost
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
FDA labeled contraindications to the requested agent
**Required Medical Information:**
Pending CMS Review

**Prior Authorization Group Description:**
Xdemvy PA
**Drug Name(s)**
Xdemvy
**Indications:**
All FDA-Approved Indications.
**Off-Label Uses:**
**Exclusion Criteria:**
**Required Medical Information:**
Criteria for approval require the following:
1. Patient has a diagnosis of Demodex blepharitis AND BOTH of the following:
    A. Patient has ONE of the following signs of Demodex infestation:
        i. Collarettes (cylindrical dandruff at the eyelash base) OR
        ii. Lid margin erythema or edema OR
        iii. Conjunctival injection OR
        iv. Eyelash misdirection/irregularity AND
    B. Patient has ONE of the following symptoms of Demodex infestation:
        i. Blurred/fluctuating vision OR
        ii. Discharge or crusting on lashes OR
        iii. Dryness OR
        iv. Foreign body sensation OR
        v. Itching OR
        vi. Pain/burning OR
        vii. Watering/tearing
**Age Restriction:**
**Prescriber Restrictions:**
Prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, ophthalmologist, optometrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis
**Coverage Duration:**
Approval will be for 6 weeks
**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., octreotide) AND
3. The requested agent will be used in combination with a somatostatin analog (e.g., octreotide)

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., octreotide)
**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 another form of denosumab AND

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

**Prior Authorization Group Description:**
Xifaxan 550 MG Tablet PA
**Drug Name(s)**
Xifaxan 550Mg
**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]
**Age Restriction:**
**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:
                1. Patient's pretreatment IgE level is 30 IU/mL to 1300 IU/mL AND
                2. Patient's weight is 20 kg to 150 kg OR
            b. Patient is 12 years of age or over AND BOTH of the following:
                1. Patient's pretreatment IgE level is 30 IU/mL to 700 IU/mL AND
                2. Patient's weight is 30 kg to 150 kg AND
        ii. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen AND
        iii. ONE of the following:
            a. 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 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 (CSU) 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 chronic rhinosinusitis with nasal polyps (CRSwNP) 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 OR

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 (CSU), patient is 12 years of age or over. For diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), patient is 18 years of age or over. For diagnosis of IgE-mediated food allergy, patient is 1 year of age or over.

**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, hematologist, immunologist, oncologist, 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:**

D. Patient has a diagnosis of IgE-mediated food allergy AND ALL of the following:
i. Patient is using the requested agent for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods AND
ii. IgE-mediated food allergy has been confirmed by an allergy diagnostic test (e.g., skin prick test, serum specific IgE test, oral food challenge) AND
iii. Patient will avoid known food allergens while treated with the requested agent AND
iv. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis AND

2. Patient will NOT be using the requested agent in combination with Dupixent or an injectable Interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, 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 BOTH of the following:
i. Patient has had clinical benefit with the requested agent AND
ii. ONE of the following:
a. 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 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 (CSU) AND the following:
a. Patient has had clinical benefit with the requested agent OR

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

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

D. Patient has a diagnosis of IgE-mediated food allergy AND ALL of the following:

a. Patient is using the requested agent for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods AND

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

c. Patient will avoid known food allergens while treated with the requested agent AND

d. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis 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, Fasenra, Nucala) for the requested indication AND

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

**Prior Authorization Group Description:**
Ztalmy PA
**Drug Name(s)**
Ztalmy
**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 seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) 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's diagnosis has been confirmed with genetic testing indicating variant in CDKL5 gene 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

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 seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) 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. 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
**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:**