2017 PRIOR AUTHORIZATION CRITERIA

TABLE OF CONTENTS

Prior Authorization Group – **Acthar HP Gel PA**

Drug Name(s):
H.P. ACTHAR GEL

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    A. Diagnosis of infantile spasm OR
    B. Diagnosis of multiple sclerosis AND
        i. Patient is experiencing an acute exacerbation AND
        ii. If indicated, the patient is currently on a disease modifying drug (DMD) in the past 90 days (e.g. Aubagio, Avonex, Betaseron, Copaxone (glatiramer acetate), Extavia, Gilenya, Glatopa (glatiramer acetate), Lemtrada, Novantrone (mitoxantrone), Plegridy, Rebif, Tecfidera, or Tysabri) to control disease progression OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a DMD AND
        iii. Patient has failed corticosteroid therapy within the last 30 days or has an FDA labeled contraindication to corticosteroid therapy (e.g. methylprednisolone 1gm IV for 3-5 days) OR
    C. Other FDA approved indications: Psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, severe erythema multiforme, Stevens-Johnson syndrome, systemic lupus erythematosus, systemic dermatomyositis (polymyositis), serum sickness, keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation and symptomatic sarcoidosis AND patient has failed corticosteroid therapy within the last 30 days or has an FDA labeled contraindication to corticosteroid therapy (e.g. methylprednisolone 1gm IV for 3-5 days) OR
    D. Patient has another indication that is supported in CMS approved compendia for the requested agent AND patient has failed corticosteroid therapy within the last 30 days or has an FDA labeled contraindication to corticosteroid therapy (e.g. methylprednisolone 1gm IV for 3-5 days) AND
2. The dose is within the FDA labeled or CMS approved compendia dosing for the requested indication

Age Restrictions:
For diagnosis of infantile spasm patient must be less than 24 months of age

Prescriber Restrictions:

Coverage Duration:
6 months for infantile spasm, 1 month for all other indications

Other Criteria:

Prior Authorization Group – **Adcirca PA**

Drug Name(s):
ADCIRCA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of:
    A. BOTH of:
        i. ONE of:
            a. There is evidence of a claim that the patient (pt) is currently being treated with requested agent within the past 90 days OR
            b. Prescriber states pt is using requested agent AND is at risk if therapy is changed AND
        ii. Pt has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
    B. Pt has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of:
        i. Pt's World Health Organization (WHO) functional class is II or greater AND
        ii. Pt has a mean pulmonary arterial pressure of greater than or equal to 25 mmHg AND
        iii. Pt has a pulmonary vascular resistance greater than 3 Wood units AND
        iv. ONE of:
            a. Requested agent will be utilized as monotherapy OR
            b. Requested agent is for use in combination with Letairis (ambrisentan) for dual therapy ONLY OR
            c. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy: except for dual therapy requests for Adcirca with Letairis), then BOTH of:
                1) Pt has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
                2) Requested agent is in a different therapeutic class OR
            d. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then ALL of:

1) A prostanoid has been started as one of the agents in the triple therapy unless the pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
2) Pt 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. Pt has an indication that is supported in CMS approved compendia for requested agent AND

2. Pt is NOT concurrently taking an PDE-5 inhibitor (e.g. Cialis, Viagra) with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Criteria for renewal require BOTH of the following:
1. Pt has been previously approved for therapy through the plan's PA criteria and is responding to therapy AND
2. Pt has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

Prior Authorization Group – **Adempas PA**

Drug Name(s):
ADEMPAS

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of:
    A. BOTH of:
        i. ONE of:
            a. There is evidence of a claim that pt is currently being treated with requested agent within the past 90 days OR
            b. Prescriber states the pt is using requested agent AND is at risk if therapy is changed AND
        ii. Pt has an FDA labeled indication for the requested agent OR
    B. Pt has a diagnosis (dx) of CTEPH, WHO Group 4 as determined by ventilation-perfusion scan and a confirmatory selective pulmonary angiography AND ALL of:
        i. ONE of:
            a. Pt is NOT a candidate for surgery OR
            b. Pt has had pulmonary endarterectomy AND has persistent or recurrent disease AND
        ii. Pt has a mean pulmonary arterial pressure of greater than or equal to 25 mmHg AND
        iii. Pt has pulmonary capillary wedge pressure less than or equal to 15 mmHg OR
    C. Pt has a dx of PAH, WHO Group 1 as determined by right heart catheterization AND ALL of:
        i. Pt's WHO functional class is II or greater AND
        ii. Pt has a mean pulmonary arterial pressure of greater than or equal to 25 mmHg AND
        iii. Pt has a pulmonary vascular resistance greater than 3 Wood units AND
2. ONE of:
    A. Requested agent will be utilized as monotherapy OR
    B. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then BOTH of:

i. Pt has unacceptable or deteriorating clinical status despite established pharmacotherapy AND
ii. Requested agent is in a different therapeutic class OR

C. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then ALL of:
i. Prostanoid therapy has been started as one of the agents in the triple therapy unless the pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND
ii. Pt has unacceptable or deteriorating clinical status despite established pharmacotherapy AND
iii. 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 require ALL of the following:
1. Pt has been previously approved for therapy through the plan's PA criteria and is responding to therapy AND
2. Pt has an FDA labeled indication for the requested agent AND
3. ONE of:
A. Pt has shown improvement from baseline in the 6-minute walk distance OR
B. Pt has a stable 6-minute walk distance AND improvement in at least ONE of:
i. Pulmonary vascular resistance OR
ii. WHO functional class OR
iii. Borg dyspnea score

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

Drug Name(s):
PROLASTIN-C

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 as determined by BOTH of the following:
    a. Pre-treatment serum alpha-1 antitrypsin (AAT) levels less than 11 µM/L (80 mg/dL by immunodifussion or 57 mg/dL using nephelometry) AND
    b. Patient has a phenotype variant associated with AAT (i.e. PiZZ, PiSZ, PiZ/Null or PiNull/Null) AND
2. Patient has emphysema with a documented FEV1 of less than or equal to 60% predicted AND
3. The dose requested is within the FDA labeled dose

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria and is responding to therapy AND
2. Patient has a diagnosis of alpha-1 antitrypsin deficiency with clinically evident emphysema AND
3. The dose requested is within the FDA labeled dose

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Amitiza PA**

Drug Name(s):
AMITIZA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has a diagnosis of ONE of the following:
    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 in a woman OR
    C. Opioid-induced constipation with chronic non-cancer pain AND BOTH of the following:
        i. Patient has chronic use of an opioid agent in the past 90 days AND
        ii. Patient is not receiving a diphenylheptane opioid (e.g. methadone) in the past 90 days AND
2. ONE of the following:
    A. Patient has tried at least one standard laxative therapy for constipation – lactulose or polyethylene glycol 3350 OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one standard laxative therapy for constipation – lactulose or polyethylene glycol 3350

Age Restrictions:
Patient must be an adult at least 18 yrs of age

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group –**Ampyra PA**

Drug Name(s):
AMPYRA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 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, Copaxone (glatiramer), Extavia, Gilenya, Glatopa (glatiramer), Lemtrada, mitoxantrone, Plegridy, Rebif, Tecfidera, or Tysabri) OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying agent AND
3. ONE of the following:
    A. Patient is being started on initial therapy with the requested agent OR
    B. Patient is currently receiving the requested agent and has been receiving the requested agent therapy for 2 months or longer AND has demonstrated an improvement from baseline in timed walking speed (timed 25 foot walk)

Age Restrictions:

Prescriber Restrictions:
Prescriber is a neurologist or has consulted a neurologist

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

Other Criteria:

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

Drug Name(s):
danazol capsule

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 will be receiving only one androgen or anabolic agent OR
    B. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 is a male or female 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 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 will be receiving only one androgen or anabolic agent OR
    B. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 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 will be receiving only one androgen or anabolic agent OR
    B. 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**

Drug Name(s):
testosterone cypionate injection
testosterone enanthate injection

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Males only: Patient has a measured current or pretreatment total serum testosterone level that is less than 300 ng/dL or is below the testing laboratory's lower limit of the normal range if greater than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory's lower limit of the normal range AND
3. ONE of the following:
    A. Patient will be receiving only one androgen or anabolic agent OR
    B. 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 Oral PA**

Drug Name(s):
ANDROXY
methyltestosterone capsule

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 cryptorchidism OR
    B. Patient is a male with hypogonadism OR
    C. Patient is an adolescent male with delayed puberty OR
    D. Patient is a female with metastatic/inoperable breast cancer AND
2. Males only: Patient has a measured current or pretreatment total serum testosterone level that is less than 300 ng/dL or is below the testing laboratory's lower limit of the normal range if greater than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory's lower limit of the normal range AND
3. ONE of the following:
    A. Patient will be receiving only one androgen or anabolic agent OR
    B. 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
ANDROGEL 1.62%
ANDROGEL 1.62% PUMP
AXIRON
testosterone 1% gel
testosterone 1% gel pump
testosterone 30 mg/act solution (generic for AXIRON)

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 or female 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 male with primary or secondary (hypogonadotropic) hypogonadism AND
2. Males only: Patient has a measured current or pretreatment total serum testosterone level that is less than 300 ng/dL or is below the testing laboratory's lower limit of the normal range if greater than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory's lower limit of the normal range AND
3. ONE of the following:
    A. Patient will be receiving only one androgen or anabolic agent OR
    B. 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):

ABILIFY DISCMELT 10 mg
ABILIFY MAINTENA
ADASUVE
aripiprazole ODT
aripiprazole solution, tablet
CHLORPROMAZINE injection
chlorpromazine tablet
clozapine tablet
clozapine ODT 25 mg, 100 mg
FANAPT
FANAPT TITRATION PACK
fluphenazine decanoate 25 mg/mL injection
FLUPHENAZINE concentrate, elixir, injection
fluphenazine tablet
GEODON injection
haloperidol decanoate injection
haloperidol lactate injection
haloperidol concentrate, tablet
INVEGA SUSTENNA
INVEGA TRINZA
LATUDA
loxapine capsule
MOLINDONE
olanzapine injection, tablet
olanzapine ODT
paliperidone er 24hr tablet
perphenazine tablet
quetiapine tablet
quetiapine er tablet
REXULTI
RISPERDAL CONSTA
risperidone solution, tablet
risperidone ODT
SAPHRIS
SEROQUEL XR
thiothixene capsule
trifluoperazine tablet
VERSACLOZ
VRAYLAR
ziprasidone capsule
ZYPREXA RELPREVV

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only. PA does NOT apply to patients less than 65 yrs 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, BOTH of the following:
        i. Dementia-related psychosis is determined to be severe or the associated agitation, combativeness, or violent 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 – **Arcalyst PA**

Drug Name(s):
ARCALYST

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy with the requested agent AND An active or chronic infection (e.g. tuberculosis, HIV, hepatitis B/C)

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) AND
2. If patient is currently being treated with another biologic the medication will be discontinued before initiating Arcalyst

Age Restrictions:
Patients must be 12 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Armodafinil PA**

Drug Name(s):
armodafinil tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 is receiving only one of the listed agents – armodafinil OR modafinil within the past 90 days OR
    B. Patient has been treated modafinil within the past 90 days and will discontinue prior to starting the requested agent

Age Restrictions:
Patients must be 17 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
ELIDEL

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Atopic dermatitis OR
        ii. Vulvar lichen sclerosus AND
    B. ONE of the following:
        i. Patient has had a trial and failure of a topical corticosteroid or topical corticosteroid combination preparation (e.g. clobetasol, hydrocortisone, triamcinolone) OR
        ii. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation OR
2. Patient has diagnosis of facial seborrhoeic dermatitis associated with HIV infection AND all 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
1. Patient has diagnosis of facial or flexural psoriasis OR
2. BOTH of the following:
    A. Patient has a diagnosis of atopic dermatitis AND
    B. ONE of the following:
        i. Patient has had a trial and failure with a topical corticosteroid or topical corticosteroid combination preparation (e.g. clobetasol, hydrocortisone, triamcinolone) OR
        ii. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation 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 – **Benlysta PA**

Drug Name(s):
BENLYSTA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 active systemic lupus erythematosus (SLE) disease AND
2. Patient has a history of positive autoantibody test results [positive antinuclear antibody (ANA greater than or equal to 1:80) and/or anti-dsDNA (greater than or equal to 30 IU/mL)] AND
3. Patient has a history of 3 other SLE diagnostic criteria (i.e. malar rash, discoid rash, photosensitivity, oral ulcers, nonerosive arthritis, pleuritis/pericarditis, renal disorder [persistent proteinuria greater than 0.5 grams/day or cellular casts], hematologic disorder [hemolytic anemia (with reticulocytosis), leukopenia, lyphopenia, or thrombocytopenia], and/or immunologic disorder [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 a standard of care 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 PA criteria AND
2. Patient has diagnosis of active SLE disease AND
3. ONE of the following:
    A. There is evidence of a claim that the patient is currently on a standard of care 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 the 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, pleuritis/pericarditis, renal disorder [persistent proteinuria greater than 0.5 grams/day or cellular casts], hematologic disorder [hemolytic anemia (with reticulocytosis), leukopenia, lymphopenia, or thrombocytopenia], and/or immunologic disorder [positive finding of antiphopholipid 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 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

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

Drug Name(s):
clonazepam ODT
clonazepam tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. 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 using the requested agent AND
    B. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
2. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Seizure disorder OR
        ii. Panic disorder AND ONE of the following:
            a. Patient's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs OR
        iii. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
    B. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. 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 using the requested agent AND
    B. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
2. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Seizure disorder OR
        ii. Anxiety disorder AND ONE of the following:
            a. Patient's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs OR
        iii. Alcohol withdrawal OR
        iv. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
    B. 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
diazepam intensol concentrate

Covered Uses:

All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:

Program applies to new starts only.
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. 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 using the requested agent AND
    B. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
2. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Seizure disorder OR
        ii. Anxiety disorder AND ONE of the following:
            a. Patient's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs OR
        iii. Skeletal muscle spasms OR
        iv. Alcohol withdrawal OR
        v. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
    B. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. 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 using the requested agent AND
    B. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
2. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Anxiety disorder AND ONE of the following:
            a. Patient's medication history includes use of a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary SSRIs or SNRIs OR
        ii. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
    B. 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 - Onfi**

Drug Name(s):
ONFI

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require ONE of the following:
1. BOTH of the following:
    A. 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 using the requested agent AND
    B. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
2. BOTH of the following:
    A. Patient has ONE of the following diagnoses:
        i. Seizure disorder OR
        ii. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
    B. 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 - Enbrel**

Drug Name(s):
ENBREL
ENBREL MINI
ENBREL SURECLICK

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 using 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 agent prerequisite OR
    E. Patient's medication history indicates use of ONE formulary conventional agent prerequisite OR
    F. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional agent AND
3. Patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB AND
4. Patient is NOT currently being treated with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for therapy 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. Patient is NOT currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Formulary conventional agent required for diagnoses of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, or psoriasis

Diagnosis of ankylosing spondylitis does NOT require formulary conventional therapy

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 topical corticosteroids, tazarotene, cyclosporine, calcipotriene, methotrexate, or acitretin

Formulary biologic immunomodulator agents for rheumatoid arthritis are Humira, Kineret, Remicade, and Rituxan, for juvenile idiopathic arthritis is Humira, for psoriatic arthritis are Humira, Remicade, and Stelara, for psoriasis are Humira, Remicade, and Stelara, and for ankylosing spondylitis are Humira and Remicade.

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

Drug Name(s):
HUMIRA
HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK
HUMIRA PEN
HUMIRA PEN-CROHNS DISEASE STARTER
HUMIRA PEN-PSORIASIS STARTER

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 using 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 agent prerequisite OR
    E. Patient's medication history indicates use of ONE formulary conventional agent prerequisite OR
    F. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional agent AND
3. Patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB AND
4. Patient is NOT currently being treated with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for therapy 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. Patient is NOT currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:
Formulary conventional agent required for diagnoses of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, psoriasis, ulcerative colitis, or crohn's disease

Diagnosis of ankylosing spondylitis, hidradenitis suppurativa, and uveitis do NOT require formulary conventional therapy

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 topical corticosteroids, tazarotene, cyclosporine, calcipotriene, methotrexate, or acitretin

Formulary conventional agents for crohn's disease or ulcerative colitis include methotrexate

aminosalicylates, corticosteroids, cyclosporine, azathioprine, 6-mercaptopurine, metronidazole, or ciprofloxacin

Formulary biologic immunomodulator agents for rheumatoid arthritis are Enbrel, Kineret, Remicade, and Rituxan, for juvenile idiopathic arthritis is Enbrel, for psoriatic arthritis are Enbrel, Remicade, and Stelara, for psoriasis are Enbrel, Remicade, and Stelara, for ankylosing spondylitis are Enbrel and Remicade, for ulcerative colitis is Remicade, and for crohn's disease is Remicade

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

Drug Name(s):
KINERET

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 using the requested agent AND is at risk if therapy is changed OR
    C. ONE of the following:
        i. Patient's medication history indicates use of TWO of the preferred biologic immunomodulator agents (Enbrel and Humira) or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to TWO of the preferred biologic agents OR
        ii. The request is for an FDA labeled indication that is not covered by TWO of the preferred biologic agents AND
3. Patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB AND
4. Patient is NOT currently being treated with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for therapy 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. Patient is NOT currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of TWO of the preferred biologics (Humira and Enbrel) are required for diagnosis of rheumatoid arthritis

NO prerequisites are required for diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS)/Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

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

Drug Name(s):
ORENCIA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 using the requested agent AND is at risk if therapy is changed OR
    C. Patient's medication history indicates use of TWO of the preferred biologic immunomodulator agents (Enbrel, Humira or Stelara) or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to TWO of the preferred biologic agents AND
3. Patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB AND
4. Patient is NOT currently being treated with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for therapy 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. Patient is NOT currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Use of TWO preferred biologics (Enbrel and Humira) are required for the diagnoses of juvenile idiopathic arthritis or rheumatoid arthritis

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

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

Drug Name(s):
REMICADE

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 using the requested agent AND is at risk if therapy is changed OR
    C. ONE of the following:
        i. Patient's medication history indicates use of TWO of the preferred biologic immunomodulator agents (Enbrel, Humira or Stelara) or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to TWO of the preferred biologic agents OR
        ii. Patient's diagnosis is indicated in only ONE of the preferred biologic immunomodulators or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to this preferred agent AND
3. Patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB AND
4. Patient is NOT currently being treated with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for therapy 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. Patient is NOT currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Use of TWO of the preferred biologics (Humira and Enbrel) are required for diagnoses of rheumatoid arthritis or ankylosing spondylitis

Use of TWO of the preferred biologics (Humira, Enbrel or Stelara) are required for diagnoses of psoriasis or psoriatic arthritis

Only the preferred biologic Humira is required for diagnoses of ulcerative colitis or crohn's disease

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

Drug Name(s):
RITUXAN

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 using 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 BOTH preferred biologic agents, Enbrel and Humira OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to BOTH preferred agents, Humira and Enbrel OR
        ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia that does not require preferred agents 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 Rituxan AND
    C. Patient is NOT currently being treated with another biologic immunomodulator AND
    D. 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:
Criteria for renewal approval require the following:
1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent 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 using the requested agent OR
    C. ALL of the following:
        i. Patient has been previously approved for therapy through the plan's PA criteria AND
        ii. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
        iii. Patient does NOT have any FDA labeled contraindications to the requested agent AND
        iv. Patient is NOT currently being treated with another biologic immunomodulator

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

Drug Name(s):
RITUXAN HYCELA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 using the requested agent OR
    c. ALL of the following:
        i. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND
        ii. Patient is NOT currently being treated with another biologic immunomodulator AND
        iii. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Criteria for renewal 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. ALL of the following
        i. Patient has been previously approved for the requested agent through the plan's PA criteria AND
        ii. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
STELARA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 using 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 agent prerequisite OR
    E. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE formulary conventional agent AND
3. Patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB AND
4. Patient is NOT currently being treated with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:
1. Patient has been previously approved for therapy 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. Patient is NOT currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Formulary conventional agent required for diagnoses of psoriatic arthritis, psoriasis, or crohn's disease

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

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

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

Prior Authorization Group – **Bosentan PA**

Drug Name(s):
TRACLEER

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND Elevated liver enzymes accompanied by signs or symptoms of liver dysfunction/injury or a bilirubin level of greater than or equal to 2 times ULN (upper limit of normal)

Required Medical:
Criteria for initial approval require ONE of the following:
1. BOTH of the following:
    A. 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 using the requested agent AND is at risk if therapy is changed AND
    B. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL the following:
    i. Patient's WHO functional class is II or greater AND
    ii. Patient has a mean pulmonary arterial pressure of 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. Requested agent will be utilized as monotherapy OR
        b. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then BOTH of the following:
            1) Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy
            AND
            2) Requested agent is in a different therapeutic class OR
        c. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then 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

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

Prior Authorization Group – **Buprenorphine PA**

Drug Name(s):
buprenorphine sublingual tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for initial approval require the following:
1. Patient has a diagnosis of opioid dependence

Criteria for renewal 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 a diagnosis of opioid dependence

Age Restrictions:
Patients must be 16 years of age or older.

Prescriber Restrictions:

Coverage Duration:
Approval will be for 6 months

Other Criteria:

Prior Authorization Group – **Buprenorphine-Naloxone PA**

Drug Name(s):
buprenorphine-naloxone sublingual tablet
SUBOXONE

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for initial approval require the following:
1. Patient has a diagnosis of opioid dependence

Criteria for renewal 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 a diagnosis of opioid dependence

Age Restrictions:
Patients must be 16 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 6 months

Other Criteria:

Prior Authorization Group – **Chorionic Gonadotropin PA**

Drug Name(s):
chorionic gonadotropin injection
pregnyl

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require 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 – **Corlanor PA**

Drug Name(s):
CORLANOR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ALL 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. Patient has a baseline OR current left ventricular ejection fraction of less than or equal to 35% AND
3. Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute AND
4. ONE of the following:
    A. Patient is on a maximally tolerated dose of beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol) OR
    B. Patient has a history of a documented intolerance, FDA labeled contraindication, 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

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

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for 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, positive cultures, positive serum galactomannan assay) OR
    B. Patient has a diagnosis of 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 – **Daklinza PA**

Drug Name(s):
DAKLINZA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Daklinza (daclatasvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Daklinza (daclatasvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Egrifta PA**

Drug Name(s):
EGRIFTA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s)

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of HIV infection AND
2. Patient has lipodystrophy defined for men as waist circumference of 95 cm [37.4 inches] or greater and waist-to-hip ratio of 0.94 or greater OR for women as waist circumference of 94 cm [37.0 inches] or greater and waist-to-hip ratio of 0.88 or greater AND
3. Patient has a CD4 cell count greater than 100 cells/mm3 and a viral load less than 10,000 copies/mL AND
4. Patient is currently on anti-retroviral therapy (ART) AND
5. Patient is not planning to become pregnant or currently breastfeeding AND
6. Patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of greater than 150 mg/dL AND
7. Patient is not currently being treated with growth hormone (GH), GH secretagogues, GH-releasing hormone/GH-releasing factor products, insulin-like growth factor (IGF)-1, or IGF-binding protein-3

Criteria for renewal require ALL of the following:
1. Patient has been approved for the requested agent previously through the plan's PA criteria AND
2. Patient has had and/or maintained a decrease in visceral adipose tissue (VAT) from baseline or maintained or decreased waist circumference AND
3. Patient has a CD4 cell count greater than 100 cells/mm3 and a viral load less than 10,000 copies/mL AND
4. Patient is currently on ART AND
5. Patient is not planning to become pregnant or currently breastfeeding AND
6. Patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of greater than 150 mg/dL AND
7. Patient is not currently being treated with GH, GH secretagogues, GH-releasing hormone/GH-releasing factor products, IGF-1, or IGF-binding protein-3

Age Restrictions:
Patient must be between 18 and 65 yrs of age

Prescriber Restrictions:

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

Other Criteria:

Prior Authorization Group – **Entresto PA**

Drug Name(s):
ENTRESTO

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND patient is pregnant

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of chronic heart failure (NYHA Class II, III, or IV) AND
2. Patient has a baseline OR current left ventricular ejection fraction of less than or equal to 40% AND
3. ONE of the following:
    A. Patient is currently taking a beta blocker (e.g., atenolol, bisoprolol, carvedilol, metoprolol) OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a beta blocker AND
4. ONE of the following:
    A. Patient is NOT currently taking another ACE inhibitor or ARB (e.g., benazepril, lisinopril, losartan) with the requested agent OR
    B. Patient will discontinue the other current ACE inhibitor or ARB before starting 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Epclusa (sofosbuvir/velpatasvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Epclusa (sofosbuvir/velpatasvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

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

Drug Name(s):
ARANESP

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. ESA is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:
        i. Patient's (pt) hemoglobin level is less than 10 g/dL for pts initiating ESA therapy or 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
    B. ESA is being prescribed for a pt with anemia associated with chronic renal failure in a pt NOT on dialysis AND pt's hemoglobin level is less than 10 g/dL for pts initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks) AND BOTH of the following:
        i. Rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
        ii. Goal is to reduce risk of alloimmunization and/or other RBC transfusion related risks OR
    C. ESA is being prescribed for a pt with 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 the previous four weeks) OR
    D. ESA is being prescribed for another indication AND BOTH of the following:
        i. Pt has an indication that is supported in CMS approved compendia for the requested agent AND
        ii. 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 the 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:
6 months for chemotherapy, 12 months for other indications

Other Criteria:

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

Drug Name(s):
EPOGEN
PROCRIT

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require BOTH of:
1.ONE of:
A.ESA prescribed (tx) to reduce possibility of allogeneic blood transfusion (tfn) in surgery patients (pt) AND pt's hemoglobin (Hg) level (lvl) is greater than 10 g/dL but less than or equal (=) to 13 g/dL OR
B.ESA tx for anemia due to myelosuppressive chemotherapy (chemo) for non-myeloid malignancy ALL of:
i.Pt's hg lvl less than 10 g/dL for pts initiating or stabilized on ESA therapy, measured within (w/in) previous 4 wks AND
ii.Pt concurrently treated w/ chemo, w/ or w/out radiation (treatment period extends to 8 wks post chemotherapy) AND
iii.Intent of chemo is non-curative OR
C.ESA tx for pt w/ anemia associated w/ chronic renal failure NOT on dialysis AND ALL of:
i.Pt's hg lvl less than 10 g/dL for pts initiating or stabilized ESA therapy, measured w/in past 4 wks AND
ii.Rate of Hg decline indicates likelihood of requiring RBC tfn AND
iii.Goal to reduce the risk of alloimmunization and/or other RBC tfn related risk OR
D.ESA tx for pt w/ anemia due to myelodysplastic syndrome AND pt's hg lvl less than 12 g/dL for initiating ESA therapy or less than or = to 12 g/dL for pts stabilized on therapy, measured w/in past 4 wks OR
E.ESA tx for pt w/ anemia from zidovudine treatment of HIV infection AND pt's hg lvl less than 12 g/dL for pts initiating ESA therapy or less than or = to 12 g/dL for pts stabilized on therapy, measured w/in past 4 wks OR
F.ESA tx for another indication AND BOTH of:
i.Pt has indication supported in CMS approved compendia for requested agent AND

ii.Pt's hg lvl is less than 12 g/dL for pts initiating ESA therapy or less than or = to 12 g/dL for pts stabilized on therapy, measured w/in past 4 wks 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 – **Fentanyl Nasal PA**

Drug Name(s):
LAZANDA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    A. BOTH of the following:
        i. Patient has a diagnosis of chronic cancer pain due to an active malignancy AND
        ii. There is evidence of a claim within the past 90 days that the patient is currently taking a long-acting opioid concurrently with the nasal fentanyl OR
    B. Patient has a CMS-approved compendia accepted indication for the requested agent AND
2. Patient is receiving only one oral or nasal fentanyl agent in one strength

Age Restrictions:
Patients must be 18 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
ABSTRAL

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    A. BOTH of the following:
        i. Patient has a diagnosis of chronic cancer pain due to an active malignancy AND
        ii. There is evidence of a claim within the past 90 days that the patient is currently taking a long-acting opioid concurrently with the oral fentanyl OR
    B. Patient has a CMS-approved compendia accepted indication for the requested agent AND
2. Patient is receiving only one oral or nasal fentanyl agent in one strength

Age Restrictions:
Patients must be 18 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
fentanyl citrate oral lozenge

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    A. BOTH of the following:
        i. Patient has a diagnosis of chronic cancer pain due to an active malignancy AND
        ii. There is evidence of a claim within the past 90 days that the patient is currently taking a long-acting opioid concurrently with the oral fentanyl OR
    B. Patient has a CMS-approved compendia accepted indication for the requested agent AND
2. Patient is receiving only one oral or nasal fentanyl agent in one strength

Age Restrictions:
Patients must be 16 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Forteo PA**

Drug Name(s):
FORTEO

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy with the requested agent AND An increased baseline risk for osteosarcoma

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has a diagnosis of osteoporosis defined as 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 (2.5 or more 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 documented intolerance, FDA labeled contraindication, or hypersensitivity to a SERM or bisphosphonate (bisphosphonate or SERM for female patients, bisphosphonates only for male patients) AND
2. ONE of the following:
    A. Patient is not receiving concomitant bisphosphonate, SERM, Prolia (denosumab), or Xgeva (denosumab) therapy within the past 90 days OR
    B. Prescriber indicates that the patient will discontinue the current bisphosphonate, SERM, Xgeva, or Prolia therapy prior to initiating therapy with the requested agent AND
3. Dose requested is within FDA approved labeling AND
4. Total duration of treatment with Forteo has not exceeded 2 years

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
No prior Forteo use approve 2 yrs, Prior Forteo use approve remainder of 2 yrs of total therapy

Other Criteria:

Prior Authorization Group – **Gattex PA**

Drug Name(s):
GATTEX

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy

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 currently receiving parenteral nutrition (PN) or intravenous fluids (IV) at least 3 days per week AND
3. Patient has had a colonoscopy with any polyps removed within the last 6 months

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved through the plan's PA criteria AND
2. Patient has had a reduction from baseline in PN or IV fluids

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

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

Drug Name(s):
OMNITROPE

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
For Children – Criteria for initial approval require ONE of:
1. Patient (pt) is a neonate less than or equal to 4 months of age, with hypoglycemia in absence of metabolic disorder AND GH level is less than 20 ng/mL OR
2. Pt has diagnosis (dx) Turner's Syndrome OR
3. Pt has dx Prader-Willi Syndrome OR
4. Pt has dx panhypopituitarism AND BOTH of:
    A. Deficiencies in 3 or more pituitary axes AND
    B. Measured serum IGF-1 levels are below the age and sex-appropriate reference range when off GH therapy OR
5. Pt has dx growth hormone deficiency (GHD) or short stature AND BOTH of:
    A. ONE of:
        i. Height (ht) more than 2 SD below the mean for age and sex OR
        ii. Ht more than 1.5 SD below the midparental height OR
        iii. A decrease in ht SD of more than 0.5 over one year (yr) in children greater than 2 years of age OR
        iv. Ht velocity more than 2 SD below the mean over one yr or more than 1.5 SD sustained over two yrs AND
    B. Failure of at least 2 GH stimulation tests (peak GH value less than10 mcg/L after stimulation) OR
6. Pt has dx small for gestational age (SGA) AND ALL of:
    A. Pt age is at least 2 yrs old AND
    B. Documented birth weight and/or length that is 2 or more SD below the mean for gestational age AND
    C. At 24 months of age, the pt fails to manifest catch-up growth evidenced by a ht 2 or more SD below the mean for age and sex

For Children – Criteria for renewal require ALL of:
1. Pt has been approved for preferred product previously through the plan's PA criteria AND

2. Pt has been dx with ONE of:
    A. Neonate (less than or equal to 4 months of age) with hypoglycemia in the absence of metabolic disorder OR
    B. GHD OR
    C. Panhypopituitarism OR
    D. Prader-Willi Syndrome OR
    E. Short Stature OR
    F. SGA OR
    G. Turner Syndrome AND
3. ALL of:
    A. Pt does not have closed epiphyses AND
    B. Pt is being monitored for adverse effects of therapy with the requested agent AND
    C. Pt's ht is increased or ht velocity has improved since initiation or last approval of the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
For Adults – Criteria for initial approval require the following:
1. Patient has been diagnosed with ONE of the following:
    A. Childhood GHD with genetic or organic origin AND ONE of the following:
        i. Low IGF-1 level without GH replacement therapy OR
        ii. Failure of at least one GH stimulation test as an adult (peak GH value of less than or equal to 5 mcg/L 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 GH stimulation test as an adult OR
    C. Idiopathic GHD (adult or childhood onset) AND the patient has failed at least two GH stimulation tests as an adult

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

1. Patient has been approved for the preferred product previously through the plan's PA criteria AND
2. Patient has been diagnosed with ONE of the following:
    A. Childhood GHD with genetic or organic origin (e.g., caused by a tumor or cancer) OR
    B. Acquired adult GHD secondary to structural lesions or trauma (e.g., pituitary surgery or lesion, high-dose irradiation damage to the hypothalamic-pituitary axis) OR
    C. Other (e.g., childhood idiopathic GHD, adult-onset idiopathic GHD) AND
3. ALL of the following:
    A. Patient is being monitored for adverse effects of therapy with the requested agent AND
    B. Patient's IGF-1 level has been evaluated to confirm the appropriateness of current dose AND
    C. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D, plus the off-label use for acute 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 diagnosed with measurement of C1-INH antigenic level, C1-INH functional level, and C4 level as follows:
    A. Type I HAE: 2 separate measurements indicating decreased quantities of C4 and C1-INH OR
    B. Type II HAE: 2 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. Family history of angioedema AND treatment with high dose antihistamine therapy was not effective OR
        ii. Patient demonstrates a Factor XII mutation associated with the disease AND
2. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. ONE of the following:
    A. Requested agent will be used to treat HAE acute attacks AND ONE of the following:
        i. Patient's medication history does not indicate the use of another HAE agent for the treatment of acute HAE attacks OR
        ii. Patient's medication history contains another HAE agent for the treatment of acute HAE attacks AND the patient will discontinue prior to starting the requested agent OR
    B. Requested agent will be used for prophylaxis against HAE attacks AND BOTH of the following:
        i. Patient has a history of at least 2 acute attacks per month OR 2 severe attacks (laryngeal or abdominal attacks) per year OR for short-term prophylaxis if prior to medical, surgical, dental procedure AND

ii. ONE of the following:
a. Patient has tried a formulary 17 alpha-alkylated androgen or antifibrinolytic agent OR
b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a formulary 17 alpha-alkylated androgen or antifibrinolytic 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 therapy through the plan's PA criteria AND
2. Patient has a diagnosis of HAE and ONE of the following:
A. Requested indication is for acute HAE and ONE of the following:
i. Patient's medication history does not indicate the use of another HAE agent for the treatment of acute HAE attacks OR
ii. Patient's medication history contains another HAE agent for the treatment of acute HAE attacks AND the patient with discontinue prior to starting the requested agent OR
B. Requested indication is for prophylaxis of HAE attacks AND
3. Patient has had a decrease in the frequency of acute attacks or has had stabilization of disease from use of the requested agent

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

Drug Name(s):
FIRAZYR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 diagnosed with measurement 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. Family history of angioedema AND treatment with high dose antihistamine therapy was not effective OR
        ii. Patient demonstrates a Factor XII mutation that is associated with the disease AND
2. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. Requested agent will be used to treat acute HAE attacks AND
4. Patient is receiving only ONE agent indicated for treatment of acute HAE attacks

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for therapy through the plan's PA criteria AND
2. Patient has a diagnosis of HAE AND
3. Patient has had a decrease in the frequency 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 – **HAE PA - Haegarda**

Drug Name(s):
HAEGARDA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 diagnosed with measurement 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. Family history of angioedema AND ONE of following:
            1. Treatment with a maximally tolerated dose of antihistamine therapy was not effective OR
            2. Patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to an antihistamine OR
        ii. Patient demonstrates a Factor XII mutation that is associated with the disease AND
2. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
3. Requested agent will be used for prophylaxis against HAE attacks AND BOTH 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 for short-term prophylaxis prior to medical, surgical, or dental procedure AND
    b. ONE of the following:
        i. Patient has tried a formulary 17 alpha-alkylated androgen or antifibrinolytic agent OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a formulary 17 alpha-alkylated androgen or antifibrinolytic agent AND

4. Patient is receiving only ONE HAE agent indicated for prophylaxis against HAE attacks

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has a diagnosis of hereditary angioedema (HAE) AND
3. Requested agent is being used for prophylaxis against HAE attacks AND
4. Patient has had a decrease in the frequency of acute attacks or has had stabilization of disease from use of the requested agent AND
5. Patient is receiving only ONE HAE agent indicated for prophylaxis against HAE attacks

Prior Authorization Group – **Harvoni PA**

Drug Name(s):
HARVONI

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Harvoni (ledipasvir/sofosbuvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Harvoni (ledipasvir/sofosbuvir) 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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Hetlioz PA**

Drug Name(s):
HETLIOZ

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND Severe hepatic impairment (Child-Pugh Class C)

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 (i.e. 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
butalbital/acetaminophen/caffeine 50-300-40 mg capsule
butalbital/acetaminophen/caffeine 50-325-40 mg capsule, tablet
butalbital/aspirin/caffeine 50-325-40 mg capsule
butalbital/acetaminophen 50-325 mg tablet
clemastine tablet
digoxin 0.25 mg tablet
ERGOLOID MESYLATES tablet
hydroxyzine syrup, tablet
promethazine suppository, syrup, tablet
TENCON

Covered Uses:

All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:

PA does NOT apply to patients less than 65 yrs of age.
High Risk Medications will be approved if ALL of the following are met:
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 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 tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 patient is greater than or equal to 65 years old, then ALL of the following:
    A. ONE of the following:
        i. Patient has fibromyalgia and has tried and failed both duloxetine and Lyrica OR
        ii. Patient has fibromyalgia and has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to both duloxetine and Lyrica 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 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 - Methocarbamol**

Drug Name(s):
methocarbamol 500 mg, 750 mg tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 patient is greater than or equal to 65 years old, then BOTH of the following:
    A. Prescriber has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND
    B. Prescriber has documented that s/he discussed risks and potential side effects of the 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):
amitriptyline tablet
clomipramine capsule
DIVIGEL
doxepin capsule
doxepin oral concentrate
estradiol patch, tablet
estradiol/norethindrone tablet
estropipate 0.75 mg, 1.5 mg tablet
ESTROPIPATE 3 mg tablet
imipramine tablet
lopreeza
megestrol suspension, tablet
MENEST
mimvey
mimvey lo
phenobarbital elixir, solution
PHENOBARBITAL injection
PHENOBARBITAL 15 mg, 30 mg, 60 mg, 100 mg tablet
phenobarbital 16.2 mg, 32.4 mg, 64.8 mg, 97.2 mg tablet
PREMARIN tablet
PREMPHASE
PREMPRO
thioridazine tablet
trimipramine capsule

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only. PA does NOT apply to patients less than 65 yrs of age.
High Risk Medications will be approved if ONE of the following is met:
1. There is evidence of a claim within the past 180 days for the requested high risk medication OR the prescriber states the patient is 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 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 - Nitrofurantoin**

Drug Name(s):
nitrofurantoin 50 mg, 100 mg capsule
nitrofurantoin suspension

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
PA does NOT apply to patients less than 65 yrs of age. Applies to greater than 90 days of therapy per calendar year.

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 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 - Zaleplon**

Drug Name(s):
zaleplon capsule

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
PA does NOT apply to patients less than 65 yrs of age. Applies to greater than 90 days of therapy per calendar year.
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 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 - Zolpidem**

Drug Name(s):
zolpidem tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
PA does NOT apply to patients less than 65 yrs of age. Applies to greater than 90 days of therapy per calendar year.
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 medication with the patient

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **HoFH PA - Juxtapid**

Drug Name(s):
JUXTAPID

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 homozygous familial hypercholesterolemia (HoFH) AND
2. ONE of the following:
    A. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, ARH adaptor protein 1/LDLRAP1 gene locus OR
    B. Untreated LDL-C greater than 13 mmol/L (greater than 500 mg/dL) or treated LDL-C greater than or equal to 7.76 mmol/L (greater than or equal to 300 mg/dL) with ONE of the following:
        i. Cutaneous or tendon xanthoma before age 10 years OR
        ii. Untreated elevated LDL-C levels consistent with heterozygous FH in both parents [untreated total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) or untreated LDL-C greater than190 mg/dL] AND
3. ONE of the following:
    A. Patient is on a maximally tolerated lipid-lowering regimen in the last 90 days (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a maximally tolerated lipid-lowering regimens (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) AND
4. Requested agent will NOT be used in combination with Kynamro (mipomersen)

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Criteria for renewal require ALL of the following:

1. Patient has been previously approved for therapy through the plan's PA criteria AND
2. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND
3. Patient has shown a reduction from baseline in at least ONE of the following metrics: LDL-C, Apo B, TC, non-HDL-C, or TG AND
4. ONE of the following:
    A. Patient is on a maximally tolerated lipid-lowering regimen in the last 90 days (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a maximally tolerated lipid lowering regimens (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) AND
5. Requested agent will NOT be used in combination with Kynamro (mipomersen)

Prior Authorization Group – **HoFH PA - Kynamro**

Drug Name(s):
KYNAMRO

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 homozygous familial hypercholesterolemia (HoFH) AND
2. ONE of the following:
    A. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, ARH adaptor protein 1/LDLRAP1 gene locus OR
    B. Untreated LDL-C greater than 13 mmol/L (greater than 500 mg/dL) or treated LDL-C greater than or equal to 7.76 mmol/L (greater than or equal to 300 mg/dL) with ONE of the following:
        i. Cutaneous or tendon xanthoma before age 10 years OR
        ii. Untreated elevated LDL-C levels consistent with heterozygous FH in both parents [untreated total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) or untreated LDL-C greater than190 mg/dL] AND
3. ONE of the following:
    A. Patient is on a maximally tolerated lipid-lowering regimen in the last 90 days (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a maximally tolerated lipid-lowering regimens (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) AND
4. Requested agent will NOT be used in combination with Juxtapid (lomitapide)

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

Criteria for renewal require ALL of the following:

1. Patient has been previously approved for therapy through the plan's PA criteria AND
2. Patient has a diagnosis of HoFH AND
3. Patient has shown a reduction from baseline in at least ONE of the following metrics: LDL-C, Apo B, TC, non-HDL-C, or TG AND
4. ONE of the following:
    A. Patient is on a maximally tolerated lipid-lowering regimen in the last 90 days (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR
    B. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a maximally tolerated lipid lowering regimens (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) AND
5. Requested agent will NOT be used in combination with Juxtapid (lomitapide)

Prior Authorization Group – **Ilaris PA**

Drug Name(s):
ILARIS

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D, plus the off-label use for acute gouty arthritis.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy with the requested agent AND An active or chronic infection (e.g. tuberculosis, HIV, hepatitis B/C)

Required Medical:
Criteria for approval require BOTH of the following:
1. ONE of the following:
    A. Patient's diagnosis is Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) OR
    B. Patient's diagnosis is Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) OR
    C. Patient's diagnosis is Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) OR
    D. Patient's diagnosis is Familial Mediterranean Fever (FMF) OR
    E. Patient's diagnosis is Systemic Juvenile Idiopathic Arthritis (SJIA) AND BOTH of the following:
        i. Prescriber 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 failed at least ONE prerequisite agent (oral or IV glucocorticosteroids, prescription oral NSAIDs, methotrexate, leflunomide, Enbrel, Humira, Kineret) OR
            b. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to a prerequisite agent OR
    F. Patient's diagnosis is acute gouty arthritis and ONE of the following:
        i. Patient has failed at least TWO conventional first-line medications (prescription oral NSAIDs, colchicine, systemic corticosteroids) OR
        ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to TWO conventional first-line medications AND
2. If patient is currently being treated with another biologic the medication will be discontinued before initiating Ilaris

Age Restrictions:
CAPS/FCAS/MWS – 4 years or greater. SJIA – 2 years or greater. Acute gouty arthritis – 18 years or greater (adult)

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Imiquimod PA**

Drug Name(s):
imiquimod 5% cream

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
This program applies to new starts only.
Criteria for approval require ONE of the following:
A. There is evidence of a claim within the past 180 days that the patient is currently being treated with the requested agent OR
B. Prescriber states the patient is using the requested agent OR
C. Patient has an FDA labeled indication for the requested agent OR
D. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
4 mo ext. genital/perianal warts, actinic keratosis, 2 mo basal/squamous cell carcinoma, 12 mo other

Other Criteria:

Prior Authorization Group – **Immunoglobulins PA**

Drug Name(s):
GAMMAPLEX
GAMUNEX-C

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for approval require ONE of the following:
1. Patient has been diagnosed with:
    a. Primary immunodeficiency (including congenital agammaglobulinemia, common variable immunodeficiency (CVID), severe combined immunodeficiency, Wiskott-Aldrich Syndrome, X-linked agammaglobulinemia (XLA), humoral immunodeficiency)
    b. Primary immune defects with absent B cells
    c. Impaired specific antibody production (normogammaglobulinemia & hypogammaglobulinemia)
    d. Prior to solid organ transplant, treatment for patients at high risk of antibody-mediated rejection (AMR) including highly sensitized patients and those receiving ABO incompatible organ
    e. Post solid organ transplant, treatment of AMR
    f. Chronic lymphocytic leukemia with reduced IgG AND
        i. Patient has a history of infections
    g. Prevention of bacterial infections in HIV-treated patients AND
        i. Patient is currently on antiretroviral therapy
    h. Adult HIV associated thrombocytopenia
    i. Prevention and treatment of neonatal sepsis
    j. Graves Ophthalmopathy
    k. Idiopathic thrombocytopenia purpura AND
        i. Patient has failed one conventional therapy (e.g. corticosteroids (e.g. methylprednisolone), or immunosuppressants) OR
        ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to one conventional therapy
    l. Dermatomyositis AND
        i. Patient has failed one conventional therapy (e.g. immunosuppressants or corticosteroids (e.g. methylprednisolone)) OR

ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to one conventional therapy

m. Polymyositis AND

i. Patient has failed one conventional therapy (e.g. immunosuppressants or corticosteroids (e.g. methylprednisolone)) OR

ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to one conventional therapy

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:

n. Severe rheumatoid arthritis AND

i. Patient has failed one conventional therapy (e.g. TNF antagonists (e.g. Humira), DMARDS (e.g. methotrexate), Remicade) OR

ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to one conventional therapy agent

o. Fetomaternal alloimmune thrombocytopenia

p. Guillain-Barre syndrome

q. Chronic inflammatory demyelinating polyneuropathy

r. Multifocal motor neuropathy

s. Paraprotein associated demyelinating neuropathy – (IgM, IgA, or IgG)

t. Lambert-Eaton myasthenia syndrome

u. Myasthenia Gravis AND

i. Crisis (e.g. acute episode of respiratory muscle weakness) AND patient has a contraindication to plasma exchange OR

ii. Complex comorbid disease (e.g. acute respiratory failure) when not controlled with cholinesterase inhibitors (e.g. pyridostigmine), corticosteroids (e.g. prednisone), or azathioprine

v. Stiff-man syndrome

w. Monoclonal gammopathy – multiple sclerosis and BOTH of the following:

i. Patient has a diagnosis of relapsing remitting MS AND

ii. Patient has had an insufficient response, documented failure, or FDA labeled contraindication(s) to TWO MS agents (e.g. Avonex, Betaseron, Copaxone, Glatopa, Plegridy, Tecfidera or Tysabri)

x. Intractable childhood epilepsy
y. Rasmussen syndrome
z. Kawasaki disease
aa. CMV-induced pneumonitis in solid organ transplant
bb. Rotaviral enterocolitis
cc. Bacterial infections in lymphoproliferative disease
dd. Prevention in acute graft vs. host disease after bone marrow transplant
ee. Prevention of acute humoral rejection in renal transplant
ff. Severe invasive group A streptococcal disease
gg. Severe, persistent, high-dose asthma
hh. Toxic epidermal necrolysis and Stevens-Johnson syndrome
ii. Low serum IgG levels following hematopoietic stem cell transplant for malignancy
jj. Multiple myeloma AND
    i. Patient has stable disease AND has recurrent infections AND is currently on (within the past 30 days) chemotherapy
kk. Acquired von Willebrand hemophilia AND
    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
ll. Hemolytic disease of the newborn AND the following:
    i. Patient has either Rhesus or ABO hemolytic disease OR

2. 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, Hemolytic disease of the newborn, Lambert-Eaton myasthenia syndrome, Myasthenia gravis, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Severe invasive group A streptococcal disease, Toxic epidermal necrolysis and Steven Johnsons syndrome

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

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

Drug Name(s):
ESBRIET

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
Severe hepatic impairment (Child-Pugh class C), or a history of end-stage renal disease requiring dialysis AND FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has either the diagnosis of idiopathic pulmonary fibrosis (IPF) or another FDA approved indication for the requested agent AND
2. If IPF, ALL of the following:
    A. Patient is a non-smoker confirmed by biochemical testing AND
    B. 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
    C. Prescriber has performed a baseline forced vital capacity (FVC) test AND
    D. Patient has a predicted FVC greater than or equal to 50% AND
    E. ONE of the following:
        i. Patient has usual interstitial pneumonia (UIP) patterns on high-resolution computed tomography (HRCT) scans [containing all of the following 4 features: 1) subpleural, basal predominance 2) reticular abnormality 3) honeycombing with or without traction bronchiectasis 4) absence of features listed as inconsistent with UIP pattern] OR
        ii. ALL of the following:
            1. Patient has possible UIP patterns on HRCT (i.e. subpleural, basal predominance and reticular abnormality with absent honeycombing) AND
            2. Patient has had a surgical lung biopsy that demonstrates UIP pattern on histopathology [containing all of the following 4 features: 1) Evidence of marked fibrosis/architectural distortion, with or without honeycombing in a predominantly subpleural/paraseptal distribution 2) presence of patchy involvement of lung parenchyma by fibrosis 3) presence of fibroblast foci 4) Absence of features against a diagnosis of UIP suggesting an alternative diagnosis] AND
3. ONE of the following:

A. Patient is not concurrently being treated Ofev (nintedanib) within the past 90 days OR
B. If patient has been treated with Ofev (nintedanib) within the past 90 days, therapy will be discontinued prior to starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:
A pulmonologist, radiologist, or if applicable a pathologist (if lung biopsy is needed) all experienced in the diagnosis of interstitial lung disease have been consulted with and determined that the patient has definitive IPF

Coverage Duration:
Approval will be for 12 months

Other Criteria:
Criteria for renewal require ALL of the following:
1. Patient has been approved for the requested agent previously through the plan's PA criteria AND
2. ONE of the following:
    A. Patient has a diagnosis of IPF and BOTH of the following:
        a. Patient is a non-smoker confirmed by biochemical testing AND
        b. Patient has not had a decline in percent predicted FVC of greater than or equal to 10% OR
    B. Patient has another FDA approved indication for the requested agent AND
3. ONE of the following:
    A. Patient is not concurrently being treated Ofev (nintedanib) within the past 90 days OR
    B. If patient has been treated with Ofev (nintedanib) within the past 90 days, therapy will be discontinued prior to starting therapy with the requested agent

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

Drug Name(s):
OFEV

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
Moderate/severe hepatic impairment (Child-Pugh class B or C) AND FDA labeled contraindication(s) to the requested agent

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has either the diagnosis of idiopathic pulmonary fibrosis (IPF) or another FDA approved indication for the requested agent AND
2. If IPF, ALL of the following:
    A. 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
    B. Prescriber has performed a baseline forced vital capacity (FVC) test AND
    C. Patient has a predicted FVC greater than or equal to 50% AND
    D. ONE of the following:
        i. Patient has usual interstitial pneumonia (UIP) patterns on high-resolution computed tomography (HRCT) scans [containing all of the following 4 features: 1) subpleural, basal predominance 2) reticular abnormality 3) honeycombing with or without traction bronchiectasis 4) absence of features listed as inconsistent with UIP pattern] OR
        ii. ALL of the following:
            1. Patient has possible UIP patterns on HRCT (i.e. subpleural, basal predominance and reticular abnormality with absent honeycombing) AND
            2. Patient has had a surgical lung biopsy that demonstrates UIP pattern on histopathology [containing all of the following 4 features: 1) Evidence of marked fibrosis/architectural distortion, with or without honeycombing in a predominantly subpleural/paraseptal distribution 2) presence of patchy involvement of lung parenchyma by fibrosis 3) presence of fibroblast foci 4) Absence of features against a diagnosis of UIP suggesting an alternative diagnosis] AND
3. ONE of the following:

A. Patient is not concurrently being treated Esbriet (pirfenidone) within the past 90 days OR

B. If patient has been treated with Esbriet (pirfenidone) within the past 90 days, therapy will be discontinued prior to starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

A pulmonologist, radiologist, or if applicable a pathologist (if lung biopsy is needed) all experienced in the diagnosis of interstitial lung disease have been consulted with and determined that the patient has definitive IPF

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal require ALL of the following:

1. Patient has been approved for the requested agent previously through the plan's PA criteria AND
2. ONE of the following:
    A. Patient has a diagnosis of IPF and the following:
        a. Patient has not had a decline in percent predicted FVC of greater than or equal to 10% OR
    B. Patient has another FDA approved indication for the requested agent AND
3. ONE of the following:
    A. Patient is not concurrently being treated Esbriet (pirfenidone) within the past 90 days OR
    B. If patient has been treated with Esbriet (pirfenidone) within the past 90 days, therapy will be discontinued prior to starting therapy with the requested agent

Prior Authorization Group – **Kalydeco PA**

Drug Name(s):
KALYDECO

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ONE of the following:
A. ALL of the following:
i. Patient has a diagnosis of cystic fibrosis AND
ii. Patient has ONE of the CFTR gene mutations as indicated in the FDA label as confirmed by genetic testing AND
iii. Patient is not homozygous for the F508del mutation AND
iv. Patient has had pre-therapeutic/baseline FEV1 levels measured OR
B. Patient has another FDA approved indication for the requested agent

Criteria for renewal require BOTH the following:
1. Patient has been approved previously for the requested agent through the plan's prior authorization criteria AND
2. ONE of the following:
A. Patient has a diagnosis of cystic fibrosis AND patient has shown improvement or stabilization in FEV1 from pretreatment levels with the requested agent OR
B. Patient has another FDA approved indication for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Korlym PA**

Drug Name(s):
KORLYM

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy with 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require ALL of the following:
1. Patient has NOT been previously treated with Kuvan (sapropterin) AND
2. Patient has a diagnosis of phenylketonuria (PKU) AND
3. Prescriber has submitted a baseline blood Phe level measured within 2 weeks prior to initiation of Kuvan therapy which is above the recommended levels indicated for patient's age range or condition AND
4. The dose is within the FDA-labeled dose range of 5 to 20 mg/kg/day

Criteria for renewal require BOTH of the following:
1. Patient has been successfully treated with Kuvan (sapropterin) as defined by one of the following:
    A. Patient's blood Phe levels are being maintained within the acceptable range OR
    B. Patient has had a greater than 30% decrease in blood Phe level from baseline AND
2. The dose is within the FDA-labeled dose range of 5 to 20 mg/kg/day

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: 6 months

Other Criteria:

Prior Authorization Group – **Letairis PA**

Drug Name(s):
LETAIRIS

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require ONE of the following:
A. BOTH of the following:
i. ONE of the following:
a. There is evidence of a claim within the past 90 days that the patient (pt) is currently being treated with the requested agent OR
b. Prescriber states the pt is using the requested agent AND is at risk if therapy is changed AND
ii. Pt has an FDA labeled indication for the requested agent OR
B. Pt has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:
i. Pt's WHO functional class is II or greater AND
ii. Pt has a mean pulmonary arterial pressure of greater than or equal 25 mmHg AND
iii. Pt has a pulmonary vascular resistance greater than 3 Wood units AND
iv. ONE of the following:
a. Requested agent will be utilized as monotherapy OR
b. Requested agent is for use in combination with Adcirca (tadalafil) for dual therapy ONLY OR
c. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy: except dual therapy requests for Letairis with Adcirca), then BOTH of the following:
1. Pt has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
2. Requested agent is in a different therapeutic class OR
d. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then ALL of the following:
1. A prostanoid has been started as one of the agents in the triple therapy unless the pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid AND

2. Pt 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 require BOTH of the following:
1. Pt has been previously approved for therapy through the plan's PA criteria and is responding to therapy AND
2. Pt 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 – **Lidocaine Transdermal PA**

Drug Name(s):
lidocaine 5% transdermal patch

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
A. Patient has a diagnosis of pain associated with postherpetic neuralgia (PHN) OR
B. Patient has a diagnosis of pain associated with diabetic neuropathy OR
C. Patient has a diagnosis of neuropathic pain associated with cancer OR
D. Patient has a 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 – **Linezolid PA**

Drug Name(s):
linezolid suspension, tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ALL of the following:
1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
    a. 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. BOTH of the following:
        i. ONE of the following diagnoses:
            a) Patient has a documented, serious life-threatening infection or sepsis due to vancomycin-resistant Enterococcus faecium or Enterococcus faecalis (not colonization) OR
            b) Patient has a documented infection due to Enterococcus faecium or Enterococcus faecalis AND the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin OR
            c) BOTH of the following:
                1) ONE of the following:
                    i. Patient has a documented infection due to Staphylococci that are resistant to beta lactams, macrolides, clindamycin, tetracycline, and co-trimoxazole OR that is resistant to vancomycin (e.g. MRSA) at the site of infection OR
                    ii. Patient has a documented infection due to Staphylococci AND the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to beta lactams, macrolides, clindamycin, tetracyclines, and co-trimoxazole OR
                    iii. Patient has a documented infection due to Staphylococci AND the patient has a documented

intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin AND

2) Infection type is within FDA labeling (e.g. skin/skin structure, pneumonia, diabetic foot infection) AND

ii. Dose is within the FDA labeled dosage AND

3. ONE of the following:

a. Patient is NOT currently being treated for the same infection with Sivextro (tedizolid) OR

b. Current treatment with Sivextro (tedizolid) for the same infection will be discontinued before starting therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 3 months

Other Criteria:

Prior Authorization Group – **Linzess PA**

Drug Name(s):
LINZESS

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy

Required Medical:
Criteria for approval require BOTH of the following:
1. Patient has a diagnosis of ONE of the following:
    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:
    i. Patient has tried at least one standard laxative therapy for constipation – lactulose or polyethylene glycol 3350 OR
    ii. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one standard laxative therapy for constipation – lactulose or polyethylene glycol 3350

Age Restrictions:
Patient must be an adult at least 18 yrs of age

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Mavyret PA**

Drug Name(s):
MAVYRET

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Mavyret (glecaprevir/pibrentasvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Mavyret (glecaprevir/pibrentasvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 the preferred agents: Harvoni (ledipasvir/sofosbuvir) for supported genotypes OR Epclusa (sofosbuvir/velpatasvir) for genotype 2 or 3 OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agents: Harvoni (ledipasvir/sofosbuvir) for supported genotypes OR Epclusa (sofosbuvir/velpatasvir) for genotype 2 or 3

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Memantine PA**

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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
PA does NOT apply to patients 30 years of age and older
Criteria for approval require 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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 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:
Patients must be 17 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
AVONEX
AVONEX PEN
AVONEX PREFILLED KIT

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 a disease modifying agent (DMA) other than the requested agent OR
    b. Patient is currently being treated with a DMA other than the requested agent AND the DMA will be discontinued before starting the requested agent

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the intended FDA labeled indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
BETASERON

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 a disease modifying agent (DMA) other than the requested agent OR
    b. Patient is currently being treated with a DMA other than the requested agent AND the DMA will be discontinued before starting the requested agent

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the intended FDA labeled indication

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 20 mg/mL, 40 mg/mL injection
glatopa

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 a disease modifying agent (DMA) other than the requested agent OR
    b. Patient is currently being treated with a DMA other than the requested agent AND the DMA will be discontinued before starting the requested agent

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the intended FDA labeled indication

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 PEN
PLEGRIDY STARTER PACK

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 a disease modifying agent (DMA) other than the requested agent OR
    b. Patient is currently being treated with a DMA other than the requested agent AND the DMA will be discontinued before starting the requested agent

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the intended FDA labeled indication

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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 a disease modifying agent (DMA) other than the requested agent OR
    b. Patient is currently being treated with a DMA other than the requested agent AND the DMA will be discontinued before starting the requested agent

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the intended FDA labeled indication

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

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

Drug Name(s):
TYSABRI

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy with 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 a disease modifying agent (DMA) other than the requested agent OR
    b. Patient is currently being treated with a DMA other than the requested agent AND the DMA will be discontinued before starting the requested agent AND
3. ONE of the following:
    a. There is evidence of a claim within the past 90 days that the patient is currently being treated with the requested agent OR
    b. Prescriber states the patient is using the requested agent AND is at risk if therapy is changed OR
    c. ONE of the following:
        i. If diagnosis is multiple sclerosis (MS), then ONE of the following:
            a. Patient's medication history indicates the use of at least two preferred agents for the treatment of MS: Avonex, Betaseron, glatiramer (i.e. Copaxone, Glatopa), Plegridy, or Tecfidera OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two preferred agents for the treatment of MS: Avonex, Betaseron, glatiramer (i.e. Copaxone, Glatopa), Plegridy, or Tecfidera OR
        ii. If diagnosis is crohn's disease (CD), then BOTH of the following:
            a. ONE of the following:
                1. Patient's medication history includes the use of at least one conventional CD therapy (e.g. aminosalicylates, metronidazole, ciprofloxacin, corticosteroids (budesonide EC), methotrexate, or immunomodulators such as azathioprine or 6-mercaptopurine) OR

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

b. ONE of the following:

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

2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to Humira or Stelara

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:

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA 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. Patient is NOT currently being treated with an additional disease modifying agent (DMA) for the intended FDA labeled indication

Prior Authorization Group – **Myalept PA**

Drug Name(s):
MYALEPT

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
Human immunodeficiency virus (HIV) infection, infectious liver disease and/or acquired lipodystrophy with hematologic abnormalities AND FDA labeled contraindication(s) to therapy with 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 drawn baseline values for HbA1C, triglycerides, and fasting insulin prior to beginning Myalept (metreleptin) therapy AND
3. Patient also has at least one of the following additional diagnosis: diabetes mellitus, hypertriglyceridemia (greater than or equal to 200 mg/dL), and/or high fasting insulin (greater than or equal to 30µU/mL) AND
4. Patient has failed maximum tolerable dosing of a conventional agent for the additional diagnosis within the past 90 days AND
5. The dose is within the FDA labeled dosing for the requested indication

Criteria for renewal require ALL of the following:
1. Patient has been previously approved through the plan's prior authorization criteria AND
2. Patient has had a reduction in at least one of the following parameters: HbA1C, triglycerides and/or fasting insulin AND
3. The dose is within the FDA labeled dosing for the requested indication

Age Restrictions:

Prescriber Restrictions:
Prescriber is a specialist (e.g. endocrinologist, cardiologist) 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND Increased baseline risk for osteosarcoma

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of the following:
    A. Patient has diagnosis of hypocalcemia with hypoparathyroidism and ALL of the following:
        i. Prescriber has confirmed the patient's 25-hydroxyvitamin D stores are not below the testing laboratory's normal range AND
        ii. Prescriber has confirmed the patient's serum calcium is above 7.5 mg/dL AND
        iii. Patient cannot be well-controlled on maximally tolerated calcium supplements and active forms of vitamin D (vitamin D metabolite or analogs) alone OR
    B. Patient has another FDA approved diagnosis AND
2. ONE of the following:
    A. Patient is not on concomitant use of alendronate OR
    B. Patient is currently on alendronate and will discontinue it prior to therapy with Natpara (parathyroid hormone)

Criteria for renewal require ALL of the following:
1. Patient has been approved for the requested agent previously through the plan's PA criteria AND
2. If diagnosis of hypocalcemia with hypoparathyroidism, then ALL of the following:
    A. Patient has had a 50% reduction from baseline in the dose of oral calcium supplementation AND
    B. Patient has had a 50% reduction from baseline in the dose of active vitamin D supplementation (vitamin D metabolite or analogs) AND
    C. Patient has an albumin-corrected total serum calcium concentration between 7.5 mg/dL and 10.6 mg/dL AND
3. ONE of the following:
    A. Patient is not on concomitant use of alendronate OR

B. Patient is currently on alendronate and will discontinue it prior to therapy with Natpara (parathyroid hormone)

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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 neurogenic orthostatic hypotension (NOH) AND
2. Prescriber has performed baseline blood pressure readings while the patient is sitting and also within 3 minutes of standing from a supine (lying face up) position AND
3. Patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing from a sitting position 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 require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan’s PA 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 injection, suspension, tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require 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, or hypersensitivity to fluconazole or an alternative antifungal agent OR
B. Patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or a patient with a hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient AND the requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida OR
C. Patient has an infection caused by Zygomycetes OR
D. Patient has a diagnosis of invasive Aspergillus AND patient has tried an alternative antifungal agent OR patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an alternative antifungal agent OR
E. Patient has another indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal 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. Requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida and patient continues to be severely immunocompromised as indicated by: neutropenia, ongoing graft versus host disease, and/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 or has an infection caused by Zygomycetes 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

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

Prior Authorization Group – **Nuplazid PA**

Drug Name(s):
NUPLAZID

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for approval require BOTH of the following:
1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
    a. There is evidence of claim that the patient is currently being treated with the requested agent within the past 180 days OR
    b. Prescriber states that 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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Ocaliva PA**

Drug Name(s):
OCALIVA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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) as evidenced by TWO of the following three criteria at the time of diagnosis:
    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 of 1:40 or higher
    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
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 require ALL of the following:
1. Patient has been previously approved for the requested agent through plan's PA criteria AND
2. 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
3. Patient has had a decrease in alkaline phosphatase (ALP) level from baseline

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Olysio PA**

Drug Name(s):
OLYSIO

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Olysio (simeprevir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Olysio (simeprevir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Oncology PA**

Drug Name(s):
AFINITOR
AFINITOR DISPERZ
ALECENSA
ALUNBRIG
bexarotene capsule
BOSULIF
CABOMETYX
CAPRELSA
COMETRIQ
COTELLIC
ERIVEDGE
FARYDAK
GILOTRIF
HEXALEN
IBRANCE
ICLUSIG
IDHIFA
imatinib mesylate tablet
IMBRUVICA
INLYTA
IRESSA
JAKAFI
KISQALI
KISQALI & FEMARA Co-Pack
LENVIMA
LONSURF
LYNPARZA
MATULANE
MEKINIST
NERLYNX
NEXAVAR
NINLARO
ODOMZO
POMALYST
REVLIMID
RUBRACA
RYDAPT
SPRYCEL
STIVARGA
SUTENT
SYLATRON
TAFINLAR
TAGRISSO
TARCEVA

TASIGNA
THALOMID
tretinoin capsule
TYKERB
VENCLEXTA
VENCLEXTA STARTING PACK
VOTRIENT
XALKORI
XTANDI
ZEJULA
ZELBORAF
ZOLINZA
ZYDELIG
ZYKADIA
ZYTIGA

Covered Uses:

All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:

This program applies to new starts only.
Criteria for approval require ONE of the following:
A. There is evidence of a claim within the past 180 days that the patient is currently being treated with the requested agent OR
B. Prescriber states the patient is using the requested agent OR
C. ALL of the following:
    i. 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
    ii. ALL of the following:
        a. Genetic testing has been completed (if applicable) using an FDA approved genetic test if required for therapy with the requested agent and results indicate therapy with the requested agent is appropriate AND
        b. Patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent AND
        c. 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

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 – **Opsumit PA**

Drug Name(s):
OPSUMIT

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require ONE of the following:
A. BOTH of the following:
i. ONE of the following:
a. There is evidence of a claim within the past 90 days that the patient is currently being treated with the requested agent 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 of greater than or equal 25 mmHg AND
iii. Patient has a pulmonary vascular resistance greater than 3 Wood units AND
iv. ONE of the following:
a. Requested agent will be utilized as monotherapy OR
b. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then BOTH of the following:
1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
2. Requested agent is in a different therapeutic class OR
c. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then 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 require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA criteria and is responding to therapy AND
2. 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 – **Oral Immunotherapy Agents PA - Grastek**

Drug Name(s):
GRASTEK

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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: Timothy grass or cross-reactive grass OR
    B. Pollen specific antibodies to ONE of the pollen extracts included in the requested agent: Timothy grass or cross-reactive 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. ONE of the following:
    A. Patient is NOT currently being treated with a beta blocker OR
    B. Patient will discontinue the beta blocker prior to starting the requested agent AND
6. Requested agent will be started 3 to 4 months before the expected onset of the applicable pollen season AND
7. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
8. Patient has been prescribed epinephrine auto-injector for at home emergency use

Age Restrictions:
Patients must be between the ages of 5 and 65 years

Prescriber Restrictions:
Prescriber is an allergy or immunology specialist or has consulted an allergy or immunology 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 – **Oral Immunotherapy Agents PA - Oralair**

Drug Name(s):
ORALAIR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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. Pollen specific antibodies to ONE of the pollen 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. ONE of the following:
    A. Patient is NOT currently being treated with a beta blocker OR
    B. Patient will discontinue the beta blocker prior to starting the requested agent AND
6. Requested agent will be started 3 to 4 months before the expected onset of the applicable pollen season AND
7. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
8. Patient has been prescribed epinephrine auto-injector for at home emergency use

Age Restrictions:
Patients must be between the ages of 10 and 65 years

Prescriber Restrictions:
Prescriber is an allergy or immunology specialist or has consulted an allergy or immunology 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 – **Oral Immunotherapy Agents PA - Ragwitek**

Drug Name(s):
RAGWITEK

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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: Short Ragweed OR
    B. Pollen specific antibodies to ONE of the pollen extracts included in the requested agent: Short Ragweed 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. ONE of the following:
    A. Patient is NOT currently being treated with a beta blocker OR
    B. Patient will discontinue the beta blocker prior to starting the requested agent AND
6. Requested agent will be started 3 to 4 months before the expected onset of the applicable pollen season AND
7. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
8. Patient has been prescribed epinephrine auto-injector for at home emergency use

Age Restrictions:
Patients must be between the ages of 18 and 65 years

Prescriber Restrictions:
Prescriber is an allergy or immunology specialist or has consulted an allergy or immunology 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ONE of the following:
A. ALL of the following:
i. Patient has a diagnosis of cystic fibrosis AND
ii. Patient has the presence of the F508del mutation on both alleles of the CFTR gene confirmed by genetic testing AND
iii. Patient has had pre-therapeutic/baseline FEV1 levels measured OR
B. Patient has another FDA approved indication for the requested agent

Criteria for renewal require BOTH the following:
1. Patient has been approved previously for the requested agent through the plan's prior authorization criteria AND
2. ONE of the following:
A. Patient has a diagnosis of cystic fibrosis AND patient has shown improvement or stabilization in FEV1 from pretreatment levels with the requested agent OR
B. Patient has another FDA approved indication for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Pegylated Interferon PA**

Drug Name(s):
PEGASYS
PEGASYS PROCLICK
PEG-INTRON
PEG-INTRON REDIPEN

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
A. Peginterferon is being prescribed for the treatment of chronic myelogenous leukemia (CML) OR
B. Patient has indication that is supported in CMS approved compendia for the requested agent OR
C. Patient has a diagnosis of chronic hepatitis B and BOTH of the following:
    i. Chronic hepatitis B infection has been confirmed by serological markers AND
    ii. Patient has not been administered peginterferon for more than 18 months for this indication OR
D. BOTH of the following:
    i. Patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND
    ii. Peginterferon will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
12 months for CML or others diagnoses, 18 months for hep B, hep C see Other Criteria

Other Criteria:
Duration of therapy for hep C: Based on FDA approved labeling or in AASLD/IDSA guideline supported

Prior Authorization Group – **Praluent PA**

Drug Name(s):
PRALUENT

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 approved diagnosis for the requested agent AND
2. ONE of the following:
    A. If the diagnosis is heterozygous familial hypercholesterolemia (HeFH), 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. Total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) (pretreatment or highest level while on treatment) OR 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. Patient has clinical atherosclerotic cardiovascular disease (ASCVD) defined as having ONE of the following:
        i. Acute coronary syndrome
        ii. History of myocardial infarction
        iii. Stable or unstable angina
        iv. Coronary or other arterial revascularization
        v. Stroke
        vi. Transient ischemic attack
        vii. Peripheral arterial disease presumed to be of atherosclerotic origin AND

Initial criteria continues: see Other Criteria

Age Restrictions:

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

Coverage Duration:
Approval will be for 12 months

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

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA approved diagnosis 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 – **Prolia PA**

Drug Name(s):
PROLIA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 is a male or a postmenopausal female with a diagnosis of osteoporosis defined as 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. Patient has a T-score that is at or below -2.5 AND
            2. ONE of the following:
                i) Patient is female and medication history includes use of either a bisphosphonate or selective estrogen receptor (SERM) OR
                ii) Patient is male and medication history includes use of a bisphosphonate OR
                iii) 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) OR
    B. Patient is requesting the agent for osteopenia (osteoporosis prophylaxis) AND ALL of the following:
        i. ONE of the following:
            1. Patient is a male 50 years of age and over OR
            2. Patient is a postmenopausal female AND
        ii. ALL of the following:
            1. Patient has a T-score between -1.0 to -2.50 AND
            2. ONE of the following:
                i) 10-year probability of a hip fracture greater than or equal to 3% per FRAX OR

ii) 10-year probability of a major OP-related fracture greater than or equal to 20% per FRAX AND
iii. ONE of the following:
1. Patient is female and medication history includes use of a bisphosphonate or SERM OR
2. Patient is male and medication history includes use of a bisphosphonate OR
3. 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) OR

Criteria continues: See Other Criteria

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:
C. Patient is a female with a diagnosis of breast cancer who is receiving aromatase inhibitor therapy 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. 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. ALL of the following:
a. ONE of the following:
i) Patient is greater than or equal to 70 years of age OR

ii) Patient is less than 70 years of age AND ONE of the following:

1. Patient has a T-score at or below -1 OR
2. Patient has a history of an osteoporotic fracture AND

b. ONE of the following:

i) Patient's medication history includes use of a bisphosphonate OR

ii) Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate AND

2. BOTH of the following:
   a. Patient's calcium level has been measured in the past 4 weeks AND
   b. If the patient is hypocalcemic, it will be corrected prior to initiating Prolia AND
3. ONE of the following:
   a. Patient is not receiving concomitant Xgeva (denosumab), bisphosphonate, SERM, or Forteo (teriparatide) therapy within the past 90 days OR
   b. Patient will discontinue the current Xgeva (denosumab), bisphosphonate, SERM, or Forteo (teriparatide) therapy prior to initiating therapy with Prolia AND
4. Dose requested is within the FDA approved labeling

Prior Authorization Group – **Promacta PA**

Drug Name(s):
PROMACTA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

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

2. Patient has an FDA labeled contraindication, intolerance, or hypersensitivity to horse ATG and cyclosporine

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Initial: 6 months ITP, 48 weeks HCV, 16 weeks SAA, Renewal: 12 months ITP & SAA, 48 weeks HCV

Other Criteria:
Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA criteria AND
2. ONE of the following:
    A. Patient has a diagnosis of chronic idiopathic thrombocytopenic purpura (ITP) and ONE of the following:
        i. Patient’s platelet count is greater than or equal to 50 x 109/L OR
        ii. Patient’s platelet count has increased sufficiently to avoid clinically important bleeding OR
    B. Patient has a diagnosis of hepatitis C associated thrombocytopenia and BOTH of the following:
        i. ONE of the following:
            1. Patient will be initiating hepatitis C therapy with interferon and ribavirin OR
            2. Patient will be maintaining hepatitis C therapy with interferon and ribavirin at the same time as Promacta (eltrombopag) AND
        ii. ONE of the following:
            1. Patient’s platelet count is greater than or equal to 90 x 109/L OR
            2. Patient’s platelet count has increased sufficiently to initiate or maintain interferon based therapy for the treatment of hepatitis C OR
    C. Patient has a diagnosis of severe aplastic anemia and has had a hematological response by week 16 defined as ONE of the following:
        i. Platelet count increases to 20 x 109/L above baseline OR
        ii. Stable platelet counts with transfusion independence for a minimum of 8 weeks OR
        iii. Hemoglobin increase by greater than 1.5 g/dL OR
        iv. Reduction in greater than or equal to 4 units of red blood cell (RBC) transfusions for 8 consecutive weeks OR
        v. An absolute neutrophil count (ANC) increase of 100% OR

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

Prior Authorization Group – **Regranex PA**

Drug Name(s):
REGRANEX

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
A. ALL of the following:
i. Patient has a diagnosis of lower extremity diabetic neuropathic ulcer(s) that extend into the subcutaneous tissue or beyond AND
ii. The ulcer(s) intended for treatment has an adequate blood supply AND
iii. Patient will practice good ulcer care practices (e.g. debridement, infection control, pressure relief) with 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 – **Relistor PA**

Drug Name(s):
RELISTOR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
A. ALL of the following:
i. ONE of the following diagnoses:
1. Patient has opioid-induced constipation (OIC), with advanced illness and is receiving palliative care AND the requested agent is Relistor (methylnaltrexone) injection OR
2. Patient has opioid-induced constipation (OIC) and chronic non-cancer pain AND
ii. Patient has chronic use of an opioid agent in the past 90 days AND
iii. ONE of the following:
1. Patient has tried at least one standard laxative treatment for constipation – lactulose or polyethylene glycol 3350 OR
2. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one standard laxative treatment for constipation – lactulose or polyethylene glycol 3350 OR
B. Patient has a diagnosis of another FDA approved indication for the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Repatha PA**

Drug Name(s):
REPATHA
REPATHA PUSHTRONEX SYSTEM
REPATHA SURECLICK

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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 approved diagnosis for the requested agent AND
2. ONE of the following:
    A. If the diagnosis is heterozygous familial hypercholesterolemia (HeFH), 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. Total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) (pretreatment or highest level while on treatment) OR 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. If the diagnosis is homozygous familial hypercholesterolemia (HoFH), 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. Untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C greater than or equal 300 mg/dL (greater than or equal 7.76 mmol/L) with ONE of the following:
            a. Cutaneous or tendon xanthoma before age 10 years OR

b. Untreated LDL-C levels consistent with HeFH in both parents [untreated LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L)] OR

C. Patient has clinical atherosclerotic cardiovascular disease (ASCVD) defined as having ONE of the following:

i. Acute coronary syndrome
ii. History of myocardial infarction
iii. Stable or unstable angina
iv. Coronary or other arterial revascularization
v. Stroke
vi. Transient ischemic attack
vii. Peripheral arterial disease presumed to be of atherosclerotic origin AND

Initial criteria continues: see Other Criteria

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

3. 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

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

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. Patient has an FDA approved diagnosis 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 – **Restasis PA**

Drug Name(s):
RESTASIS

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require 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 – **Samsca PA**

Drug Name(s):
SAMSCA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to therapy with the request agent AND Underlying liver disease, including cirrhosis

Required Medical:
Criteria for approval require ALL of the following:
1. Samsca therapy was initiated (or re-initiated) in the hospital AND
2. Prior to initiating Samsca, patient has or had a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia defined by ONE of the following:
    a. Serum sodium less than 125 mEq/L OR
    b. Serum sodium greater than or equal to 125 mEq/L and patient has symptomatic hyponatremia that has resisted correction with fluid restriction AND
3. Medications known to cause hyponatremia have been evaluated and discontinued when appropriate AND
4. Patient has not already received 30 days of Samsca therapy following the most recent hospitalization for initiation of therapy AND
5. Requested dose is within the FDA approved labeled dosing (Initial dose is 15 mg once daily. May be increased to 30 mg once daily after 24 hours, up to a maximum daily dose of 60 mg, as needed to achieve the desired level of serum sodium. Do not administer Samsca for more than 30 days to minimize the risk of liver injury)

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 30 days

Other Criteria:

Prior Authorization Group – **Sensipar PA**

Drug Name(s):
SENSIPAR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ONE of the following:
A. Patient has an FDA approved indication or has 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 within the past 90 days that the patient is currently being treated with the requested agent OR
    ii. Prescriber states the patient is using the requested agent AND is at risk if therapy is changed OR
B. Patient has a diagnosis of hypercalcemia due to parathyroid carcinoma OR
C. Patient has a diagnosis of primary hyperparathyroidism (HPT) AND BOTH of the following:
    i. Patient has severe hypercalcemia, defined as serum calcium greater than12.5 mg/dL AND
    ii. Patient is unable to undergo parathyroidectomy OR
D. Patient has a diagnosis of secondary hyperparathyroidism (HPT) due to chronic kidney disease (CKD) AND ALL of the following:
    i. Patient is on dialysis AND
    ii. Patient has an intact PTH (iPTH) level greater than 300 pg/mL AND
    iii. Patient's medication history indicates previous use of a formulary prerequisite agent [Fosrenol (lanthanum carbonate), sevelamer, or calcium acetate] or patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a formulary prerequisite agent OR
E. 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 12 months

Other Criteria:

Prior Authorization Group – **Signifor LAR PA**

Drug Name(s):
SIGNIFOR LAR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND Severe hepatic impairment (i.e. Child Pugh C)

Required Medical:
Criteria for initial approval require ONE of the following:
1. Patient has a diagnosis of acromegaly AND ONE of the following:
    i. Patient had an inadequate response to surgery defined by ONE of the following:
        a. Growth hormone level greater than 5 ng/mL OR
        b. IGF-1 level greater than 1.9 U/mL for males or greater than 2.2 U/mL for females OR
    ii. Patient is NOT a candidate for surgical resection OR
2. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. ONE of the following:
    A. Patient has a diagnosis of acromegaly AND ONE of the following:
        i. Growth hormone level less than 5 ng/mL OR
        ii. IGF-1 level less than 1.9 U/mL for males or less than 2.2 U/mL for females OR
        iii. Clinical improvement (e.g. reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) OR
    B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

Prior Authorization Group – **Signifor PA**

Drug Name(s):
SIGNIFOR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND Severe hepatic impairment (i.e. Child Pugh C)

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

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for the requested agent through the plan's PA criteria AND
2. ONE of the following:
    A. Patient has a diagnosis of Cushing's disease AND BOTH of the following:
        i. Patient has had a 15% or greater decrease in urinary free cortisol levels 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: 3 months for CD, 12 months for all other diagnoses, Renewal approval: 12 months

Other Criteria:

Prior Authorization Group – **Sildenafil PA**

Drug Name(s):
sildenafil tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:
FDA labeled contraindication(s) to the requested agent AND Concurrently taking an phosphodiesterase type 5 (PDE-5) inhibitor (e.g. Cialis, Viagra) with the requested agent

Required Medical:
Criteria for initial approval require ONE of the following:
A. BOTH of the following:
i. ONE of the following:
a. There is evidence of a claim within the past 90 days that the patient is currently being treated with requested agent 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 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 of 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. Requested agent will be utilized as monotherapy OR
b. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then BOTH of the following:
1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
2. Requested agent is in a different therapeutic class OR
c. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then 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 requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

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

Prior Authorization Group – **Sivextro PA**

Drug Name(s):
SIVEXTRO

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require ALL of:
1. ONE of:
    a. If 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 (pt) then ONE of:
        1. Pt has 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) OR
        2. Pt has another indication that is supported in CMS approved compendia for the requested agent OR
    b. If 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 pt then ONE of:
        i. ALL of:
            1. Pt has 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
            2. ONE of:
                a. Infection is due to Staphylococci that are resistant to beta lactams, macrolides, clindamycin, tetracycline, and co-trimoxazole, or vancomycin (e.g. MRSA) or pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to beta lactams, macrolides, clindamycin, tetracyclines, and co-trimoxazole, or vancomycin OR
                b. Infection is due to vancomycin-resistant Enterococcus faecalis or pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin OR
        ii. Pt has another indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of:

a. Pt is NOT currently being treated for the same infection concomitantly with Zyvox (linezolid) OR
b. Current treatment with Zyvox (linezolid) for the same infection will be discontinued before starting therapy with the requested agent AND

3. Requested dose is within the FDA and/or compendia labeled dosage

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be 6 days for FDA labeled indications or 30 days for all other indications

Other Criteria:

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

Drug Name(s):
octreotide injection

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of the following:
    A. There is evidence of a claim within past 90 days that the patient is currently being treated with the requested agent OR
    B. Prescriber states the patient is using the requested agent AND is at risk if therapy is changed OR
    C. Patient has a diagnosis of acromegaly AND ONE of the following:
        i. Patient is not a candidate for both surgical resection AND pituitary irradiation OR
        ii. The use of requested agent is for adjunctive therapy with irradiation to alleviate acromegaly symptoms OR
        iii. Patient had an inadequate response to surgery or pituitary irradiation defined by ONE of the following:
            a. Growth hormone level greater than 5 ng/mL OR
            b. IGF-1 level greater than 1.9 U/mL for males or greater than 2.2 U/mL for females OR
    D. Patient has a diagnosis of carcinoid tumor, meningioma, lung neuroendocrine tumor, neuroendocrine tumor poorly differentiated (high-grade)/large or small cell, pancreatic islet cell neuroendocrine tumor, vasoactive intestinal polypeptidoma, thymoma, or thymic carcinoma AND ONE of the following:
        i. Patient will be using the medication for symptom control for carcinoid syndrome or hormone hypersecretion OR
        ii. Patient has had an inadequate response to or is not a candidate for both surgical resection AND radiation therapy OR
    E. Patient has a diagnosis of dumping syndrome AND BOTH of the following:
        i. Patient has had an inadequate response to dietary management AND
        ii. Patient has tried acarbose or has a documented intolerance, FDA labeled contraindication, or hypersensitivity to acarbose OR

F. Patient has an 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 require ALL of the following:

1. Patient has been previously approved for therapy through the plan's PA criteria and has responded to therapy AND

2. If the patient has a diagnosis of acromegaly, ONE of the following:

A. Growth hormone level less than 5 ng/mL OR

B. IGF-1 level less than 1.9 U/mL for males or less than 2.2 U/mL for females OR

C. Clinical improvement (e.g. reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) AND

3. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Program applies to new starts only.
Criteria for initial approval require ONE of the following:
1. There is evidence of a claim within past 180 days that the patient is currently being treated with the requested agent OR
2. Prescriber states the patient is using the requested agent OR
3. ALL 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 both surgical resection AND pituitary irradiation OR
            b. The use of requested agent is for adjunctive therapy with irradiation to alleviate acromegaly symptoms OR
            c. Patient had an inadequate response to surgery or pituitary irradiation defined by ONE of the following:
                1) Growth hormone level greater than 5 ng/mL OR
                2) IGF-1 level greater than 1.9 U/mL for males or greater than 2.2 U/mL for females OR
        ii. Patient has a diagnosis of carcinoid syndrome OR
        iii. Patient has a diagnosis of carcinoid tumor, locally advanced/metastatic gastroenteropancreatic neuroendocrine tumor or poorly differentiated (high-grade)/large or small cell neuroendocrine tumor, pancreatic islet cell neuroendocrine tumor, or vasoactive intestinal polypeptidoma AND ONE of the following:
            a. Patient will be using the medication for symptom control for carcinoid syndrome or hormone hypersecretion OR
            b. Patient has had an inadequate response to or is not a candidate for both surgical resection AND radiation therapy OR
        iv. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

B. Patient does NOT have any FDA labeled contraindication(s) to therapy 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

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 require ONE of the following:
1. There is evidence of a claim within past 180 days that the patient is currently being treated with the requested agent OR
2. Prescriber states the patient is using the requested agent OR
3. Patient has been previously approved for therapy through the plan's PA criteria and has responded to therapy AND ALL of the following:
A. If the patient has a diagnosis of acromegaly, ONE of the following:
i. Growth hormone level less than 5 ng/mL OR
ii. IGF-1 level less than 1.9 U/mL for males or less than 2.2 U/mL for females OR
iii. Clinical improvement (e.g. reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) AND
B. Patient does NOT have any FDA labeled contraindication(s) to therapy 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require BOTH of the following:
1. ONE of the following:
    A. There is evidence of a claim within the past 90 days that the patient is currently being treated with the requested agent OR
    B. Prescriber states the patient is using the requested agent AND is at risk if therapy is changed OR
    C. Patient has a diagnosis of acromegaly AND BOTH of the following:
        i. ONE of the following:
            a. Patient is not a candidate for both surgical resection AND pituitary irradiation OR
            b. Patient had an inadequate response to surgery or pituitary irradiation defined by an IGF-1 level greater than 1.9 U/mL for males or greater than 2.2 U/mL for females AND
        ii. ONE of the following:
            a. Patient has tried and failed a prerequisite agent (octreotide or Somatuline Depot) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to prerequisite agents AND
2. The dose requested is within the FDA approved dosing for the requested agent and indication

Criteria for renewal require ALL of the following:
1. Patient has been previously approved for therapy through the plan's PA criteria and has responded to therapy AND
2. If the patient has a diagnosis of acromegaly, ONE of the following:
    A. Growth hormone level less than 5 ng/mL OR
    B. IGF-1 level less than 1.9 U/mL for males or less than 2.2 U/mL for females OR
    C. Clinical improvement (e.g. reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) AND

3. 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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Sovaldi (sofosbuvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Sovaldi (sofosbuvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Technivie PA**

Drug Name(s):
TECHNIVIE

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Technivie (paritaprevir/ritonavir/ombitasvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Technivie (paritaprevir/ritonavir/ombitasvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Tetrabenazine PA**

Drug Name(s):
tetrabenazine tablet

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria:
Impaired hepatic function

Required Medical:
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. If the patient has a 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 – **Uptravi PA**

Drug Name(s):
UPTRAVI

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require ONE of the following:
A. BOTH of the following:
i. ONE of the following:
a. There is evidence of a claim within the past 90 days that the patient is currently being treated with requested agent 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 of 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. Requested agent will be utilized as monotherapy OR
b. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then BOTH of the following:
1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
2. Requested agent is in a different therapeutic class OR
c. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then 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 require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA criteria and is responding to therapy AND
2. 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 – **Ventavis PA**

Drug Name(s):
VENTAVIS

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require ONE of the following:
A. BOTH of the following:
i. ONE of the following:
a. There is evidence of a claim within the past 90 days that the patient is currently being treated with requested agent 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 of 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. Requested agent will be utilized as monotherapy OR
b. Requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then BOTH of the following:
1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
2. Requested agent is in a different therapeutic class OR
c. Requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then ALL of the following:
1. Patient is WHO functional class III or IV AND
2. 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
3. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

4. 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 require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA criteria and is responding to therapy AND
2. Patient has an FDA labeled indication for the requested agent

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

Prior Authorization Group – **Viekira PA**

Drug Name(s):
VIEKIRA PAK

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Viekira Pak (paritaprevir/ritonavir/ombitasvir + dasabuvir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Viekira Pak (paritaprevir/ritonavir/ombitasvir + dasabuvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. If genotype 1, the patient's subtype has been identified and provided 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Viekira XR PA**

Drug Name(s):
VIEKIRA XR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. If genotype 1, the patient's subtype has been identified and provided 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Voriconazole PA**

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

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for initial approval require ONE of the following:
A. Patient has a diagnosis of invasive Aspergillus, Scedosporium apiospermum, or Fusarium OR
B. 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, or hypersensitivity to an alternative antifungal agent OR
C. Patient has a diagnosis of blastomycosis AND patient has tried itraconazole OR patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to itraconazole OR
D. Patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or a patient with a hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient OR
E. Patient has another indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal 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 the patient has continued indicators of active disease (e.g. continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR
    B. Requested agent is being prescribed for prophylaxis and the patient continues to be severely immunocompromised as indicated by: neutropenia, ongoing graft

versus host disease, and/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

Age Restrictions:

Prescriber Restrictions:

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

Other Criteria:

Prior Authorization Group – **Vosevi PA**

Drug Name(s):
VOSEVI

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. 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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Xiidra PA**

Drug Name(s):
XIIDRA

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
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 – **Xolair PA**

Drug Name(s):
XOLAIR

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:

Required Medical:
Criteria for initial approval require ALL of the following:
1. ONE of:
    a. Patient (pt) has a diagnosis (dx) of asthma OR
    b. Pt has a dx of chronic idiopathic urticaria (CIU) OR
    c. Pt has another FDA approved indication for the requested agent AND
2. If asthma, ALL of:
    a. If pt is 6 to less than 12 years of age, BOTH of:
        i. Pretreatment IgE level is 30 IU/mL to 1300 IU/mL AND
        ii. Pt's weight is 20 kg to 150 kg AND
    b. If pt is 12 years of age and over, ALL of:
        i. Pretreatment IgE level is 30 IU/mL to 700 IU/mL AND
        ii. Pt's weight is 30 kg to150 kg AND
        iii. Pt has a baseline FEV1 less than 80% predicted AND
    c. Allergic asthma has been confirmed by positive skin test or in vitro reactivity test (RAST) AND
    d. There is evidence of a claim within the past 90 days of an inhaled corticosteroid OR the pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to inhaled corticosteroids AND
    e. ONE of:
        i. There is evidence of a claim within the past 90 days of a long-acting beta-2 agonist OR the pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to long-acting beta-2 agonists OR
        ii. There is evidence of a claim within the past 90 days of a leukotriene modifier or theophylline OR the pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a leukotriene modifier or theophylline AND
    f. Pt is experiencing exacerbations of asthma symptoms AND
    g. The dose is within dosing parameters (pre-treatment serum IgE level and body weight) defined in product labeling AND does not exceed 375 mg every 2 weeks AND

Initial criteria continues: see Other Criteria

Age Restrictions:
Asthma: 6 years of age and over CIU: 12 years of age and over

Prescriber Restrictions:

Coverage Duration:
Initial: 24 weeks for asthma and CIU, 12 months for other diagnoses, Renewal: 12 months

Other Criteria:
3. If CIU, ALL of:
    a. Pt is 12 years of age and over AND
    b. Pt has a history of chronic CIU for at least 6 months AND
    c. Pt has a history of hives and itching AND
    d. ONE of:
        i. Pt is currently on maximum tolerable H1 antihistamine therapy within the past 90 days OR
        ii. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to H1 antihistamine therapy AND
    e. The dose is within the FDA labeled dose not to exceed 300 mg every 4 weeks AND
4. If another FDA approved dx, the dosing is within the FDA approved dosing limit

Criteria for renewal require ALL of the following:
1. Pt has been previously approved for the requested agent through the plan's PA criteria AND
2. If asthma, ALL of:
    a. Pt's weight is within the FDA indicated range for their age (i.e. 20 kg to 150 kg for pts age 6 to less than 12 years and 30 kg to 150 kg for pts 12 years of age and over AND
    b. Pt does not have clinical worsening defined as ONE of:
        i. Increase in inhaled corticosteroid use
        ii. Treatment with systemic corticosteroids
        iii. Increased use of short acting beta-2 agonist rescue medication
        iv. Unscheduled care visits (urgent care, ER, or hospitalizations) due to exacerbations AND
    c. ONE of the following:
        i. There is evidence of a claim within the past 90 days with 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) OR

ii. Pt has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies AND

d. The dose is within dosing parameters (pre-treatment serum IgE level and body weight) defined in product labeling or does not exceed 375 mg every 2 weeks AND

3. If CIU, BOTH of the following:

a. Improvement in symptoms (e.g. number of hives, size of hives, reduction in itching) AND

b. The dose is within the FDA labeled dose not to exceed 300 mg every 4 weeks AND

4. If another FDA approved dx, the dosing is within the FDA approved dosing limit

Prior Authorization Group – **Xyrem PA**

Drug Name(s):
XYREM

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

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

Required Medical:
Criteria for approval require 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 ONE of the following:
    i. Patient's medication history includes use of one standard stimulant agent (e.g. methlyphenidate) OR
    ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to one standard stimulant agent (e.g. methlyphenidate) OR
C. Patient has another FDA approved indication for the requested agent

Age Restrictions:
Patient is 18 years of age or older

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group – **Zepatier PA**

Drug Name(s):
ZEPATIER

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D.

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. Zepatier (elbasvir/grazoprevir) will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
3. The dosing of Zepatier (elbasvir/grazoprevir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. If genotype 1, the patient's subtype has been identified and provided AND
5. If genotype 1a, the prescriber has tested the patient for the presence of virus with NS5A resistance-associated polymorphisms 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 the preferred agent [Harvoni (ledipasvir/sofosbuvir)] OR
    C. Prescriber has submitted documentation based on FDA approved labeling or in AASLD/IDSA guidelines to support the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent [Harvoni (ledipasvir/sofosbuvir)]

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 in AASLD/IDSA guideline supported

Other Criteria:

Prior Authorization Group – **Zohydro ER PA**

Drug Name(s):
ZOHYDRO ER

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria:
Prescribed as an as-needed (prn) analgesic AND 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 a diagnosis of chronic cancer pain due to an active malignancy OR
    b. Patient is undergoing treatment of chronic non-cancer pain AND ALL of the following:
        i. Prescriber provides documentation of a formal, consultative evaluation including:
            a) Diagnosis AND
            b) A complete medical history which includes previous pharmacological and non-pharmacological therapy AND
        ii. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND
        iii. Prescriber has confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND
2. ONE of the following:
    a. Patient's medication history includes use of an immediate-acting or another long-acting opioid OR
    b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to other immediate-acting or long-acting opioids

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months

Other Criteria: