2020 PRIOR AUTHORIZATION CRITERIA

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Prior Authorization Group – **Actimmune PA**

Drug Name(s):
ACTIMMUNE

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. The dose requested is within the FDA labeled or CMS approved compendia dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Aimovig PA**

Drug Name(s):
AIMOVIG

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of migraine AND
2. Patient has 4 migraine headaches or more per month AND
3. ONE of the following:
    a. Patient has failed a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a conventional migraine prophylaxis agent AND
4. ONE of the following:
    a. Patient is NOT currently taking another calcitonin gene-related peptide (CGRP) agent OR
    b. Patient is currently being treated with another calcitonin gene-related peptide (CGRP) agent AND will discontinue prior to initiating therapy with 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 a diagnosis of migraine AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    a. Patient is NOT currently taking another calcitonin gene-related peptide (CGRP) agent OR
    b. Patient is currently being treated with another calcitonin gene-related peptide (CGRP) agent AND will discontinue prior to continuing therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Alosetron PA**

Drug Name(s):
alosetron tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Alpha-1-Proteinase Inhibitor PA - Prolastin-C**

Drug Name(s):
PROLASTIN-C

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of alpha-1 antitrypsin deficiency (AATD) AND
2. Patient has a pre-treatment serum alpha-1 antitrypsin (AAT) level less than 11 µM/L (80 mg/dL by immunodiffusion or 57 mg/dL using nephelometry) AND
3. Patient has one of the following phenotype variants associated with AATD: PiZZ, PiSZ, PiZ/Null or PiNull/Null AND
4. Patient has emphysema with a documented baseline FEV1 of 65% or less of predicted AND
5. The dose requested is within the FDA labeled dose 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 shown clinical benefit with the requested agent AND
4. The dose requested is within the FDA labeled dose for the requested indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Amitiza PA**

Drug Name(s):
AMITIZA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has ONE of the following diagnoses:
    a. Chronic idiopathic constipation with documentation of symptoms for at least 3 months OR
    b. Irritable bowel syndrome with constipation with documentation of symptoms for at least 3 months AND the patient is female OR
    c. Opioid-induced constipation with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND BOTH of the following:
        i. Patient has chronic use of an opioid agent within the past 90 days AND
        ii. Patient has NOT received methadone within the past 90 days AND
2. ONE of the following:
    a. Patient has tried and had an inadequate response to lactulose OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to lactulose

Age Restrictions:
Patient is 18 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Anabolic Steroid PA - Danazol**

Drug Name(s):
danazol capsule

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 is NOT currently being treated with another androgen or anabolic steroid within the past 90 days OR
    b. The current androgen or anabolic steroid will be discontinued prior to starting the requested agent OR
    c. Prescriber has submitted documentation in support of therapy with more than one agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Anabolic Steroid PA - Oxandrolone**

Drug Name(s):
oxandrolone tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has ONE of the following diagnoses:
    a. Patient has AIDS/HIV-associated wasting syndrome, defined as unexplained involuntary weight loss (greater than 10% baseline body weight) with obvious wasting or body mass index less than 18.5 kg/m2 AND all other causes of weight loss have been ruled out OR
    b. Patient is a female child or adolescent with Turner syndrome AND is currently receiving growth hormone OR
    c. Patient has weight loss following extensive surgery, chronic infections, or severe trauma OR
    d. Patient has chronic pain from osteoporosis OR
    e. Patient is on long-term administration of oral or injectable corticosteroids AND
2. ONE of the following:
    a. Patient is NOT currently being treated with another androgen or anabolic steroid within the past 90 days OR
    b. The current androgen or anabolic steroid will be discontinued prior to starting the requested agent OR
    c. Prescriber has submitted documentation in support of therapy with more than one agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Anabolic Steroid PA - Oxymetholone**

Drug Name(s):
ANADROL-50

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has ONE of the following diagnoses:
    a. Patient has anemia caused by deficient red cell production, including acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs OR
    b. Patient has anemia associated with chronic renal failure AND ONE of the following:
        i. Patient's medication history indicates previous use of an erythropoiesis-stimulating agent OR
        ii. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to an erythropoiesis-stimulating agent AND
2. Patient has a hematocrit (Hct) value less than 30% AND
3. ONE of the following:
    a. Patient is NOT currently being treated with another androgen or anabolic steroid within the past 90 days OR
    b. The current androgen or anabolic steroid will be discontinued prior to starting the requested agent OR
    c. Prescriber has submitted documentation in support of therapy with more than one agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Androgen Injectable PA - testosterone cypionate**

Drug Name(s):
testosterone cypionate injection

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has ONE of the following diagnoses:
    a. Patient is a male with AIDS/HIV-associated wasting syndrome, defined as unexplained involuntary weight loss (greater than 10% baseline body weight) with obvious wasting OR body mass index less than 18.5 kg/m2 AND all other causes of weight loss have been ruled out OR
    b. Patient is a female with metastatic/inoperable breast cancer OR
    c. Patient is a male with primary or secondary (hypogonadotropic) hypogonadism OR
    d. Patient is an adolescent male with delayed puberty AND
2. Patient is a male with 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 treated levels:
        i. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR
        ii. Free serum testosterone level is within OR below the testing laboratory's normal range AND
3. ONE of the following:
    a. Patient is NOT currently being treated with another androgen or anabolic steroid within the past 90 days OR
    b. The current androgen or anabolic steroid will be discontinued prior to starting the requested agent OR
    c. Prescriber has submitted documentation in support of therapy with more than one agent

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

Prior Authorization Group – **Androgen Topical PA**

Drug Name(s):

ANDRODERM
testosterone 1% gel
testosterone 1% gel pump
testosterone 1.62% gel
testosterone 1.62% gel pump

Off-Label Uses:

Exclusion Criteria:

FDA labeled contraindication(s) to the requested agent

Required Medical:

Criteria for approval require ALL of the following:

1. Patient has ONE of the following diagnoses:
    a. Patient has AIDS/HIV-associated wasting syndrome, defined as unexplained involuntary weight loss (greater than 10% baseline body weight) with obvious wasting OR body mass index less than 18.5 kg/m2 AND all other causes of weight loss have been ruled out OR
    b. Patient is a male with primary or secondary (hypogonadotropic) hypogonadism AND
2. Patient is a male with 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 treated levels:
        i. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR
        ii. Free serum testosterone level is within OR below the testing laboratory's normal range AND
3. ONE of the following:
    a. Patient is NOT currently being treated with another androgen or anabolic steroid within the past 90 days OR
    b. The current androgen or anabolic steroid will be discontinued prior to starting the requested agent OR
    c. Prescriber has submitted documentation in support of therapy with more than one agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Antipsychotics PA**

Drug Name(s):
ADASUVE
CHLORPROMAZINE injection
chlorpromazine tablet
FLUPHENAZINE concentrate, elixir, injection
fluphenazine decanoate 25 mg/mL injection
fluphenazine tablet
haloperidol concentrate, tablet
haloperidol decanoate injection
haloperidol lactate injection
loxapine capsule
MOLINDONE
perphenazine tablet
thioridazine tablet
thiothixene capsule
trifluoperazine tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only. 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 using the requested agent OR
    C. IF dementia-related psychosis and/or dementia related behavioral symptoms, BOTH of the following:
        i. Dementia-related psychosis is determined to be severe or the associated behavior puts the patient or others in danger AND
        ii. Prescriber has documented that s/he has discussed the risk of increased mortality with the patient and/or the patient's surrogate decision maker

Approval authorizations will apply to the requested medication only.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Apokyn PA**

Drug Name(s):
APOKYN

Off-Label Uses:

Exclusion Criteria:
Patient will be receiving a 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) concomitantly with the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. The requested agent will be used to treat acute, intermittent hypomobility, “off” episodes (“end of dose wearing off” and unpredictable “on/off” episodes) associated with advanced Parkinson’s disease AND
2. Patient is receiving concurrent therapy for Parkinson’s disease (e.g., levodopa, dopamine agonist, or monoamine oxidase B inhibitor) within the past 30 days

Age Restrictions:

Prescriber Restrictions:
Prescriber is a neurologist or the prescriber has consulted with a neurologist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Arcalyst PA**

Drug Name(s):
ARCALYST

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) AND
2. ONE of the following:
    A. Patient is NOT currently being treated with another biologic agent OR
    B. Patient is currently being treated with another biologic agent and the agent will be discontinued prior to initiating the requested agent

Age Restrictions:
Patient is at least 12 years of age

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Armodafinil PA**

Drug Name(s):
armodafinil tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. Patient is receiving only one of the listed agents, armodafinil OR modafinil, within the past 90 days OR
    B. Patient has been treated with modafinil within the past 90 days AND will discontinue prior to starting the requested agent

Age Restrictions:
Patient is 17 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Atopic Dermatitis PA - Pimecrolimus**

Drug Name(s):
pimecrolimus 1% cream

Off-Label Uses:

Exclusion Criteria:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Atopic Dermatitis PA - Tacrolimus**

Drug Name(s):
tacrolimus ointment

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require ONE of the following:
1. Patient has a diagnosis of atopic dermatitis AND ONE of the following:
    a. Patient has had a trial and failure with a topical corticosteroid or topical corticosteroid combination preparation (e.g., hydrocortisone, triamcinolone) OR
    b. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity 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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Benlysta PA**

Drug Name(s):
BENLYSTA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of active systemic lupus erythematosus (SLE) disease AND
2. Patient has a history of positive antinuclear antibody (ANA) and/or positive anti-dsDNA results AND
3. Patient has a history of 3 other SLE diagnostic criteria {i.e., malar rash, discoid rash, photosensitivity, oral ulcers, nonerosive arthritis, serositis [e.g., pleuritis/pericarditis], renal disorder [e.g., persistent proteinuria greater than 0.5 grams/day or cellular casts], hematologic disorder [e.g., hemolytic anemia (with reticulocytosis), leukopenia, lymphopenia, or thrombocytopenia], and/or immunologic disorder [e.g., positive finding of antiphospholipid antibodies or anti-Sm antibodies]} AND
4. ONE of the following:
    a. There is evidence of a claim that the patient is currently on SLE treatment regimen within the past 90 days comprised of at least ONE of the following: corticosteroids (e.g., methylprednisolone, prednisone), antimalarials (e.g., hydroxychloroquine, chloroquine), prescription nonsteroidal anti-inflammatory drugs (NSAIDS) (e.g., ibuprofen, naproxen), and/or immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine, or oral cyclophosphamide) OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to any standard of care drug classes listed above AND
5. ONE of the following:
    a. Patient has NOT been treated with intravenous (IV) cyclophosphamide in the past 30 days OR
    b. Patient has been treated with IV cyclophosphamide in the past 30 days AND will discontinue prior to starting the requested agent AND
6. ONE of the following:
    a. Patient has NOT been treated with another biologic agent in the past 30 days OR
    b. Patient has been treated with another biologic agent in the past 30 days AND will discontinue prior to starting the requested agent

Age Restrictions:

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 diagnosis of active systemic lupus erythematosus (SLE) disease AND
3. ONE of the following:
    a. There is evidence of a claim that the patient is currently on SLE treatment regimen within the past 90 days comprised of at least ONE of the following: corticosteroids (e.g., methylprednisolone, prednisone), antimalarials (e.g., hydroxychloroquine, chloroquine), prescription nonsteroidal anti-inflammatory drugs (NSAIDS) (e.g., ibuprofen, naproxen), and/or immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine, or oral cyclophosphamide) OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to any standard of care drug classes listed above AND
4. Patient has had a decrease in symptoms or stabilization in at least ONE SLE diagnostic criteria {i.e., malar rash, discoid rash, photosensitivity, oral ulcers, nonerosive arthritis, serositis [e.g., pleuritis/pericarditis], renal disorder [e.g., persistent proteinuria greater than 0.5 grams/day or cellular casts], hematologic disorder [e.g., hemolytic anemia (with reticulocytosis), leukopenia, lymphopenia, or thrombocytopenia], and/or immunologic disorder [e.g., positive finding of antiphospholipid antibodies or anti-Sm antibodies]} AND
5. ONE of the following:
    a. Patient has NOT been treated with intravenous (IV) cyclophosphamide in the past 30 days OR
    b. Patient has been treated with IV cyclophosphamide in the past 30 days AND will discontinue prior to continuing the requested agent AND
6. ONE of the following:
    a. Patient has NOT been treated with another biologic agent in the past 30 days OR
    b. Patient has been treated with another biologic agent in the past 30 days AND will discontinue prior to continuing the requested agent

Prior Authorization Group – **Benzodiazepines PA - Clobazam**

Drug Name(s):
clobazam suspension, tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
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 using 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 contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Benzodiazepines PA - Clorazepate**

Drug Name(s):
clorazepate tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
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 using 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's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
                2) Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs 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 contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Benzodiazepines PA - Diazepam**

Drug Name(s):
DIAZEPAM 1 mg/mL oral solution
diazepam tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
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 using 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's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
                2) Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs 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 contraindication(s) to the requested agent

Age Restrictions:
Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Benzodiazepines PA - Lorazepam**

Drug Name(s):
lorazepam tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
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 using 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's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
                2) Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs 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 contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Benzodiazepines PA - Sympazan**

Drug Name(s):
SYMPAZAN

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
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 using 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 contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Biologic Immunomodulators PA - Cosentyx**

Drug Name(s):
COSENTYX

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

NO prerequisites are required for a diagnosis of ankylosing spondylitis

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

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group – **Biologic Immunomodulators PA - Enbrel**

Drug Name(s):
ENBREL

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

NO prerequisites are required for a diagnosis of ankylosing spondylitis

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

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group – **Biologic Immunomodulators PA - Humira**

Drug Name(s):
HUMIRA
HUMIRA KIT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:

A. Patient is NOT currently being treated with another biologic immunomodulator
OR
B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

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

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

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

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

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Formulary conventional agents for crohn's disease or ulcerative colitis include methotrexate, aminosalicylates, corticosteroids, cyclosporine, azathioprine, 6-mercaptopurine, metronidazole, or ciprofloxacin

Prior Authorization Group – **Biologic Immunomodulators PA - Kineret**

Drug Name(s):
KINERET

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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:
            1. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
            2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity 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. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:

A. Patient is NOT currently being treated with another biologic immunomodulator OR
B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of TWO preferred biologics (Enbrel, Humira, or Rinvoq) is required for diagnosis of rheumatoid arthritis

NO preferred biologic is required for diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Prior Authorization Group – **Biologic Immunomodulators PA - Orencia**

Drug Name(s):
ORENCIA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 is at risk if therapy is changed OR
    C. Patient's diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
        1. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
        2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to preferred biologic immunomodulator agent(s) AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of TWO preferred biologics (Enbrel and Humira) is required for diagnosis of juvenile idiopathic arthritis

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

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

Prior Authorization Group – **Biologic Immunomodulators PA - Renflexis**

Drug Name(s):
RENFLEXIS

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity 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. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND

4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of TWO preferred biologics (Enbrel, Humira, or Rinvoq) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred biologics (Cosentyx, Enbrel, Humira, Otezla, or Stelara) is required for diagnoses of psoriatic arthritis

Use of TWO preferred biologics (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

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

Use of TWO preferred biologics (Humira and Stelara) is required for diagnosis of adult Crohn’s disease

Use of ONE preferred biologic (Humira or Stelara) is required for diagnosis of adult ulcerative colitis

Only the preferred biologic Humira is required for diagnosis of pediatric Crohn’s disease

NO preferred biologic is required for diagnoses of adult fistulizing Crohn’s disease or pediatric ulcerative colitis

Prior Authorization Group – **Biologic Immunomodulators PA - Rinvoq**

Drug Name(s):
RINVOQ

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
    E. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of ONE conventional prerequisite agent is required for diagnosis of rheumatoid arthritis

Formulary conventional agents for rheumatoid arthritis include methotrexate, hydroxychloroquine, sulfasalazine, minocycline, or leflunomide

Prior Authorization Group – **Biologic Immunomodulators PA - Rituxan**

Drug Name(s):
RITUXAN

Off-Label Uses:

Exclusion Criteria:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

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

ALL other diagnoses do NOT require any preferred biologics

Prior Authorization Group – **Biologic Immunomodulators PA - Rituxan Hycela**

Drug Name(s):
RITUXAN HYCELA

Off-Label Uses:

Exclusion Criteria:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

There are no preferred biologics required for Rituxan Hycela

Prior Authorization Group – **Biologic Immunomodulators PA - Ruxience**

Drug Name(s):
RUXIENCE

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

There are no preferred biologics required for Ruxience

Prior Authorization Group – **Biologic Immunomodulators PA - Skyrizi**

Drug Name(s):
SKYRIZI

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
    E. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of ONE conventional prerequisite agent is required for diagnosis of psoriasis

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group – **Biologic Immunomodulators PA - Stelara**

Drug Name(s):
STELARA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
    E. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

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

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Formulary conventional agents for Crohn's disease or ulcerative colitis include methotrexate 5-aminosalicylates, corticosteroids, cyclosporine, azathioprine, mercaptopurine, metronidazole, or ciprofloxacin

Prior Authorization Group – **Biologic Immunomodulators PA - Tremfya**

Drug Name(s):
TREMFYA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 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 medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
    E. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR

B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of ONE conventional prerequisite agent is required for diagnosis of psoriasis

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group – **Biologic Immunomodulators PA - Truxima**

Drug Name(s):
TRUXIMA

Off-Label Uses:

Exclusion Criteria:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

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

There are no preferred biologics required for Truxima

Prior Authorization Group – **Biologic Immunomodulators PA - Xeljanz**

Drug Name(s):
XELJANZ

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 is at risk if therapy is changed OR
    C. 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to preferred biologic immunomodulator agent(s) AND
3. ONE of the following:
A. Patient is NOT currently being treated with another biologic immunomodulator OR
B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting 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 for the requested agent AND
3. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. ONE of the following:
    A. Patient is NOT currently being treated with another biologic immunomodulator OR
    B. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of TWO preferred biologics (Enbrel, Humira, or Rinvoq) is required for diagnosis of rheumatoid arthritis

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

Use of ONE preferred biologic (Humira or Stelara) is required for diagnosis of ulcerative colitis

Prior Authorization Group – **Bivigam/Flebogamma/Gammaplex/Octagam/Privigen PA**

Drug Name(s):
GAMMAPLEX

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require ONE of the following:
1. Patient has ONE of the following diagnoses:
    A. Primary immunodeficiency [including 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. Chronic lymphocytic leukemia OR multiple myeloma with reduced IgG AND ONE of the following:
        i. Patient has a history of infections OR
        ii. Patient has evidence of specific antibody deficiency OR
    C. Idiopathic thrombocytopenia purpura AND ONE of the following:
        i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone), or immunosuppressants (e.g., azathioprine)] OR
        ii. Patient has a documented 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 a documented 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
    F. Severe rheumatoid arthritis AND ONE of the following:
        i. Patient has failed ONE conventional therapy [e.g., tumor necrosis factor antagonists (e.g., Humira), DMARDS (e.g., methotrexate), infliximab] OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

Criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 3 months for indications in NHS guidelines, 12 months 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 a documented 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(s) to TWO MS agents (e.g., Aubagio, Avonex, Betaseron, Copaxone, Gilenya, glatiramer, Glatopa, Mayzent, Plegridy, Tecfidera) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:
i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, Rituxan, or recombinant factor VIIa) OR
ii. Patient has a documented 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 a documented 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 3 month approval duration:
Idiopathic thrombocytopenia purpura, Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Myasthenia gravis, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Steven Johnsons syndrome

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

Prior Authorization Group – **Carbaglu PA**

Drug Name(s):
CARBAGLU

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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) AND
2. The dose requested is within the FDA labeled dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., geneticist, metabolic disorders) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Chenodal PA**

Drug Name(s):
CHENODAL

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has a diagnosis of radiolucent stones in a well-opacifying gallbladder AND
2. The dose requested is within the FDA labeled dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Chorionic Gonadotropin PA**

Drug Name(s):
CHORIONIC GONADOTROPIN
PREGNYL

Off-Label Uses:

Exclusion Criteria:
Requested agent will be used to promote fertility or to treat erectile dysfunction AND FDA labeled contraindication(s) to the requested agent

Required Medical:
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 is a 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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Cinacalcet PA**

Drug Name(s):
cinacalcet tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require the following:
1. Patient has ONE of the following:
    A. An FDA approved indication or has an indication that is 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] 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 is at risk if therapy is changed OR
    B. A diagnosis of hypercalcemia due to parathyroid carcinoma OR
    C. 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
    D. Another indication that is supported in CMS approved compendia for the requested agent not otherwise excluded from Part D

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Colony Stimulating Factors PA - Granix**

Drug Name(s):
GRANIX

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 6 months

Other Criteria:

Prior Authorization Group – **Colony Stimulating Factors PA - Leukine**

Drug Name(s):
LEUKINE

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 6 months

Other Criteria:

Prior Authorization Group – **Corlanor PA**

Drug Name(s):
CORLANOR

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has stable, symptomatic chronic heart failure (e.g., NYHA Class II, III, IV: ACCF/AHA Class C, D) AND
2. ONE of following:
    a. ALL of the following:
        i. The requested agent is for a pediatric patient, 6 months or over AND
        ii. Patient has heart failure due to dilated cardiomyopathy (DCM) AND
        iii. Patient is in sinus rhythm with an elevated heart rate OR
    b. ALL of the following:
        i. The requested agent is for an adult patient AND
        ii. Patient has a baseline OR current left ventricular ejection fraction of 35% or less AND
        iii. Patient is in sinus rhythm with a resting heart rate of 70 beats or greater per minute prior to initiating therapy with the requested agent AND
        iv. ONE of the following:
            1. Patient is on a maximally tolerated dose of beta blocker (e.g., bisoprolol, carvedilol, metoprolol) OR
            2. Patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to a beta blocker

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Cresemba PA**

Drug Name(s):
CRESEMBA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of invasive aspergillosis OR
    B. Patient has a diagnosis of invasive mucormycosis OR
    C. Patient has another indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following
    A. Patient has a diagnosis of invasive aspergillosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR
    B. Patient has a diagnosis of invasive mucormycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR
    C. Patient has another indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 6 months

Other Criteria:

Prior Authorization Group – **Crysvita PA**

Drug Name(s):
CRYSVITA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of X-linked hypophosphatemia (XLH) as confirmed by testing for renal phosphate wasting AND radiography AND
2. 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) AND
3. The dose requested is within the 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 X-linked hypophosphatemia (XLH) AND
3. Patient has had clinical improvement 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, and improvement in fracture healing) AND
4. The dose requested is within the FDA labeled dosing for the requested indication

Age Restrictions:
Patient is 6 months of age or over

Prescriber Restrictions:
Prescriber is a specialist (e.g., nephrologist, endocrinologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Cystaran PA**

Drug Name(s):
CYSTARAN

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require the following:
1. Patient has an FDA labeled indication for the requested agent

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., ophthalmologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Cystinosis Agents PA - Cystagon**

Drug Name(s):
CYSTAGON

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 dose requested is within the 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 improvement (e.g., decrease in WBC cystine levels from baseline) with the requested agent AND
4. The dose requested is within the FDA labeled dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Daklinza PA**

Drug Name(s):
DAKLINZA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic hepatitis C infection 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
5. ONE of the following:
    A. There is documentation that the patient is currently being treated with the requested agent OR
    B. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes OR
    C. Prescriber has submitted documentation based on FDA approved labeling or AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

Coverage Duration:

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

Other Criteria:

Prior Authorization Group – **Dalfampridine PA**

Drug Name(s):
dalfampridine ER tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require BOTH of the following:
1. Patient has a diagnosis of multiple sclerosis (MS) AND
2. If the patient has relapsing form of MS, ONE of the following:
    A. There is evidence of a claim that the patient is receiving concurrent therapy within the past 30 days with a disease modifying agent (e.g., Aubagio, Avonex, Betaseron, Extavia, Gilenya, glatiramer (i.e., Copaxone, Glatopa), Lemtrada, mitoxantrone, Plegridy, Rebif, Tecfidera, or Tysabri) OR
    B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying 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 a diagnosis of multiple sclerosis (MS) AND
3. Patient has demonstrated a stabilization or improvement from baseline in timed walking speed (timed 25-foot walk)

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., neurologist) or the prescriber has consulted with a specialist

Coverage Duration:
Initial approval 3 months.
12 months for renewal.

Other Criteria:

Prior Authorization Group – **Daliresp PA**

Drug Name(s):
DALIRESP

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of following:
    a. Patient has had an inadequate response to an agent from two of the following categories:
        i. long-acting beta-2 agonist (LABA) [e.g., salmeterol]
        ii. long-acting muscarinic antagonist/anticholinergic (LAMA) [e.g., umeclidinium]
        iii. inhaled corticosteroid (ICS) [e.g., fluticasone] OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an agent from two of the following categories:
        i. long-acting beta-2 agonist (LABA) [e.g., salmeterol]
        ii. long-acting muscarinic antagonist/anticholinergic (LAMA) [e.g., umeclidinium]
        iii. inhaled corticosteroid (ICS) [e.g., fluticasone]

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Dupixent PA**

Drug Name(s):
DUPIXENT

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of:
    A. Patient (pt) has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of:
        i. ONE of:
            a. Pt has tried and failed a topical steroid (e.g., triamcinolone) OR
            b. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a topical steroid AND
        ii. ONE of:
            a. Pt has tried and failed a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR
            b. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a topical calcineurin inhibitor OR
    B. Pt has a diagnosis of moderate-to-severe asthma AND ALL of:
        i. ONE of:
            a. Pt has an eosinophilic phenotype AND the pt has a baseline blood eosinophil count of 150 cells/microliter or higher OR
            b. Pt has oral corticosteroid dependent asthma AND
        ii. Pt has a baseline Forced Expiratory Volume (FEV1) that is less than 80% of predicted AND
        iii. ONE of:
            a. BOTH of:
                1. Pt is NOT currently being treated with the requested agent AND
                2. Pt is currently being treated with a maximally tolerated inhaled corticosteroid within the past 90 days OR
            b. BOTH of:
                1. Pt is currently being treated with the requested agent AND
                2. Pt is also currently being treated with an inhaled corticosteroid that is dosed as needed to control symptoms OR
            c. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an inhaled corticosteroid AND
        iv. ONE of:
            a. There is evidence of a claim within the past 90 days that the pt is currently being treated with ONE of:

1. A long-acting beta-2 agonist (LABA) OR
2. A leukotriene receptor antagonist (LRTA) OR
3. A long-acting muscarinic antagonist (LAMA) OR
4. Theophylline OR

b. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), or theophylline AND

Initial criteria continues: see Other Criteria

Age Restrictions:

For a diagnosis of moderate-to-severe atopic dermatitis, patient is 6 years of age or over. For a diagnosis of moderate-to-severe asthma, patient is 12 years of age or over. For a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), patient is 18 years of age or over.

Prescriber Restrictions:

Prescriber is a specialist (e.g., allergist, dermatologist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist

Coverage Duration:

Approval will be for 12 months

Other Criteria:

v. The requested agent will NOT be used in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR

C. Pt has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of:

i. There is documentation indicating pt's diagnosis was confirmed by ONE of:

a. Anterior rhinoscopy or endoscopy OR
b. Computed tomography (CT) of the sinuses AND

ii. BOTH of:

a. ONE of:

1. Pt has tried and had an inadequate response to an oral systemic corticosteroid in the past 90 days OR
2. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an oral systemic corticosteroid AND

b. ONE of:

1. Pt has tried and had an inadequate response to an intranasal corticosteroid (e.g., fluticasone) for at least a 3-month trial OR

2. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid AND

iii. Pt will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent AND

2. The dose requested is within the FDA labeled 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:

A. BOTH of:

i. Pt has a diagnosis of moderate-to-severe atopic dermatitis AND

ii. Pt has a reduction or stabilization from baseline in at least ONE of:

a. Affected body surface area OR

b. Flares OR

c. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification OR

B. Pt has a diagnosis of moderate-to-severe asthma AND ALL of:

i. Pt has had clinical response or disease stabilization with the requested agent AND

ii. ONE of:

a. There is evidence of a claim within the past 90 days that the pt is being treated with standard therapy [e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), theophylline] OR

b. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a standard therapy AND

iii. The requested agent will NOT be used in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR

C. Pt has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND BOTH of:

i. Pt has shown clinical benefit with the requested agent AND

ii. Pt will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent AND

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

Prior Authorization Group – **Egrifta PA**

Drug Name(s):
EGRIFTA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of HIV infection AND
2. The requested agent will be used to reduce excess abdominal fat in an HIV-infected patient with lipodystrophy AND
3. Patient is currently on anti-retroviral therapy (ART) within the past 90 days AND
4. Prescriber has measured baseline visceral adipose tissue (VAT) and waist circumference

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. The requested agent will be used to reduce excess abdominal fat in an HIV-infected patient with lipodystrophy AND
3. Patient is currently on anti-retroviral therapy (ART) within the past 90 days AND
4. Patient has achieved or maintained a decrease in visceral adipose tissue (VAT) from baseline OR maintained or decreased waist circumference from baseline

Age Restrictions:
Patient is 18 years of age or over

Prescriber Restrictions:

Coverage Duration:
Initial approval 6 months. Renewal approval 12 months.

Other Criteria:

Prior Authorization Group – **Emgality PA**

Drug Name(s):
EMGALITY

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. ONE of the following:
    a. Patient has a diagnosis of migraine AND BOTH of the following:
        i. Patient has 4 migraine headaches or more per month AND
        ii. ONE of the following:
            A. Patient has failed a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
            B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a conventional migraine prophylaxis agent 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 AND
2. ONE of the following:
    a. Patient is NOT currently taking another calcitonin gene-related peptide (CGRP) agent OR
    b. Patient is currently being treated with another calcitonin gene-related peptide (CGRP) agent AND will discontinue prior to initiating therapy with 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 migraine OR
    b. Patient has a diagnosis of episodic cluster headache AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:

a. Patient is NOT currently taking another calcitonin gene-related peptide (CGRP) agent OR
b. Patient is currently being treated with another calcitonin gene-related peptide (CGRP) agent AND will discontinue prior to continuing therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Epclusa PA**

Drug Name(s):
EPCLUSA
SOFOSBUVIR/VELPATASVIR

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:

Prior Authorization Group – **Epidiolex PA**

Drug Name(s):
EPIDIOLEX

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of the following:
1. ONE of the following:
    a. Patient has a diagnosis of Lennox-Gastaut syndrome OR
    b. Patient has a diagnosis of Dravet syndrome AND
2. The dose requested is within the FDA labeled dosing for the requested indication

Age Restrictions:
Patient is 2 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Erythropoietin Stimulating Agents PA-Epogen/Procrit**

Drug Name(s):
EPOGEN
PROCRIT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of:
1. Requested agent is being prescribed for ONE of:
    A. To reduce the possibility of allogeneic blood transfusion in surgery patient (pt) AND pt's hemoglobin level is greater than 10 g/dL but 13 g/dL or less OR
    B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of:
        i. Pt's hemoglobin level is less than 10 g/dL for pts initiating ESA therapy OR less than 12 g/dL for pts stabilized on therapy (measured within the previous 4 weeks) AND
        ii. Pt is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
        iii. Intent of chemotherapy is non-curative OR
    C. Anemia associated with chronic kidney disease in a pt NOT on dialysis AND ALL of:
        i. Pt's hemoglobin level is less than 10 g/dL for pts initiating ESA therapy OR 11 g/dL or less for pts stabilized on therapy (measured within the previous 4 weeks) AND
        ii. Rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
        iii. 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 pt’s hemoglobin level is less than 12 g/dL for pts initiating ESA therapy OR less than or equal to 12 g/dL for pts stabilized on therapy (measured within previous 4 weeks) OR
    E. Anemia resulting from zidovudine treatment of HIV infection AND pt’s hemoglobin level is less than 12 g/dL for pts initiating ESA therapy OR less than or equal to 12 g/dL for pts stabilized on therapy (measured within previous 4 weeks) OR
    F. Another indication supported in CMS approved compendia for requested agent AND pt’s hemoglobin level is less than 12 g/dL for pts initiating ESA

therapy OR less than or equal to 12 g/dL for pts stabilized on therapy (measured within previous 4 weeks) AND

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

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

Prior Authorization Group – **Erythropoietin Stimulating Agents PA - Retacrit**

Drug Name(s):
RETACRIT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. The requested agent is being prescribed for ONE of the following:
    A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but 13 g/dL or less OR
    B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:
        i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND
        ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
        iii. The intent of chemotherapy is non-curative OR
    C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:
        i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND
        ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
        iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR
    D. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR
    E. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND
2. Patient's transferrin saturation and serum ferritin have been evaluated

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

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

Prior Authorization Group – **Fentanyl Nasal PA - Lazanda**

Drug Name(s):
LAZANDA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    a. Patient has a diagnosis of chronic cancer pain due to an active malignancy AND the following:
        i. There is evidence of a claim that the patient is currently taking a long-acting opioid with the nasal fentanyl within the past 90 days 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 is NOT currently receiving any other oral or nasal fentanyl agent OR
    b. Patient is currently receiving another oral or nasal fentanyl agent AND will be discontinued prior to initiating the requested agent

Age Restrictions:
Patient is 18 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Fentanyl Oral PA - Fentanyl lozenge**

Drug Name(s):
fentanyl citrate oral lozenge

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    a. Patient has a diagnosis of chronic cancer pain due to an active malignancy AND the following:
        i. There is evidence of a claim that the patient is currently taking a long-acting opioid with the oral fentanyl within the past 90 days 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 is NOT currently receiving any other oral or nasal fentanyl agent OR
    b. Patient is currently receiving another oral or nasal fentanyl agent AND will be discontinued prior to initiating the requested agent

Age Restrictions:
Patient is 16 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Gammagard/Gammaked/Gamunex-C PA**

Drug Name(s):
GAMMAGARD
GAMMAGARD SD
GAMUNEX-C

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require ONE of the following:
1. Patient has ONE of the following diagnoses:
    A. Primary immunodeficiency [including 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. Chronic lymphocytic leukemia OR multiple myeloma with reduced IgG AND ONE of the following:
        i. Patient has a history of infections OR
        ii. Patient has evidence of specific antibody deficiency OR
    C. Idiopathic thrombocytopenia purpura AND ONE of the following:
        i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone), or immunosuppressants (e.g., azathioprine)] OR
        ii. Patient has a documented 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 a documented 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR
    F. Severe rheumatoid arthritis AND ONE of the following:
        i. Patient has failed ONE conventional therapy [e.g., tumor necrosis factor antagonists (e.g., Humira), DMARDS (e.g., methotrexate), infliximab] OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

Criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 3 months for indications in NHS guidelines, 12 months 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 a documented 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(s) to TWO MS agents (e.g., Aubagio, Avonex, Betaseron, Copaxone, Gilenya, glatiramer, Glatopa, Mayzent, Plegridy, Tecfidera) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:
i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, Rituxan, or recombinant factor VIIa) OR
ii. Patient has a documented 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 a documented 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 3 month approval duration:
Idiopathic thrombocytopenia purpura, Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Myasthenia gravis, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome

due to invasive group A streptococcus, Toxic epidermal necrolysis and Steven Johnsons syndrome

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

Prior Authorization Group – **Gattex PA**

Drug Name(s):
GATTEX

Off-Label Uses:

Exclusion Criteria:

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

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of short bowel syndrome (SBS) AND
3. Patient has had a reduction from baseline in parenteral nutrition OR intravenous (PN/IV) fluids

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist) or the prescriber has consulted with a specialist

Coverage Duration:
Initial approval 6 months. Renewal approval 12 months.

Other Criteria:

Prior Authorization Group – **Gaucher Enzyme Replacement PA - Cerezyme**

Drug Name(s):
CEREZYME

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of Gaucher disease type 1 confirmed by ONE of the following:
    A. A baseline glucocerebrosidase enzyme activity of less than 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
    B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline levels of hemoglobin, platelets, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had ONE of the following:
    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 (growth velocity below the standard mean for age) OR
    F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 AND
3. Patient has shown clinical improvement and/or stabilization from baseline in ONE of the following:
    A. Hemoglobin (Hb) levels OR
    B. Platelet count OR
    C. Liver volume OR
    D. Spleen volume OR
    E. Growth OR
    F. Bone pain or disease

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Gaucher Enzyme Replacement PA - Elelyso**

Drug Name(s):
ELELYSO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of Gaucher disease type 1 confirmed by ONE of the following:
    A. A baseline glucocerebrosidase enzyme activity of less than 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
    B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline levels of hemoglobin, platelets, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had ONE of the following:
    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 (growth velocity below the standard mean for age) OR
    F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 AND
3. Patient has shown clinical improvement and/or stabilization from baseline in ONE of the following:
    A. Hemoglobin (Hb) levels OR
    B. Platelet count OR
    C. Liver volume OR
    D. Spleen volume OR
    E. Growth OR
    F. Bone pain or disease

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Gaucher Enzyme Replacement PA - Vpriv**

Drug Name(s):
VPRIV

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of Gaucher disease type 1 confirmed by ONE of the following:
    A. A baseline glucocerebrosidase enzyme activity of less than 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
    B. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline levels of hemoglobin, platelets, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had ONE of the following:
    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 (growth velocity below the standard mean for age) OR
    F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 AND
3. Patient has shown clinical improvement and/or stabilization from baseline in ONE of the following:
    A. Hemoglobin (Hb) levels OR
    B. Platelet count OR
    C. Liver volume OR
    D. Spleen volume OR
    E. Growth OR
    F. Bone pain or disease

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Growth Hormone PA - Omnitrope**

Drug Name(s):
OMNITROPE

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
For Children – Criteria for initial approval require the following:
1. ONE of the following:
    a. Patient is a neonate (4 months of age or younger) with hypoglycemia in the absence of metabolic disorder AND
        i. The GH level is less than 20 ng/mL OR
    b. Patient has a diagnosis of Turner Syndrome OR
    c. Patient has a diagnosis of Prader-Willi Syndrome OR
    d. 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
    e. 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 (peak GH value of less than 10 mcg/L after stimulation) OR
    f. 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 standard deviations (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 2 or more SD below the mean for age and sex

Age Restrictions:

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. Neonate (4 months of age or younger) with hypoglycemia in the absence of metabolic disorder OR
    b. Growth Hormone Deficiency, Short Stature OR
    c. Panhypopituitarism OR
    d. Prader-Willi Syndrome OR
    e. Small for Gestational Age (SGA) OR
    f. 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 is 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 (peak GH value of 5 mcg/L or lower after stimulation) 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. Other (e.g., childhood idiopathic GHD, adult-onset idiopathic GHD) 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 benefits from therapy with the requested agent in any of the following response parameters: body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life

Prior Authorization Group – **HAE PA - Cinryze**

Drug Name(s):
CINRYZE

Off-Label Uses:
Acute HAE attacks

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed with measurements of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
    a. Type I HAE: Two separate measurements indicating decreased quantities of C4 and C1-INH OR
    b. Type II HAE: Two separate measurements indicating decreased quantities of C4 and decreased C1-INH function (C1-INH protein level may be normal) OR
    c. Type III HAE: Normal levels of C4 and C1-INH (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, or plasminogen (PLG) mutation that is associated with the disease AND
2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. ONE of the following:
    a. The requested agent will be used to treat acute HAE attacks AND ONE of the following:
        i. Patient is receiving only ONE agent indicated for treatment of acute HAE attacks OR
        ii. The other agent being used for acute HAE attacks will be discontinued before starting the requested agent OR
    b. The requested agent will be used for prophylaxis against HAE attacks AND BOTH of the following:
        i. ONE of the following:

1. Patient is receiving only ONE HAE agent indicated for prophylaxis against HAE attacks OR
2. The other agent being used for prophylaxis will be discontinued before starting the requested agent AND

ii. ONE of the following:

1. Patient has a history of at least 2 acute attacks per month OR 2 severe attacks (laryngeal or abdominal attacks) per year OR
2. Patient requires short-term prophylaxis prior to a medical, surgical, or dental procedure

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of hereditary angioedema (HAE) AND ONE of the following:
    a. The requested indication is for acute HAE AND ONE of the following:
        i. Patient is receiving only ONE agent indicated for treatment of acute HAE attacks OR
        ii. The other agent being used for acute HAE attacks will be discontinued before starting the requested agent OR
    b. The requested indication is for prophylaxis of HAE attacks AND ONE of the following:
        i. Patient is receiving only ONE HAE agent indicated for prophylaxis against HAE attacks OR
        ii. The other agent being used for prophylaxis will be discontinued before starting the requested agent AND
3. Patient has had a decrease in the frequency or severity of acute attacks or has had stabilization of disease from use of the requested agent

Prior Authorization Group – **HAE PA - Haegarda**

Drug Name(s):
HAEGARDA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed with measurements of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
    a. Type I HAE: Two separate measurements indicating decreased quantities of C4 and C1-INH OR
    b. Type II HAE: Two separate measurements indicating decreased quantities of C4 and decreased C1-INH function (C1-INH protein level may be normal) OR
    c. Type III HAE: Normal levels of C4 and C1-INH (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, or plasminogen (PLG) 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 ONE of the following:
    a. Patient has a history of at least 2 acute attacks per month OR 2 severe attacks (laryngeal or abdominal attacks) per year OR
    b. Patient requires short-term prophylaxis prior to a medical, surgical, or dental procedure AND
4. ONE of the following:
    a. Patient is receiving only ONE HAE agent indicated for prophylaxis against HAE attacks OR
    b. The other agent being used for prophylaxis will be discontinued before starting the requested agent

Age Restrictions:

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. ONE of the following:
    a. Patient is receiving only ONE HAE agent indicated for prophylaxis against HAE attacks OR
    b. The other agent being used for prophylaxis will be discontinued before starting the requested agent

Prior Authorization Group – **HAE PA - Icatibant**

Drug Name(s):
icatibant 30 mg/3 mL injection

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed with measurements of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
    a. Type I HAE: Two separate measurements indicating decreased quantities of C4 and C1-INH OR
    b. Type II HAE: Two separate measurements indicating decreased quantities of C4 and decreased C1-INH function (C1-INH protein level may be normal) OR
    c. Type III HAE: Normal levels of C4 and C1-INH (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, or plasminogen (PLG) 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. ONE of the following:
    a. Patient is receiving only ONE agent indicated for treatment of acute HAE attacks OR
    b. The other agent being used for acute HAE attacks will be discontinued before starting 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 a diagnosis of hereditary angioedema (HAE) AND
3. The requested agent will be used to treat acute HAE attacks AND

4. ONE of the following:
    a. Patient is receiving only ONE agent indicated for treatment of acute HAE attacks OR
    b. The other agent being used for acute HAE attacks will be discontinued before starting the requested agent 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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Harvoni PA**

Drug Name(s):
HARVONI
HARVONI PACK
LEDIPASVIR/SOFOSBUVIR

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:

Prior Authorization Group – **Hetlioz PA**

Drug Name(s):
HETLIOZ

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require the following:
1. Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder AND the patient is totally blind (i.e., no light perception)

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., neurologist, sleep specialist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **High Risk Medication PA - All Starts**

Drug Name(s):
benztropine tablet
CLEMASTINE tablet
dicyclomine capsule, tablet
promethazine 25 mg tablet
promethazine syrup

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 documented that s/he discussed risks and potential side effects of the requested high-risk medication with the patient

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **High Risk Medication PA - Cyclobenzaprine**

Drug Name(s):
cyclobenzaprine 5 mg, 10 mg tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 medication AND
2. If the patient is 65 years of age or over, then ALL of the following:
    A. ONE of the following:
        i. Patient has fibromyalgia and has tried and failed both duloxetine and pregabalin OR
        ii. Patient has fibromyalgia and has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to both duloxetine and pregabalin OR
        iii. Patient has a diagnosis other than fibromyalgia which does NOT require any prerequisites AND
    B. Prescriber has indicated that the benefits of the requested high-risk medication outweigh the risks for the patient AND
    C. Prescriber has documented that s/he discussed risks and potential side effects of the requested high-risk medication with the patient

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **High Risk Medication PA - New Starts**

Drug Name(s):
megestrol 40 mg/mL suspension
megestrol tablet
PAXIL suspension
paroxetine tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only. PA does NOT apply to patients less than 65 years of age.
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested high-risk medication AND
    B. There is evidence of a claim that the patient is currently being treated with the requested high-risk medication within the past 180 days OR the prescriber states the patient is currently using the requested high-risk medication OR
2. ALL of the following:
    A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested high-risk medication AND
    B. Prescriber has indicated that the benefits of the requested high-risk medication outweigh the risks for the patient AND
    C. Prescriber has documented that s/he discussed risks and potential side effects of the requested high-risk medication with the patient

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Ilaris PA**

Drug Name(s):
ILARIS

Off-Label Uses:
Acute gouty arthritis

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    A. Patient has been diagnosed with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) OR
    B. Patient has been diagnosed with Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) OR
    C. Patient has been diagnosed with Familial Mediterranean Fever (FMF) AND ONE of the following:
        i. Patient has tried and failed colchicine OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to colchicine OR
    D. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) OR
    E. Patient has been diagnosed with systemic juvenile idiopathic arthritis (SJIA) AND BOTH of the following:
        i. Patient has documented active systemic features (e.g., ongoing fever, anemia, rash, C-Reactive Protein levels greater than 50 mg/L, 2 or more joints with active arthritis) AND
        ii. ONE of the following:
            a. Patient has tried and failed at least ONE prerequisite agent (oral or IV glucocorticosteroids, prescription oral NSAIDs, methotrexate, leflunomide, or Humira) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE prerequisite agent OR
    F. Patient has been diagnosed with acute gouty arthritis AND ONE of the following:
        i. Patient has tried and failed at least TWO conventional first-line agents (prescription oral NSAIDs, colchicine, systemic corticosteroids) OR

ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least TWO conventional first-line agents AND

2. ONE of the following:

A. Patient is NOT currently being treated with another biologic agent OR

B. Patient is currently being treated with another biologic agent and the agent will be discontinued prior to initiating the requested agent

Age Restrictions:

For diagnosis of CAPS including FCAS or MWS, patient is at least 4 years of age. For diagnosis of SJIA, patient is at least 2 years of age.

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Imiquimod PA**

Drug Name(s):
imiquimod 5% cream

Off-Label Uses:

Exclusion Criteria:

Required Medical:
PA applies to new starts only.
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 Restrictions:

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, and Basal cell carcinoma

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

12 months for All other diagnoses

Prior Authorization Group – **Inbrija PA**

Drug Name(s):
INBRIJA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require ALL of the following:
1. The requested agent will be used for intermittent treatment of OFF episodes in patients with Parkinson's disease AND
2. Patient is receiving concurrent therapy with carbidopa/levodopa within the past 30 days AND
3. Patient is not currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine) or the patient has not recently (within 2 weeks) taken a nonselective MAO inhibitor

Age Restrictions:

Prescriber Restrictions:
Prescriber is a neurologist or the prescriber has consulted with a neurologist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Injectable Oncology PA**

Drug Name(s):

ABRAXANE
ADCETRIS
ALIMTA
ALIQOPA
ARRANON
ARZERRA
AVASTIN
BELEODAQ
BESPONSA
BLINCYTO
CYRAMZA
DARZALEX
DARZALEX FASPRO
doxorubicin liposomal injection
EMPLICITI
ENHERTU
ERBITUX
FASLODEX
FOLOTYN
fulvestrant injection
GAZYVA
HALAVEN
HERCEPTIN 150 mg injection
HERCEPTIN HYLECTA
HERZUMA
ISTODAX
JEVTANA
KADCYLA
KANJINTI
KYPROLIS
LARTRUVO
LUMOXITI
MVASI
MYLOTARG
OGIVRI
ONIVYDE
ONTRUZANT
PADCEV

PERJETA
PHESGO
POLIVY
PORTRAZZA
POTELIGEO
ROMIDEPSIN 27.5 mg injection
SARCLISA
SYNRIBO
TRAZIMERA
TRODELVY
UNITUXIN
VECTIBIX
VELCADE
VYXEOS
YONDELIS
ZALTRAP
ZEPZELCA
ZIRABEV

Off-Label Uses:

Exclusion Criteria:

Required Medical:

This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:

a. Patient has tried and failed the appropriate FDA labeled or CMS approved compendia supported first-line agent(s) for the requested indication (if applicable, will vary by diagnosis) OR
b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent(s) AND

iii. Patient does NOT have any FDA labeled contraindication(s) to the requested agent AND
iv. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **IPF PA - Esbriet**

Drug Name(s):
ESBRIET

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL 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) AND
3. ONE of the following:
    A. Patient is NOT currently treated with Ofev (nintedanib) within the past 90 days OR
    B. Patient has been treated with Ofev (nintedanib) within the past 90 days AND therapy will be discontinued prior to starting therapy with 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 a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
3. The requested agent has been clinically beneficial to the patient AND
4. ONE of the following:
    A. Patient is NOT currently treated with Ofev (nintedanib) within the past 90 days OR
    B. Patient has been treated with Ofev (nintedanib) within the past 90 days AND therapy will be discontinued prior to starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., pulmonologist, radiologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **IPF PA - Ofev**

Drug Name(s):
OFEV

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 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) AND
2. ONE of the following:
    A. Patient is NOT currently treated with Esbriet (pirfenidone) within the past 90 days OR
    B. Patient has been treated with Esbriet (pirfenidone) within the past 90 days AND therapy will be discontinued prior to starting therapy with 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 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. The requested agent has been clinically beneficial to the patient AND
4. ONE of the following:
    A. Patient is NOT currently treated with Esbriet (pirfenidone) within the past 90 days OR
    B. Patient has been treated with Esbriet (pirfenidone) within the past 90 days AND therapy will be discontinued prior to starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Iron Chelating Agents PA - Exjade**

Drug Name(s):
deferasirox tablet for oral suspension

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require 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:
        1. A liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR
        2. A serum ferritin greater than 300 mcg/L OR
        3. MRI confirmation of iron deposition OR
    b. Patient has a diagnosis of chronic iron overload due to blood transfusions

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 shown clinical benefit with the requested agent

Age Restrictions:
For diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome, patient is at least 10 years of age. For diagnosis of chronic iron overload due to blood transfusions, patient is at least 2 years of age.

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Iron Chelating Agents PA - Jadenu**

Drug Name(s):
deferasirox 90 mg, 180 mg, 360 mg tablet
JADENU
JADENU SPRINKLE

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require 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:
        1. A liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR
        2. A serum ferritin greater than 300 mcg/L OR
        3. MRI confirmation of iron deposition OR
    b. Patient has a diagnosis of chronic iron overload due to blood transfusions

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 shown clinical benefit with the requested agent

Age Restrictions:
For diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome, patient is at least 10 years of age. For diagnosis of chronic iron overload due to blood transfusions, patient is at least 2 years of age.

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Kalydeco PA**

Drug Name(s):
KALYDECO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of cystic fibrosis AND
2. Patient has ONE of the CFTR gene mutations as indicated in the FDA label as confirmed by genetic testing AND
3. Patient is NOT homozygous for the F508del mutation AND
4. ONE of the following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Orkambi (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor and ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to starting 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 a diagnosis of cystic fibrosis AND
3. Patient has shown clinical 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 Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. ONE of the following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Orkambi (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor and ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to continuing the requested agent

Age Restrictions:
Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:
Prescriber is a specialist (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Korlym PA**

Drug Name(s):
KORLYM

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for 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 (defined as 2-hour glucose tolerance test with glucose value of 140-199 mg/dL) AND
3. ONE of the following:
    A. Patient has failed surgical resection OR
    B. Patient is NOT a candidate for surgical resection

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Kuvan PA**

Drug Name(s):
KUVAN

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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. ONE of the following:
    a. Patient is not also receiving Palynziq OR
    b. Patient has been receiving Palynziq, AND will discontinue prior to receiving Kuvan AND
4. The dose is within the FDA labeled dose 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. ONE of the following:
    a. Patient is not also receiving Palynziq OR
    b. Patient has been receiving Palynziq, AND will discontinue prior to receiving Kuvan AND
5. The dose is within the FDA labeled dose for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist with knowledge and expertise in metabolic diseases or genetic diseases or has consulted with a specialist in metabolic or genetic diseases

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 – **Lidocaine Topical PA - Lidocaine Gel/Jelly**

Drug Name(s):
lidocaine 2% gel

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require the following:
1. The requested agent will be used for ONE of the following:
    A. Surface anesthesia and lubrication for urethral procedure OR
    B. Topical treatment for pain of urethritis OR
    C. Surface anesthesia and lubrication for endotracheal intubation (oral and nasal) OR
    D. Another indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Lidocaine Topical PA - Lidocaine Patch**

Drug Name(s):
lidocaine 5% transdermal patch

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require 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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Lidocaine Topical PA - Lidocaine Solution**

Drug Name(s):
lidocaine 4% solution

Off-Label Uses:

Exclusion Criteria:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Lidocaine Topical PA - Lidocaine/prilocaine Cream**

Drug Name(s):
lidocaine/prilocaine 2.5-2.5% cream

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Linezolid PA**

Drug Name(s):
linezolid suspension, tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. 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 AND the patient has an FDA labeled indication for the requested agent 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 at least two of the following: beta lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole, OR that is resistant to vancomycin OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two of the following: beta lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole, OR
        iii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity 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 at least 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two of the following: beta lactams, macrolides, clindamycin, tetracyclines or co-trimoxazole OR
        iii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin AND

Criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 3 months

Other Criteria:
2. ONE of the following:
    a. Patient is NOT currently being treated for the same infection with Sivextro (tedizolid) OR
    b. The current treatment with Sivextro (tedizolid) for the same infection will be discontinued before starting therapy with the requested agent AND
3. The dose is within the FDA labeled dosage

Prior Authorization Group – **Linzess PA**

Drug Name(s):
LINZESS

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has ONE of the following diagnoses:
    a. Chronic idiopathic constipation with documentation of symptoms for at least 3 months OR
    b. Irritable bowel syndrome with constipation with documentation of symptoms for at least 3 months AND
2. ONE of the following:
    a. Patient has tried and had an inadequate response to lactulose OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to lactulose

Age Restrictions:
Patient is 18 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Mavyret PA**

Drug Name(s):
MAVYRET

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:

Prior Authorization Group – **Memantine PA**

Drug Name(s):
memantine solution, tablet
memantine titration pak

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Modafinil PA**

Drug Name(s):
modafinil tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. Patient is receiving only one of the listed agents, armodafinil OR modafinil, within the past 90 days OR
    B. Patient has been treated with armodafinil within the past 90 days AND will discontinue prior to starting the requested agent

Age Restrictions:
Patient is 17 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Aubagio**

Drug Name(s):
AUBAGIO

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Avonex**

Drug Name(s):
AVONEX
AVONEX PREFILLED KIT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Betaseron**

Drug Name(s):
BETASERON

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Gilenya**

Drug Name(s):
GILENYA 0.5 mg capsule

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent 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 shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Glatiramer**

Drug Name(s):
COPAXONE
glatiramer injection

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Mayzent**

Drug Name(s):
MAYZENT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Plegridy**

Drug Name(s):
PLEGRIDY
PLEGRIDY STARTER PACK

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Tecfidera**

Drug Name(s):
TECFIDERA
TECFIDERA STARTER PACK

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **MS PA - Tysabri**

Drug Name(s):
TYSABRI

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 90 days OR
    B. Prescriber states the patient is currently using the requested agent AND is at risk if therapy is changed OR
    C. Patient has ONE of the following diagnoses:
        i. Relapsing form of Multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease AND ONE of the following:
            a. Prescriber states the patient has highly active disease OR
            b. ONE of the following:
                1. Patient's medication history indicates the use of at least TWO preferred agents [Aubagio, Avonex, Betaseron, Gilenya, glatiramer (i.e., Copaxone, Glatopa), Mayzent, Plegridy, or Tecfidera] for the treatment of MS OR
                2. Patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to at least TWO preferred agents [Aubagio, Avonex, Betaseron, Gilenya, glatiramer (i.e., Copaxone, Glatopa), Mayzent, Plegridy, or Tecfidera] for the treatment of MS OR

Initial criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

ii. Moderately to severely active Crohn's disease (CD) AND BOTH of the following:

a. ONE of the following:

1. Patient's medication history indicates the use of at least ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, sulfasalazine) OR

2. Patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to at least ONE conventional CD therapy AND

b. ONE of the following:

1. Patient's medication history indicates use of ONE preferred biologic agent (Humira or Stelara) for the treatment of CD OR

2. Patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to ONE preferred biologic agent (Humira or Stelara)

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 shown clinical benefit with the requested agent AND
4. ONE of the following:

A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR

B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before continuing the requested agent

Prior Authorization Group – **MS PA - Vumerity**

Drug Name(s):
VUMERITY

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting 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 for the requested agent AND
3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the requested indication OR
    B. Patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Myalept PA**

Drug Name(s):
MYALEPT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND
2. Prescriber has provided the patient's baseline levels for HbA1C, triglycerides, and fasting insulin, prior to beginning therapy with the requested agent AND
3. Patient also has at least ONE of the following additional diagnosis: diabetes mellitus, hypertriglyceridemia (200 mg/dL or higher), and/or high fasting insulin (30µU/mL or higher) AND
4. Patient has failed maximum tolerable dosing of a conventional agent for the additional diagnosis AND
5. The dose is within the FDA labeled dose 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 either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND
3. Patient has had a reduction in at least ONE of the following parameters: HbA1C, triglycerides and/or fasting insulin from baseline levels documented prior to continuing the requested agent AND
4. The dose is within the FDA labeled dose for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Conventional agent examples include:

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

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

Prior Authorization Group – **Natpara PA**

Drug Name(s):
NATPARA

Off-Label Uses:

Exclusion Criteria:
Increased baseline risk for osteosarcoma

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of hypocalcemia associated with hypoparathyroidism AND
2. Patient does NOT have a baseline vitamin D level below the testing laboratory's lower limit of normal AND
3. Patient's baseline serum calcium level (albumin-corrected) is above 7.5 mg/dL AND
4. ONE of the following:
    A. Patient is NOT currently being treated with alendronate OR
    B. Patient is currently being treated with alendronate AND will discontinue prior to initiating therapy with 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 a diagnosis of hypocalcemia associated with hypoparathyroidism AND
3. Patient has shown clinical benefit with the requested agent AND
4. Patient has a serum calcium level (albumin-corrected) between 7.5 mg/dL and 10.6 mg/dL AND
5. ONE of the following:
    A. Patient is NOT currently being treated with alendronate OR
    B. Patient is currently being treated with alendronate and will discontinue prior to continuing therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Northera PA**

Drug Name(s):
NORTHERA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 3 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 3 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

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 demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND
4. Patient had an increase in systolic blood pressure from baseline of at least 10 mmHg upon standing from a supine (laying face up) position

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., cardiologist, neurologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be 1 month for initial, 3 months for renewal

Other Criteria:

Prior Authorization Group – **Noxafil PA**

Drug Name(s):
NOXAFIL
posaconazole 100 mg delayed release tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of oropharyngeal candidiasis AND patient has tried fluconazole or an alternative antifungal agent OR patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity 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 patient has tried an alternative antifungal agent OR patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to an alternative antifungal agent OR
    D. Patient has another indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
One month for oropharyngeal candidiasis, 6 months for all other indications

Other Criteria:
Criteria for renewal approval require BOTH of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of the following:
    A. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida and patient continues to be severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR
    B. Patient has a diagnosis of invasive Aspergillus AND patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR
    C. Patient has another indication that is supported in CMS approved compendia for the requested agent

Prior Authorization Group – **Nuedexta PA**

Drug Name(s):
NUEDEXTA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has a diagnosis of pseudobulbar affect AND
2. Patient is NOT currently receiving a monoamine oxidase inhibitor (MAOI) [e.g., Marplan (isocarboxazid), Nardil (phenelzine), and Parnate (tranylcypromine)] OR the patient's MAOI will be discontinued at least 14 days prior to starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Nuplazid PA**

Drug Name(s):
NUPLAZID

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require the following:
1. Patient has an FDA labeled indication for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Ocaliva PA**

Drug Name(s):
OCALIVA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of Primary Biliary Cholangitis (PBC) confirmed by TWO of the following:
    A. There is biochemical evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal
    B. Presence of antimitochondrial antibody (AMA): a titer greater than or equal to 1:40 OR a level that is above the testing laboratory's upper limit of the normal range
    C. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND
2. Prescriber has documented the patient's baseline (prior to any treatment with the requested agent) alkaline phosphatase (ALP) level AND total bilirubin level AND
3. ONE of the following:
    A. BOTH of the following:
        i. Patient has tried treatment with ursodiol and had an inadequate response AND
        ii. Patient will continue treatment with ursodiol with the requested agent OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Primary Biliary Cholangitis (PBC) AND
3. ONE of the following:
    A. Patient is currently on AND will continue treatment with ursodiol with the requested agent OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol AND

4. Patient has had a decrease in alkaline phosphatase (ALP) level from baseline AND
5. Patient's total bilirubin is less than or equal to the upper limit of normal (ULN)

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Bavencio**

Drug Name(s):
BAVENCIO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Imfinzi**

Drug Name(s):
IMFINZI

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Keytruda**

Drug Name(s):
KEYTRUDA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Libtayo**

Drug Name(s):
LIBTAYO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Opdivo**

Drug Name(s):
OPDIVO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Tecentriq**

Drug Name(s):
TECENTRIQ

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oncology Immunotherapy PA - Yervoy**

Drug Name(s):
YERVOY

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
    C. ALL of the following:
        i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND
        ii. ONE of the following:
            a. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Ophthalmic Immunomodulators PA - Restasis**

Drug Name(s):
RESTASIS
RESTASIS MULTIDOSE

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require ONE of the following:
1. Patient has an FDA labeled indication for the requested agent OR
2. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Opioids ER PA - Fentanyl Patch**

Drug Name(s):
fentanyl transdermal patch

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
    B. Patient 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 180 days OR
        ii. Prescriber states the patient is currently using the requested agent within the past 180 days OR
    C. Patient is undergoing treatment of chronic non-cancer pain AND ALL of the following:
        i. Prescriber provides documentation of a formal, consultative evaluation including:
            1. Diagnosis AND
            2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND
        ii. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
        iii. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
        iv. ONE of the following:
            1. Patient's medication history includes use of an immediate-acting opioid OR
            2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to immediate-acting opioid AND
        v. Patient does NOT have any FDA labeled contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Opioids ER PA - Morphine**

Drug Name(s):
morphine sulfate ER tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
    B. Patient 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 180 days OR
        ii. Prescriber states the patient is currently using the requested agent within the past 180 days OR
    C. Patient is undergoing treatment of chronic non-cancer pain AND ALL of the following:
        i. Prescriber provides documentation of a formal, consultative evaluation including:
            1. Diagnosis AND
            2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND
        ii. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
        iii. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
        iv. ONE of the following:
            1. Patient's medication history includes use of an immediate-acting opioid OR
            2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to immediate-acting opioid AND
        v. Patient does NOT have any FDA labeled contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Oral Immunotherapy Agents PA - Oralair**

Drug Name(s):
ORALAIR

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

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

Age Restrictions:
Patient is between the ages of 5 and 65 years

Prescriber Restrictions:
Prescriber is a specialist (e.g., allergist, immunologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Standard allergy medications:
Oral antihistamines, oral corticosteroids, intranasal corticosteroids, intranasal antihistamines, or leukotriene inhibitors

Prior Authorization Group – **Orkambi PA**

Drug Name(s):
ORKAMBI

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of cystic fibrosis AND
2. Patient has the presence of the F508del mutation on both alleles (homozygous) of the CFTR gene confirmed by genetic testing AND
3. ONE of the following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Kalydeco (ivacaftor), Symdeko (tezacaftor/ivacaftor and ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to starting 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 a diagnosis of cystic fibrosis AND
3. Patient has shown clinical 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 Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. ONE of the following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Kalydeco (ivacaftor), Symdeko (tezacaftor/ivacaftor and ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to continuing the requested agent

Age Restrictions:
Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:
Prescriber is a specialist (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Otezla PA**

Drug Name(s):
OTEZLA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ONE of the following:
1. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Moderate-to-severe plaque psoriasis OR
        ii. Active psoriatic arthritis AND
    B. ONE of the following:
        i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient is currently using the requested agent AND is at risk if therapy is changed OR
        iii. Patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication OR
        iv. Patient's medication history indicates use of ONE conventional prerequisite agent for the requested indication OR
        v. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE conventional prerequisite agent for the requested indication OR
2. Patient has a diagnosis of oral ulcers associated with Behcet's disease (BD)

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of moderate-to-severe plaque psoriasis, active psoriatic arthritis, OR oral ulcers associated with Behcet's disease (BD) AND
3. Patient has shown clinical improvement (i.e., slowing of disease progression or decrease in symptom severity and/or frequency)

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Formulary conventional agent required for diagnoses of moderate-to-severe plaque psoriasis or active psoriatic arthritis

Formulary conventional topical or systemic agents for moderate-to-severe plaque psoriasis include methotrexate, topical corticosteroids, calcipotriene, acitretin, tazarotene, cyclosporine, tacrolimus, pimecrolimus, or topical calcitriol

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

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

Prior Authorization Group – **Palynziq PA**

Drug Name(s):
PALYNZIQ

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of phenylketonuria (PKU) AND
2. Patient has a baseline blood Phe level greater than 600 micromol/L (10 mg/dL) AND
3. ONE of the following:
    a. Patient is not also receiving Kuvan OR
    b. Patient has been receiving Kuvan, AND will discontinue at least 14 days prior to receiving Palynziq AND
4. The dose is within the FDA labeled dose 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. ONE of the following:
    a. Patient is not also receiving Kuvan OR
    b. Patient has been receiving Kuvan, AND will discontinue at least 14 days prior to receiving Palynziq AND
5. The dose is within the FDA labeled dose for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist with knowledge and expertise in metabolic diseases or genetic diseases or has consulted with a specialist in metabolic or genetic diseases

Coverage Duration:
Approval will be 9 months for initial, 12 months for renewal

Other Criteria:

Prior Authorization Group – **Pegylated Interferon PA**

Drug Name(s):
PEGASYS
PEGASYS PROCLICK

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require the following:
1. ONE of the following:
    a. Patient has a diagnosis of chronic hepatitis B AND BOTH of the following:
        i. The chronic hepatitis B infection has been confirmed by serological markers AND
        ii. Patient has NOT been administered the requested agent for more than 48 weeks for the treatment of chronic hepatitis B OR
    b. BOTH of the following:
        i. Patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND
        ii. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype OR
    c. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

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 virus infection. Prior peginterferon alfa use, approve remainder of 48 weeks of total therapy for hepatitis B virus infection

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

Prior Authorization Group – **Prolia PA**

Drug Name(s):
PROLIA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. ONE of the following:
    A. Patient (pt) is a male or a postmenopausal female with a diagnosis of osteoporosis defined as ONE of the following:
        i. Pt has a history of vertebral fracture(s), or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR
        ii. Pt has a T-score that is -2.5 or lower AND ONE of the following:
            1. Pt is female and medication history includes use of either a bisphosphonate or selective estrogen receptor (SERM) OR
            2. Pt is male and medication history includes use of a bisphosphonate OR
            3. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate or SERM (bisphosphonate or SERM for female pts, bisphosphonate for male pts) OR
    B. Pt is requesting the agent for osteopenia (osteoporosis prophylaxis) AND ALL of the following:
        i. ONE of the following:
            1. Pt is a male 50 years of age and over OR
            2. Pt is a postmenopausal female AND
        ii. Pt has a T-score between -1.0 to -2.50 AND
        iii. ONE of the following:
            1. 10-year probability of a hip fracture 3% and greater per FRAX OR
            2. 10-year probability of a major OP-related fracture 20% and greater per FRAX AND
        iv. ONE of the following:
            1. Pt is female and medication history includes use of a bisphosphonate or SERM OR
            2. Pt is male and medication history includes use of a bisphosphonate OR

3. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate or SERM (bisphosphonate or SERM for female pts, bisphosphonate for male pts) OR

C. Pt is a female with a diagnosis of breast cancer who is receiving aromatase inhibitor therapy AND ONE of the following:

i. Pt has a history of vertebral fracture(s), or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR

Criteria continues: See Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

ii. Patient has a T-score at or below -1 AND ONE of the following:

1. Patient's medication history includes use of a bisphosphonate OR
2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR

D. Patient is a male with a diagnosis of prostate cancer receiving androgen deprivation therapy (ADT) AND ONE of the following:

i. Patient has a history of vertebral fracture(s), or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR

ii. BOTH of the following:

1. ONE of the following:
   a. Patient has a T-score at or below -1 OR
   b. Patient has a history of an osteoporotic fracture AND
2. ONE of the following:
   a. Patient's medication history includes use of a bisphosphonate OR
   b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR

E. Patient has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of the following:

i. Patient is either initiating or continuing systemic glucocorticoids in a daily dose equivalent to 7.5 mg or greater of prednisone AND
ii. Patient is expected to remain on glucocorticoids for at least 6 months AND
iii. ONE of the following:
1. Patient has a history of vertebral fracture(s), or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR
2. Patient has a T-score that is -2.5 or lower AND ONE of the following:
a. Patient is female and medication history includes use of either a bisphosphonate or SERM OR
b. Patient is male and medication history includes use of a bisphosphonate OR
c. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate or SERM (bisphosphonate or SERM for female patients, bisphosphonate for male patients) AND

2. ONE of the following:
A. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
B. 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
C. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) AND
3. ONE of the following:
A. Patient is not receiving concomitant Forteo (teriparatide), Tymlos (abaloparatide), Xgeva (denosumab), bisphosphonate, or SERM therapy within the past 90 days OR
B. Patient will discontinue the current Forteo (teriparatide), Tymlos (abaloparatide), Xgeva (denosumab), bisphosphonate, or SERM therapy prior to initiating therapy with the requested agent AND
4. The dose requested is within the FDA approved labeling

Prior Authorization Group – **Promacta PA**

Drug Name(s):
PROMACTA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ONE of the following:
1. Patient (pt) has a diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of:
    A. Pt has tried and had an insufficient response to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
    B. Pt has had an insufficient response to a splenectomy OR
    C. BOTH of:
        i. Pt is NOT a candidate for splenectomy AND
        ii. Pt has a documented intolerance, FDA labeled contraindication or hypersensitivity to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
2. Pt has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of:
    A. Pt's platelet count is less than 75 x109/L AND the intent is to increase platelet counts sufficiently to initiate pegylated interferon therapy OR
    B. Pt is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia OR
3. Pt has a diagnosis of severe aplastic anemia (SAA) AND ALL of:
    A. Pt has at least 2 of the following blood criteria:
        i. Neutrophils less than 0.5 X 109/L OR
        ii. Platelets less than 20 X 109/L OR
        iii. Reticulocytes less than 1% corrected [percentage of actual hematocrit (Hct) to normal Hct] or reticulocyte count less than 20 X 109/L AND
    B. Pt has at least 1 of the following marrow criteria:
        i. Severe hypocellularity is less than 25% OR
        ii. Moderate hypocellularity is 25-50% with hematopoietic cells representing less than 30% of residual cells AND
    C. ONE of:
        i. BOTH of:
            1. Pt will be using the requested agent as first-line treatment AND
            2. Pt will use the requested agent in combination with standard immunosuppressive therapy [i.e., antithymocyte globulin (ATG) AND cyclosporine] OR
        ii. ONE of:

1. Pt has tried and had an insufficient response to immunosuppressive therapy [defined as failure to BOTH antithymocyte globulin (ATG) AND cyclosporine] OR
2. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to BOTH ATG and cyclosporine

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Initial 6 mo ITP & First-line SAA, 48 wks HCV, 16 wks other SAA Renewal 12 mo ITP & SAA, 48 wks HCV

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 chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
        i. Patient's platelet count is 50 x 109/L or greater OR
        ii. Patient's platelet count has increased sufficiently to avoid clinically significant bleeding OR
    B. Patient has a diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following:
        i. ONE of the following:
            a. Patient will be initiating hepatitis C therapy with pegylated interferon and ribavirin OR
            b. Patient will be maintaining hepatitis C therapy with pegylated interferon and ribavirin at the same time as the requested agent AND
        ii. ONE of the following:
            a. Patient's platelet count is 90 x 109/L or greater OR
            b. Patient's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C OR
    C. Patient has a diagnosis of severe aplastic anemia AND ONE of the following:
        i. BOTH of the following:
            1. Patient is using the requested agent in combination with standard immunosuppressive therapy [i.e., antithymocyte globulin

(ATG) AND cyclosporine] for the first-line treatment of severe aplastic anemia AND

2. ONE of the following:

a. Patient has had a complete response by 6 months defined as hematological parameters meeting ALL of the following values:

i. An absolute neutrophil count (ANC) greater than 1,000/mcL AND

ii. Platelet count greater than 100 x 109/L AND

iii. Hemoglobin greater than 10 g/dL OR

b. Patient has had a partial response by 6 months defined as meeting TWO of the following values:

i. An absolute neutrophil count (ANC) greater than 500/mcL OR

ii. Platelet count greater than 20 x 109/L OR

iii. Reticulocyte count greater than 60,000/mcL OR

ii. Patient is not using the requested agent in combination with standard immunosuppressive therapy AND has had a hematological response by week 16 defined as ONE of the following:

1. Platelet count increases to 20 x 109/L above baseline OR

2. Stable platelet counts with transfusion independence for a minimum of 8 weeks OR

3. Hemoglobin increase by greater than 1.5 g/dL OR

4. Reduction in 4 units or greater of red blood cell (RBC) transfusions for 8 consecutive weeks OR

5. An absolute neutrophil count (ANC) increase of 100% OR

6. An absolute neutrophil count (ANC) increase greater than 0.5 x 109/L

Prior Authorization Group – **Pulmonary Hypertension PA - Adempas**

Drug Name(s):
ADEMPAS

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 or equal to 25 mmHg AND
        iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg 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 or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. 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

Initial criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:
1. Prostanoid therapy has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
2. Patient has unacceptable or deteriorating clinical status despite established pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is responding to therapy with the requested agent

Prior Authorization Group – **Pulmonary Hypertension PA - Ambrisentan**

Drug Name(s):
ambrisentan tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 WHO functional class is II or greater AND
        ii. Patient has a mean pulmonary arterial pressure greater than or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. ONE of the following:
            a. The requested agent will be utilized as monotherapy OR
            b. The request is for ambrisentan for use in combination with Adcirca or Alyq (tadalafil) 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 ambrisentan with Adcirca or Alyq (tadalafil)], 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
            d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is responding to therapy with the requested agent

Prior Authorization Group – **Pulmonary Hypertension PA - Bosentan**

Drug Name(s):
bosentan tablet
TRACLEER 32 mg tablet

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 contraindication(s) to the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 WHO functional class is II or greater AND
        ii. Patient has a mean pulmonary arterial pressure greater than or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. 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. A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class OR

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

Age Restrictions:

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. Patient is responding to therapy with the requested agent

Prior Authorization Group – **Pulmonary Hypertension PA - Opsumit**

Drug Name(s):
OPSUMIT

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 WHO functional class is II or greater AND
        ii. Patient has a mean pulmonary arterial pressure greater than or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. 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. A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is responding to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Pulmonary Hypertension PA - Sildenafil**

Drug Name(s):
sildenafil 20 mg tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND concurrently taking a phosphodiesterase type 5 (PDE-5) inhibitor [tadalafil (Adcirca, Alyq or Cialis) or sildenafil (Revatio or Viagra)] with the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. 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. A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class OR

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

Age Restrictions:

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. Patient is responding to therapy with the requested agent

Prior Authorization Group – **Pulmonary Hypertension PA - Tadalafil**

Drug Name(s):
tadalafil 20 mg tablet (generic ADCIRCA)

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND concurrently taking a phosphodiesterase type 5 (PDE-5) inhibitor [tadalafil (Adcirca, Alyq or Cialis) or sildenafil (Revatio or Viagra)] with the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. ONE of the following:
            a. The requested agent will be utilized as monotherapy OR
            b. The request is for Adcirca or Alyq (tadalafil) for use in combination with Letairis (ambrisentan) 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 Adcirca or Alyq (tadalafil) with Letairis (ambrisentan)], 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

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

Initial criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
1. A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class OR
C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. Patient is responding to therapy with the requested agent

Prior Authorization Group – **Pulmonary Hypertension PA - Uptravi**

Drug Name(s):
UPTRAVI

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. ONE of the following:
            a. The requested agent will be utilized as monotherapy OR
            b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:
                1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
                2. The requested agent is in a different therapeutic class OR
            c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND BOTH of the following:
                1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
                2. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is responding to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Pulmonary Hypertension PA - Ventavis**

Drug Name(s):
VENTAVIS

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 using the requested agent AND is at risk if therapy is changed 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 or equal to 25 mmHg AND
        iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. ONE of the following:
            a. The requested agent will be utilized as monotherapy OR
            b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:
                1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
                2. The requested agent is in a different therapeutic class OR
            c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:
                1. Patient is WHO functional class III or IV AND
                2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

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

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 is responding to therapy with the requested agent

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Relistor PA**

Drug Name(s):
RELISTOR

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. ONE of the following diagnoses:
    A. Patient has opioid-induced constipation (OIC) with advanced illness or pain caused by active cancer and is receiving palliative care AND the requested agent is Relistor (methylnaltrexone) injection OR
    B. Patient has opioid induced constipation (OIC) and chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND
2. Patient has chronic use of an opioid agent in the past 90 days AND
3. ONE of the following:
    A. Patient has tried and had an inadequate response to lactulose OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to lactulose

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Repatha PA**

Drug Name(s):
REPATHA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has ONE of the following:
    A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by ONE of the following:
        i. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or ARH adaptor protein 1/LDLRAP1 gene locus OR
        ii. BOTH of the following:
            1. History of total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) (pretreatment or highest level while on treatment) OR history of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment or highest level while on treatment) AND
            2. History of tendon xanthomas in ONE of the following:
                a. Patient
                b. Patient's first degree relative (i.e., parent, sibling, or child)
                c. Patient's second degree relative (e.g., grandparent, uncle, or aunt) OR
        iii. Patient has a Dutch Lipid Clinic Network Criteria score of greater than 8 OR
    B. A diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by ONE of the following:
        i. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or ARH adaptor protein 1/LDLRAP1 gene locus OR
        ii. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C 300 mg/dL or greater (7.76 mmol/L or greater) with ONE of the following:
            a. Patient had cutaneous or tendon xanthoma before age 10 years OR
            b. Untreated elevated cholesterol levels consistent with heterozygous FH in both parents [untreated LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) or untreated total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L)] OR

Initial criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., cardiologist, endocrinologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:
C. A diagnosis of established cardiovascular disease [angina pectoris, coronary heart disease, myocardial infarction, transient ischemic attacks, cerebrovascular disease (CeVD) or peripheral vascular disease (PVD) or after coronary revascularization or carotid endarterectomy] AND the requested agent will be used to reduce the risk of myocardial infarction, stroke, and coronary revascularization OR

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

2. ONE of the following:

A. ONE of the following:

1. Patient is currently (for the past 90 days) on high-intensity statin therapy (i.e., rosuvastatin 20-40 mg or atorvastatin 40-80 mg) OR

2. BOTH of the following:

a. Patient has tried and is intolerant to high-intensity statin therapy AND

b. Patient is currently (for the past 90 days) on low or moderate intensity statin therapy OR

B. Patient has documented intolerance* to TWO different statins (*intolerance is defined as inability to tolerate the lowest FDA approved starting dose of a statin) OR

C. Patient has an FDA labeled contraindication to a statin AND

3. Praluent (alirocumab) and Repatha (evolocumab) will not be used concurrently with each other

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 approved indication for the requested agent AND

3. Patient has shown clinical benefit with the requested agent AND
4. ONE of the following:
    A. ONE of the following:
        1. Patient is currently (for the past 90 days) on high-intensity statin therapy (i.e., rosuvastatin 20-40 mg or atorvastatin 40-80 mg) OR
        2. BOTH of the following:
            a. Patient has tried and is intolerant to high-intensity statin therapy AND
            b. Patient is currently (for the past 90 days) on low or moderate intensity statin therapy OR
    B. Patient has documented intolerance* to TWO different statins (*intolerance is defined as inability to tolerate the lowest FDA approved starting dose of a statin) OR
    C. Patient has an FDA labeled contraindication to a statin AND
5. Praluent (alirocumab) and Repatha (evolocumab) will not be used concurrently with each other

Prior Authorization Group – **Self - Administered Oncology PA**

Drug Name(s):
abiraterone tablet
AFINITOR
AFINITOR DISPERZ
ALECENSA
ALUNBRIG
AYVAKIT
BALVERSA
bexarotene capsule
BOSULIF
BRAFTOVI 75 mg capsule
BRUKINSA
CABOMETYX
CALQUENCE
CAPRELSA
COMETRIQ
COPIKTRA
COTELLIC
DAURISMO
ERIVEDGE
ERLEADA
erlotinib tablet
everolimus 2.5 mg, 5 mg, 7.5 mg tablet
FARYDAK
GILOTRIF
HEXALEN
IBRANCE
ICLUSIG
IDHIFA
imatinib mesylate tablet
IMBRUVICA
INLYTA
INREBIC
IRESSA
JAKAFI
KISQALI
KISQALI FEMARA CO PACK
KOSELUGO
LENVIMA
LONSURF
LORBRENA
LYNPARZA
MATULANE
MEKINIST
MEKTOVI

NERLYNX
NEXAVAR
NINLARO
NUBEQA
ODOMZO
PEMAZYRE
PIQRAY
POMALYST
QINLOCK
RETEVMO
REVLIMID
ROZLYTREK
RUBRACA
RYDAPT
SPRYCEL
STIVARGA
SUTENT
SYLATRON
TABRECTA
TAFINLAR
TAGRISSO
TALZENNA
TASIGNA
TAZVERIK
THALOMID
TIBSOVO
tretinoin capsule
TUKYSA
TURALIO
TYKERB
VENCLEXTA
VENCLEXTA STARTING PACK
VERZENIO
VITRAKVI
VIZIMPRO
VOTRIENT
XALKORI
XOSPATA
XPOVIO
XTANDI
YONSA
ZEJULA
ZELBORAF
ZOLINZA
ZYDELIG
ZYKADIA

ZYTIGA 500 mg tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:

This program applies to new starts only.
Criteria for approval require BOTH of 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 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 contraindication(s) to the requested agent AND
        iii. ONE of the following:
            1. Patient has tried and failed the first-line agent for the intended indication (if applicable) OR
            2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first-line agent AND
        iv. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Signifor PA**

Drug Name(s):
SIGNIFOR

Off-Label Uses:

Exclusion Criteria:
Severe hepatic impairment (i.e., Child Pugh C)

Required Medical:
Criteria for initial approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of Cushing's disease (CD) AND ONE of the following:
        i. Patient had an inadequate response to pituitary surgical resection OR
        ii. Patient is NOT a candidate for pituitary surgical resection OR
    B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
    A. Patient has a diagnosis of Cushing's disease (CD) AND BOTH of the following:
        i. Patient has a urinary free cortisol level less than or equal to the upper limit of normal AND
        ii. Patient has shown improvement in at least ONE of the following clinical signs and symptoms
            1. Fasting plasma glucose OR
            2. Hemoglobin A1c OR
            3. Hypertension OR
            4. Weight OR
    B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Initial approval: 6 months for CD, 12 months for all other diagnoses, Renewal approval: 12 months

Other Criteria:

Prior Authorization Group – **Sivextro PA**

Drug Name(s):
SIVEXTRO tablet

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has ONE of the following:
    a. BOTH of the following:
        i. A documented acute bacterial skin and skin structure infection (ABSSSI) defined as a bacterial infection of the skin with a lesion size area of at least 75 cm2 (lesion size measured by the area of redness, edema, or induration) AND
        ii. The infection is due to Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis OR
    b. Another indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
    a. The requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient OR
    b. The requested agent is NOT prescribed by an infectious disease specialist or the prescriber has NOT consulted with an infectious disease specialist on treatment of this patient AND ONE of the following:
        i. There is documentation of resistance to at least two of the following: beta lactams, macrolides, clindamycin, tetracycline, or co-trimoxazole at the site of infection OR the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two of the following: beta lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR
        ii. There is documentation of resistance to vancomycin at the site of infection OR the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin AND
3. ONE of the following:
    a. Patient is NOT currently being treated for the same infection with linezolid OR
    b. The current treatment with linezolid for the same infection will be discontinued before starting therapy with the requested agent AND
4. The requested dose is within the FDA and/or compendia labeled dosage

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be 6 days for ABSSSI or 30 days for all other indications

Other Criteria:

Prior Authorization Group – **Sodium Oxybate PA**

Drug Name(s):
XYREM

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of narcolepsy with cataplexy OR
    B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following:
        i. ONE of the following:
            a. Patient is under 18 years of age OR
            b. ONE of the following:
                1. Patient's medication history indicates the use of modafinil or armodafinil OR
                2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to modafinil or armodafinil AND
        ii. ONE of the following:
            a. Patient's medication history indicates the use of ONE standard stimulant agent (e.g., methylphenidate) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate)

Age Restrictions:
Patient is 7 years of age or over

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Somatostatin Analogs PA - Octreotide**

Drug Name(s):
octreotide injection

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of the following:
    A. Patient has an FDA approved 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 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 failed acarbose OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to acarbose OR
        v. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
2. The dose requested is within the FDA approved or CMS approved compendia dosing for the requested agent and indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Initial approval will be for 6 months, renewal 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 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 improvement with the requested agent AND
4. The dose requested is within the FDA approved or CMS approved compendia dosing for the requested agent and indication

Prior Authorization Group – **Somatostatin Analogs PA - Somatuline Depot**

Drug Name(s):
SOMATULINE DEPOT

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for initial approval require ONE of the following:
1. Patient has an FDA approved indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
2. BOTH of the following:
    A. 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 ONE of the following:
            a. The tumors are unresectable, locally advanced, well or moderately differentiated OR
            b. The tumors have metastasized 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
    B. The dose requested is within the FDA approved or CMS approved compendia dosing for the requested agent and indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Initial approval will be for 6 months, renewal approval will be for 12 months

Other Criteria:
Criteria for renewal approval require ONE of the following:
1. Patient has an FDA approved indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient is currently being treated with the requested agent OR
2. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND ALL of the following:
    A. ONE of the following:
        i. Patient has a diagnosis of acromegaly OR
        ii. Patient has a diagnosis of metastatic OR unresectable, locally advanced, well or moderately differentiated gastroenteropancreatic neuroendocrine tumors 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
    B. Patient has had clinical improvement with the requested agent AND
    C. The dose requested is within the FDA approved or CMS approved compendia dosing for the requested agent and indication

Prior Authorization Group – **Somatostatin Analogs PA - Somavert**

Drug Name(s):
SOMAVERT

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require BOTH of the following:
1. Patient has a diagnosis of acromegaly AND ONE of the following:
    A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
    B. Prescriber states the patient is currently being treated with the requested agent AND is at risk if therapy is changed OR
    C. BOTH of the following:
        i. ONE of the following:
            a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR
            b. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by serum IGF-1 levels that are above the reference range AND
        ii. ONE of the following:
            a. Patient has tried and failed a prerequisite agent [octreotide or Somatuline Depot (lanreotide)] OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prerequisite agent AND
2. The dose requested is within the FDA approved dosing for the requested agent and indication

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of acromegaly AND
3. Patient has had clinical improvement with the requested agent AND
4. The dose requested is within the FDA approved dosing for the requested agent and indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Initial approval will be for 6 months, renewal approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Sovaldi PA**

Drug Name(s):
SOVALDI
SOVALDI PACK

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
5. ONE of the following:
    A. There is documentation that the patient is currently being treated with the requested agent OR
    B. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes OR
    C. Prescriber has submitted documentation based on FDA approved labeling or AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:
Prior Authorization Group – **Spravato PA**

Drug Name(s):
SPRAVATO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require BOTH of the following:
1. BOTH of following:
    a. Patient has a diagnosis of treatment-resistant depression (TRD) AND
    b. Patient is currently receiving treatment with an oral antidepressant and will continue to receive the antidepressant with the requested agent AND
2. ONE of 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 an inadequate response to at least two different oral antidepressants (e.g., SSRIs, SNRIs) AND
        ii. Prescriber is a specialist (e.g., psychiatrist) or the prescriber has consulted with a specialist AND
        iii. Patient does NOT have any FDA labeled contraindication(s) to 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. BOTH of the following:
    a. Patient has a diagnosis of treatment-resistant depression (TRD) AND
    b. Patient is currently receiving treatment with an oral antidepressant and will continue to receive the antidepressant with 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 shown clinical benefit with the requested agent AND
    ii. Prescriber is a specialist (e.g., psychiatrist) or the prescriber has consulted with a specialist AND
    iii. Patient does NOT have any FDA labeled contraindication(s) to the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Strensiq PA**

Drug Name(s):
STRENSIQ

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 dose requested is within the FDA labeled dosing (based on the patient’s weight) for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist or geneticist with expertise in metabolic bone diseases) or the prescriber has consulted with a specialist

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 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 dose requested is within the FDA labeled dosing (based on the patient's weight) for the requested indication

Prior Authorization Group – **Substrate Reduction Therapy PA - Miglustat**

Drug Name(s):
miglustat 100 mg capsule

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of Gaucher disease type 1 confirmed by ONE of the following:
    a. A baseline glucocerebrosidase enzyme activity of less than 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR
    b. Confirmation of genetic mutation of GBA gene with two disease-causing alleles AND
2. ONE of the following:
    a. Patient's medication history indicates use of at least ONE enzyme replacement therapy (i.e., Cerezyme, Vpriv, Elelyso) OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE enzyme replacement therapy AND
3. Prescriber has drawn baseline levels of hemoglobin, platelets, liver volume, and spleen volume AND
4. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following:
    a. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
    b. Thrombocytopenia (defined as platelet count of less than 100,000 per microliter) OR
    c. Hepatomegaly OR
    d. Splenomegaly OR
    e. Growth failure (i.e., growth velocity is below the standard mean for age) OR
    f. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 AND
3. Patient has shown improvement and/or stabilization from baseline in at least ONE of the following:

a. Spleen volume OR
b. Hemoglobin level OR
c. Liver volume OR
d. Platelet count OR
e. Growth OR
f. Bone pain or crisis

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Symdeko PA**

Drug Name(s):
SYMDEKO

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of cystic fibrosis AND
2. ONE of the following:
    a. Patient has the presence of the F508del mutation on both alleles (homozygous) of the CFTR gene confirmed by genetic testing OR
    b. Patient has ONE of the CFTR gene mutations as indicated in the FDA label as confirmed by genetic testing AND
3. ONE of following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Kalydeco (ivacaftor), Orkambi (lumacaftor/ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to starting 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 a diagnosis of cystic fibrosis AND
3. Patient has shown clinical 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 Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. ONE of the following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Kalydeco (ivacaftor), Orkambi (lumacaftor/ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to continuing the requested agent

Age Restrictions:
Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:
Prescriber is a specialist (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Teriparatide PA**

Drug Name(s):
FORTEO

Off-Label Uses:

Exclusion Criteria:
Increased baseline risk for osteosarcoma

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has ONE of the following diagnoses:
    a. Postmenopausal female with osteoporosis OR
    b. Male with primary or hypogonadal osteoporosis OR
    c. Osteoporosis with sustained systemic glucocorticoid therapy AND
2. ONE of the following:
    a. Patient has a history of vertebral fracture(s), or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR
    b. Patient has a T-score that is -2.5 or lower (greater than or equal to 2.5 SD below the mean BMD value for a young adult) AND ONE of the following:
        i. Patient is female and has failed either a bisphosphonate or SERM OR
        ii. Patient is male and has failed a bisphosphonate OR
        iii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a SERM or bisphosphonate (bisphosphonate or SERM for female patients, bisphosphonates only for male patients) AND
3. ONE of the following:
    a. Patient is not receiving concomitant bisphosphonate, SERM, Tymlos (abaloparatide), Prolia (denosumab), or Xgeva (denosumab) therapy within the past 90 days OR
    b. Prescriber indicates that the patient will discontinue the current bisphosphonate, SERM, Tymlos (abaloparatide), Prolia (denosumab) or Xgeva (denosumab) therapy prior to initiating therapy with the requested agent AND
4. The dose requested is within the FDA approved labeling AND
5. The total cumulative duration of treatment with Forteo and Tymlos has not exceeded 2 years

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
No prior Forteo use approve 2 years, Prior Forteo use - see Other Criteria

Other Criteria:
Prior Forteo and/or Tymlos use approve remainder of 2 years of total cumulative therapy

Prior Authorization Group – **Tetrabenazine PA**

Drug Name(s):
tetrabenazine tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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. If the patient has a current diagnosis of depression, the patient is being treated for depression AND
3. If the patient has a diagnosis of suicidal ideation and/or behavior, the patient must not be actively suicidal AND
4. Patient is NOT receiving a monoamine oxidase inhibitor (MAOI) OR the patient's MAOI will be discontinued at least 14 days before starting therapy with the requested agent AND
5. Patient is NOT receiving reserpine OR the patient's reserpine will be discontinued at least 20 days before starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Topical NSAID PA - Voltaren**

Drug Name(s):
diclofenac 1% gel

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require BOTH of 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 AND
2. ONE of the following:
    a. Patient's medication history includes use of any prescription oral NSAID (non-steroidal anti-inflammatory drug) OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to any prescription oral NSAID

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
3 months for acute pain, 12 months for all other diagnoses

Other Criteria:

Prior Authorization Group – **Topical Retinoids PA - Tazarotene**

Drug Name(s):
tazarotene 0.1% cream
TAZORAC 0.5% cream
TAZORAC gel

Off-Label Uses:

Exclusion Criteria:
Requested agent will be used for cosmetic purposes

Required Medical:
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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Topical Retinoids PA - Tretinoin**

Drug Name(s):
tretinoin 0.025% cream
tretinoin 0.025% gel

Off-Label Uses:

Exclusion Criteria:
Requested agent will be used for cosmetic purposes

Required Medical:
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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Trelstar PA**

Drug Name(s):
TRELSTAR MIXJECT

Off-Label Uses:

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require ALL of 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 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 contraindication(s) to the requested agent AND
3. The dose requested is within the FDA labeled or CMS approved compendia dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Trientine PA**

Drug Name(s):
trientine capsule

Off-Label Uses:

Exclusion Criteria:

Required Medical:
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 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's medication history indicates use of a penicillamine (e.g., Depen) OR
    b. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to a 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 responded to treatment 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 Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist, or neurologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Trikafta PA**

Drug Name(s):
TRIKAFTA

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of cystic fibrosis AND
2. Patient has the presence of the F508del mutation in at least ONE allele (heterozygous OR homozygous) of the CFTR gene confirmed by genetic testing AND
3. ONE of following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Kalydeco (ivacaftor), Orkambi (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor and ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to starting 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 a diagnosis of cystic fibrosis AND
3. Patient has shown clinical 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 Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. ONE of the following:
    a. Patient is NOT currently being treated with another CFTR agent [e.g., Kalydeco (ivacaftor), Orkambi (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor and ivacaftor)] OR
    b. Patient is currently being treated with another CFTR agent AND will discontinue the other CFTR agent prior to continuing the requested agent

Age Restrictions:
Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:
Prescriber is a specialist (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Tymlos PA**

Drug Name(s):
TYMLOS

Off-Label Uses:

Exclusion Criteria:
Increased baseline risk for osteosarcoma

Required Medical:
Criteria for approval require ALL of the following:
1. Patient is a postmenopausal female with a diagnosis of osteoporosis AND ONE of the following:
    a. Patient has a history of vertebral fracture(s), or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR
    b. Patient has a T-score that is -2.5 or lower (greater than or equal to 2.5 SD below the mean BMD value for a young adult) AND ONE of the following:
        i. Patient has failed either a bisphosphonate or SERM OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate or SERM AND
2. ONE of the following:
    a. Patient is not receiving concomitant bisphosphonate, SERM, Forteo (teriparatide), Prolia (denosumab), or Xgeva (denosumab) therapy within the past 90 days OR
    b. Prescriber indicates that the patient will discontinue the current bisphosphonate, SERM, Forteo (teriparatide), Prolia (denosumab), or Xgeva (denosumab) therapy prior to initiating therapy with the requested agent AND
3. The dose requested is within the FDA approved labeling AND
4. The total cumulative duration of treatment with Forteo and Tymlos has not exceeded 2 years

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
No prior Tymlos use approve 2 years, Prior Tymlos use - see Other Criteria

Other Criteria:

Prior Tymlos and/or Forteo use approve remainder of 2 years of total cumulative therapy

Prior Authorization Group – **Urea Cycle Disorders PA - Buphenyl**

Drug Name(s):
sodium phenylbutyrate powder, tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
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 dose requested is within the FDA labeled dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., geneticist, metabolic disorders) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Viekira PA**

Drug Name(s):
VIEKIRA PAK

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
5. If genotype 1, the patient's subtype has been identified and provided AND
6. ONE of the following:
    A. There is documentation that the patient is currently being treated with the requested agent OR
    B. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes OR
    C. Prescriber has submitted documentation based on FDA approved labeling or AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:

Prior Authorization Group – **Viekira XR PA**

Drug Name(s):
VIEKIRA XR

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
5. If genotype 1, the patient's subtype has been identified and provided AND
6. ONE of the following:
    A. There is documentation that the patient is currently being treated with the requested agent OR
    B. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes OR
    C. Prescriber has submitted documentation based on FDA approved labeling or AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:

Prior Authorization Group – **Voriconazole PA**

Drug Name(s):
voriconazole injection, suspension, tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require the following:
1. ONE of the following:
    A. Patient has a diagnosis of invasive Aspergillus OR
    B. Patient has an infection caused by Scedosporium apiospermum or Fusarium species OR
    C. Patient has a diagnosis of esophageal candidiasis or candidemia in nonneutropenic patient AND patient has tried fluconazole or an alternative antifungal agent OR patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to fluconazole or an alternative antifungal agent OR
    D. Patient has a diagnosis of blastomycosis AND patient has tried itraconazole OR patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity 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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
One month for esophageal candidiasis, 6 months for all other indications

Other Criteria:

Criteria for renewal approval require BOTH of the following:

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

2. ONE of the following:

    A. Patient has a diagnosis of invasive Aspergillus, Scedosporium apiospermum, Fusarium, esophageal candidiasis, candidemia in nonneutropenic patient or blastomycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR

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

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

Prior Authorization Group – **Vosevi PA**

Drug Name(s):
VOSEVI

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
5. If genotype 1, the patient's subtype has been identified and provided

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

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

Other Criteria:

Prior Authorization Group – **Vyndamax PA**

Drug Name(s):
VYNDAMAX

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine) will not be used concurrently with each other

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
4. Patient has shown clinical benefit with the requested agent AND
5. Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine) will not be used concurrently with each other

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., cardiologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Vyndaqel PA**

Drug Name(s):
VYNDAQEL

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine) will not be used concurrently with each other

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
4. Patient has shown clinical benefit with the requested agent AND
5. Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine) will not be used concurrently with each other

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., cardiologist) or the prescriber has consulted with a specialist

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Xgeva PA**

Drug Name(s):
XGEVA

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. ONE of the following:
    A. Patient has a diagnosis of multiple myeloma AND ALL 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 tried and failed zoledronic acid (Zometa) OR
            2. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to zoledronic acid (Zometa) 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
    B. Patient has a solid tumor cancer diagnosis (e.g., thyroid, non-small cell lung, kidney cancer, prostate 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 tried and failed zoledronic acid (Zometa) OR
            2. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to zoledronic acid (Zometa) AND
        iv. 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 Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
C. 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
D. Patient has a diagnosis of hypercalcemia of malignancy AND ONE of the following:
i. Patient has tried and failed zoledronic acid (Zometa) OR
ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to zoledronic acid (Zometa) AND
2. ONE of the following:
A. Patient is NOT receiving concomitant Prolia (denosumab) therapy within the past 90 days OR
B. Patient will discontinue the current Prolia (denosumab) therapy prior to initiating therapy with the requested agent AND
3. The requested dose is within the FDA labeled dosing for the requested indication

Prior Authorization Group – **Xifaxan PA**

Drug Name(s):
XIFAXAN 550 mg tablet

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require the following:
1. Patient has ONE of the following:
    a. A diagnosis of irritable bowel syndrome with diarrhea (IBS-D) OR
    b. A diagnosis of hepatic encephalopathy [reduction in risk of overt hepatic encephalopathy (HE) recurrence] OR
    c. ALL of the following:
        i. A diagnosis of traveler's diarrhea (TD) AND
        ii. The traveler's diarrhea is caused by noninvasive strains of Escherichia coli AND
        iii. Patient is 12 years of age or over

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Xolair PA**

Drug Name(s):
XOLAIR

Off-Label Uses:

Exclusion Criteria:

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of the following:
    A. Patient has a diagnosis of asthma AND ALL of the following:
        i. If the patient is 6 to less than 12 years of age, the patient meets BOTH of the following:
            a. Patient's pretreatment IgE level is 30 IU/mL to 1300 IU/mL AND
            b. Patient's weight is 20 kg to 150 kg AND
        ii. If the patient is 12 years of age or over, the patient meets ALL of the following:
            a. Patient's pretreatment IgE level is 30 IU/mL to 700 IU/mL AND
            b. Patient's weight is 30 kg to 150 kg AND
            c. Patient has a baseline FEV1 less than 80% predicted AND
        iii. Allergic asthma has been confirmed by positive skin test or in vitro reactivity test (RAST) to a perennial aeroallergen AND
        iv. ONE of the following:
            a. Patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid in the past 90 days OR
            b. Patient is currently being treated with the requested agent AND is currently treated with an inhaled corticosteroid that is dosed as needed to control symptoms OR
            c. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an inhaled corticosteroid AND
        v. ONE of the following:
            a. There is evidence of a claim that the patient is currently using a long-acting beta-2 agonist within the past 90 days OR the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to long-acting beta-2 agonist OR
            b. There is evidence of a claim that the patient is currently using a leukotriene modifier or theophylline within the past 90 days OR the patient has a documented intolerance, FDA labeled

contraindication, or hypersensitivity to a leukotriene modifier or theophylline AND

vi. Patient is experiencing exacerbations of asthma symptoms AND

Initial criteria continues: see Other Criteria

Age Restrictions:

For diagnosis of asthma, patient is 6 years of age or over. For diagnosis of chronic idiopathic urticaria, patient is 12 years of age or over.

Prescriber Restrictions:

Prescriber is a specialist (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist

Coverage Duration:

Initial: 6 months for asthma and chronic idiopathic urticaria Renewal: 12 months

Other Criteria:

vii. The requested agent will NOT be used in combination with Dupixent or an injectable Interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR

B. Patient has a diagnosis of chronic idiopathic urticaria AND ALL of the following:

i. Patient has a history of chronic idiopathic urticaria for at least 6 weeks AND

ii. Patient has a history of hives and itching AND

iii. ONE of the following:

a. There is evidence of a claim that the patient is currently on maximum tolerable H1 antihistamine therapy within the past 90 days OR

b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to H1 antihistamine therapy AND

2. The requested dose is within the FDA labeled dose 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 asthma AND ALL of the following:

i. Patient's weight is within the FDA indicated range for their age (i.e., 20 kg to 150 kg for patients age 6 to less than 12 years and 30 kg to 150 kg for patients 12 years of age or over) AND
ii. Patient does not have clinical worsening defined as ONE of the following:
1. Increase in inhaled corticosteroid use
2. Treatment with systemic corticosteroids
3. Increased use of short acting beta-2 agonist rescue medication
4. Unscheduled care visits (urgent care, ER, or hospitalizations) due to exacerbations AND
iii. ONE of the following:
1. There is evidence of a claim that the patient is currently on standard therapy (such as a combination of an inhaled corticosteroid, long acting beta-2 agonist, leukotriene receptor antagonist, theophylline, oral corticosteroid or an oral beta-2 agonist tablet) within the past 90 days OR
2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies AND
iv. The requested agent will NOT be used in combination with Dupixent or an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR
b. Patient has a diagnosis of chronic idiopathic urticaria AND has had improvement in symptoms (e.g., number of hives, size of hives, reduction in itching) AND
3. The requested dose is within the FDA labeled dose for the requested indication

Prior Authorization Group – **Zepatier PA**

Drug Name(s):
ZEPATIER

Off-Label Uses:

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic 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 dosing of the requested agent is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
5. If genotype 1, the patient's subtype has been identified and provided AND
6. If genotype 1a, the prescriber has tested the patient for the presence of virus with NS5A resistance-associated polymorphisms AND
7. ONE of the following:
    A. There is documentation that the patient is currently being treated with the requested agent OR
    B. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes OR
    C. Prescriber has submitted documentation based on FDA approved labeling or AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa, Harvoni, ledipasvir/sofosbuvir, Mavyret, or sofosbuvir/velpatasvir for supported genotypes

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist

Coverage Duration:

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

Other Criteria: