2015 PRIOR AUTHORIZATION CRITERIA

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Prior Authorization Group – Acthar HP Gel PA

Drug Name(s):

ACTHAR HP GEL

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of the following:
1. ONE of:
    A. Diagnosis of infantile spasm OR
    B. Diagnosis of multiple sclerosis AND
        i. Patient is experiencing an acute exacerbation AND
        ii. Patient has failed corticosteroid therapy within the last 30 days or has an FDA labeled contraindication to corticosteroid therapy 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
    OR
    D. Use is supported by clinical evidence or the prescriber has submitted documentation in support of therapy with H.P. Acthar Gel for the intended diagnosis AND Patient has failed corticosteroid therapy within the last 30 days or has an FDA labeled contraindication to corticosteroid therapy
AND
2. Patient does not have an FDA contraindication to therapy
AND
3. For infantile spasms and multiple sclerosis, the dose is within the FDA labeled dose

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.

Exclusion Criteria:

Required Medical:

This program applies to new starts only.
Criteria for initial approval require ONE of the following:
1. There is evidence of a claim within the past 90 days that patient is currently being treated with requested agent OR
2. Prescriber states patient is using requested agent AND is at risk if therapy is changed OR
3. ALL of the following:
    A. ONE of the following:
        i. Patient has a diagnosis of pulmonary arterial hypertension, WHO Group 1 as determined by right heart catheterization OR
        ii. Prescriber has submitted documentation in support of the use of the prescribed agent for the intended diagnosis (erectile dysfunction is not a covered diagnosis)
    AND
    B. The patient's mean pulmonary arterial pressure is greater than 25 mm Hg AND
    C. The patient has a pulmonary vascular resistance greater than 3 Wood units AND
    D. Patient's NYHA functional class is II or greater AND
    E. Patient is not concurrently taking oral erectile dysfunction agents (e.g. Cialis, Viagra, Levitra) AND
    F. Patient does not have any FDA labeled contraindications to therapy

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA process and is responding to therapy AND
2. Patient does not have any FDA labeled contraindications to therapy

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:

Required Medical:

Criteria for approval require ALL 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 treatment 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 treatment for constipation – lactulose or polyethylene glycol 3350

AND

3. Patient does not have any FDA labeled contraindications to therapy

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:

Required Medical:

Criteria for approval require ALL of the following:
1. Patient has a diagnosis of multiple sclerosis AND
2. Patient is receiving concurrent therapy with a disease modifying agent (e.g. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Novantrone, Rebif, Tecfidera, or Tysabri) if indicated AND
3. There is documentation of significant limitations of instrumental activities of daily living attributable to slow ambulation AND
4. Patient is ambulatory with a baseline timed 25 foot walk between 8 to 45 seconds OR patient has an expanded disability status scale (EDSS) of greater than or equal to 4.5 but less than 7 AND
5. Patient does not have any FDA labeled contraindications to therapy AND
6. ONE of the following:
    A. Patient is being started on initial therapy with Ampyra OR
    B. Patient is currently receiving Ampyra and has been receiving Ampyra therapy for 2 months or longer AND has demonstrated an improvement from baseline in timed walking speed (timed 25 foot walk) OR
    C. Patient has a documented EDSS score of less than 7

Age Restrictions:

Prescriber Restrictions:

The prescriber is a neurologist or has consulted a neurologist

Coverage Duration:

Approval will be 3 months for initial, 12 months for renewal.

Other Criteria:

Prior Authorization Group – Anabolic Steroid PA - Danazol

Drug Name(s):

danazol

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of the following:
1. Patient has ONE of the following diagnoses:
    A. Patient has fibrocystic breast disease OR
    B. Patient has hereditary angioedema OR
    C Patient has endometriosis

AND
2. Patient does NOT have any FDA labeled contraindication(s)
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 – Anabolic Steroid PA - oxandrolone

Drug Name(s):

oxandrolone

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are 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 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. Patient does NOT have any FDA labeled contraindication(s)

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 – 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:

Required Medical:

Criteria for approval are 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. Patient does NOT have any FDA labeled contraindication(s)
AND
4. 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):

DEPO-TESTOSTERONE
testosterone cypionate
testosterone enanthate

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are 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. Patient does NOT have any FDA labeled contraindication(s)

AND

4. 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):

ANDROID
ANDROXY
methyltestosterone

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are 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. Patient does NOT have any FDA labeled contraindication(s)

AND

4. 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
AXIRON

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are 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. Patient does NOT have any FDA labeled contraindication(s)

AND

4. 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 – Arcalyst PA

Drug Name(s):

ARCALYST

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL 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. Patient does NOT have any FDA labeled contraindication(s) to therapy AND
3. Patient does not have an active or chronic infection (for example, tuberculosis, HIV, hepatitis B/C) AND
4. If patient has been previously treated with another IL-1 inhibitor (for example, Kineret [anakinra] or Ilaris) or a TNF-alpha blocking agent (for example, Enbrel [etanercept], Remicade [infliximab], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab]) the agent 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 – Biologic Immunomodulators PA - Enbrel

Drug Name(s):

ENBREL

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a FDA labeled indication for the requested agent
AND
2. 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 patient is using requested agent AND is at risk if therapy is changed OR
C. Diagnosis is ankylosing spondylitis OR
D. Diagnosis is rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, or psoriasis AND patient's medication history indicates use of one formulary conventional agent prerequisite OR
E. Diagnosis is rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, or psoriasis AND patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary conventional agents OR
F. Patient's medication history indicates use of another biologic agent for an FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent
AND
4. Patient has been tested for latent TB AND if positive patient has begun therapy for latent TB
AND
5. Patient is not currently being treated with another biologic immunomodulator

Criteria for renewal approval are:
1. Patient has been previously approved for therapy through the plan's prior authorization process
AND
2. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent
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 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, and acitretin

No formulary conventional agents are required for ankylosing spondylitis

Prior Authorization Group – Biologic Immunomodulators PA - Humira

Drug Name(s):

HUMIRA

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a FDA labeled indication for the requested agent
AND
2. 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 patient is using requested agent AND is at risk if therapy is changed OR
C. Diagnosis is ankylosing spondylitis OR
D. Diagnosis is rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, psoriasis, ulcerative colitis, or Crohn's disease AND patient's medication history indicates use of one formulary conventional agent prerequisite OR
E. Diagnosis is rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, psoriasis, ulcerative colitis, or Crohn's disease AND patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary conventional agents OR
F. Patient's medication history indicates use of another biologic agent for an FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent
AND
4. Patient has been tested for latent TB AND if positive patient has begun therapy for latent TB
AND
5. Patient is not currently being treated with another biologic immunomodulator

Criteria for renewal approval are:
1. Patient has been previously approved for therapy through the plan's prior authorization process
AND
2. Patient has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent
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 UC, 12 months for all others

Other Criteria:

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, and acitretin

Formulary conventional agents for Crohn's disease include aminosalicylates, methotrexate, corticosteroids (budesonide EC), metronidazole, ciprofloxacin, cyclosporine, or immunomodulators such as 6-mercaptopurine or azathioprine

No formulary conventional agents are required for ankylosing spondylitis

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:

Required Medical:

Criteria for initial approval are:
1. Patient (pt) has FDA labeled indication for requested agent
AND
2. ONE of the following:
    A. There is evidence of a claim within the past 90 days that pt is currently being treated with requested agent OR
    B. Prescriber states pt is using requested agent AND is at risk if therapy is changed OR
    C. Pt's diagnosis is rheumatoid arthritis AND ONE of the following:
        i. Pt's medication history indicates use of BOTH preferred biologic agents (Humira and Enbrel) OR
        ii. Pt has documented intolerance, FDA labeled contraindication, or hypersensitivity to BOTH preferred biologic agents (Humira and Enbrel)
    OR
    D. Pt's diagnosis is Cryopyrin-Associated Periodic Syndrome (CAPS)/Neonatal-Onset Multisystem Inflammatory Disease (NOMID) AND
3. Pt does not have any FDA labeled contraindications to therapy AND
4. Pt has been tested for latent TB AND if positive has begun therapy for latent TB AND
5. Pt is not currently being treated with another biologic immunomodulator

Criteria for renewal approval are:
1. Pt has been previously approved for therapy through the plan's prior authorization process AND
2. Pt has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
3. Pt does not have any FDA labeled contraindications to therapy AND
4. Pt is not currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

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:

Required Medical:

Criteria for initial approval are:
1. Patient (pt) has FDA labeled indication for requested agent
AND
2. ONE of the following:
    A. There is evidence of a claim within the past 90 days that pt is currently being treated with requested agent OR
    B. Prescriber states pt is using requested agent AND is at risk if therapy is changed OR
    C. ONE of the following:
        i. Pt's medication history indicates use of BOTH preferred biologic agents (Humira and Enbrel, Humira only for Crohn's Disease [CD] or Ulcerative Colitis [UC]) OR
        ii. Pt has documented intolerance, FDA labeled contraindication, or hypersensitivity to BOTH preferred biologic agents (Humira and Enbrel, Humira only for CD or UC)
AND
3. Pt does not have any FDA labeled contraindications to therapy AND
4. Pt has been tested for latent TB AND if positive has begun therapy for latent TB AND
5. Pt is not currently being treated with another biologic immunomodulator

Criteria for renewal approval are:
1. Pt has been previously approved for therapy through the plan's prior authorization process
AND
2. Pt has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
3. Pt does not have any FDA labeled contraindications to therapy AND
4. Pt is not currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

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 include ONE of:
1. There is evidence of a claim within the past 180 days that patient (pt) is currently being treated with requested agent OR
2. Prescriber states pt is using requested agent OR
3. ALL of the following:
    A. ONE of:
        i. Diagnosis is Non-Hodgkin's lymphoma, chronic lymphocytic leukemia, Wegener's granulomatosis, or microscopic polyangiitis OR
        ii. Use of the target agent is for an indication that is supported by compendia or prescriber has submitted additional documentation supporting the requested therapeutic use OR
        iii. Diagnosis is rheumatoid arthritis
        AND ONE of:
            a. Pt's medication history indicates use of BOTH preferred biologic agents (Humira and Enbrel) OR
            b. Pt has documented intolerance, FDA labeled contraindication, or hypersensitivity to BOTH preferred agents (Humira and Enbrel)
    AND
    B. Pt does not have any FDA labeled contraindications to therapy with requested agent AND
    C. Pt has been tested for latent TB AND if positive pt has begun therapy for latent TB AND
    D. Pt 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
    E. Pt is not currently being treated with another biologic immunomodulator

Criteria for renewal approval are:
1. There is evidence of a claim within the past 180 days that pt is currently being treated with requested agent OR
2. Prescriber states pt is using requested agent OR
3. ALL of:
    A. Pt has been previously approved for therapy through the plan's PA process AND
    B. Pt has shown clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
    C. Pt does not have any FDA labeled contraindications to therapy with requested agent AND
    D. Pt is not currently being treated with another biologic immunomodulator

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – bosentan PA

Drug Name(s):

TRACLEER

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of pulmonary arterial hypertension, WHO Group 1 as determined by right heart catheterization AND
2. The patient's NYHA functional class is II or greater AND
3. The patient's mean pulmonary arterial pressure is greater than 25 mm Hg AND
4. The patient has a pulmonary vascular resistance greater than 3 Wood units AND
5. The patient does not have any FDA labeled contraindications to therapy AND
6. Patient does not have elevated liver enzymes or a bilirubin level of greater than 2 times upper limit of normal (ULN)

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA process and is responding to therapy AND
2. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – buprenorphine PA

Drug Name(s):

buprenorphine

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of opioid dependence AND
2. Patient is compliant with all elements of treatment plan (including recovery-oriented activities, psychotherapy, and/or other psychosocial modalities) AND
3. Prescriber has confirmed that patient is not diverting requested medication, according to patient's records in the state's prescription drug monitoring program (PDMP), if applicable

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's prior authorization process AND
2. Patient is abstinent from illicit drug use (including problematic alcohol and/or benzodiazepine use) AND
3. Patient continues to be compliant with all elements of the treatment plan (including recovery-oriented activities, psychotherapy, and/or other psychosocial modalities) AND
4. 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
5. If patient is receiving any other opioid medication, prescriber has submitted information supporting medical necessity of opioid, including specific pain that current opioid is being used to treat and expected duration of therapy with opioid

Age Restrictions:

Patients must be 16 years of age or older.

Prescriber Restrictions:

Prescriber meets qualification certification criteria in the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified prescriber under the DATA to prescribe buprenorphine

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group – buprenorphine-naloxone PA

Drug Name(s):

buprenorphine-naloxone
SUBOXONE

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of opioid dependence AND
2. Patient is compliant with all elements of treatment plan (including recovery-oriented activities, psychotherapy, and/or other psychosocial modalities) AND
3. Prescriber has confirmed that patient is not diverting requested medication, according to patient's records in the state's prescription drug monitoring program (PDMP), if applicable

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for the requested agent through the plan's prior authorization process AND
2. Patient is abstinent from illicit drug use (including problematic alcohol and/or benzodiazepine use) AND
3. Patient continues to be compliant with all elements of the treatment plan (including recovery-oriented activities, psychotherapy, and/or other psychosocial modalities) AND
4. 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
5. If patient is receiving any other opioid medication, prescriber has submitted information supporting medical necessity of opioid, including specific pain that current opioid is being used to treat and expected duration of therapy with opioid

Age Restrictions:

Patients must be 16 years of age or older

Prescriber Restrictions:

Prescriber meets qualification certification criteria in the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified prescriber under the DATA to prescribe buprenorphine/naloxone

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group – Clonazepam PA

Drug Name(s):

clonazepam
clonazepam odt

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 ONE of:
1. There is evidence of a claim within the 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 a diagnosis of seizure disorder OR
4. Patient has a diagnosis of 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

5. Prescriber has submitted documentation in support of the requested therapeutic use of the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – Clorazepate PA

Drug Name(s):

clorazepate

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 ONE of:
1. There is evidence of a claim within the 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 a diagnosis of seizure disorder OR
4. Patient has a diagnosis of 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
5. Patient has a diagnosis of alcohol withdrawal OR
6. Prescriber has submitted documentation in support of the requested therapeutic use of 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:

Patient does NOT have any 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:

Patient does NOT have any 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 aspergillosis OR
b. Patient has a diagnosis of mucormycosis OR
c. Patient has another indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal are BOTH of the following:
1. Patient has been approved for requested agent through the plan's Prior Authorization process 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 a 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:

Patient will NOT be receiving Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Technivie (ombitasvir/paritaprevir/ritonavir), or Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir) concomitantly with Daklinza (daclatasvir) AND
Patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent

Required Medical:

Criteria will be approved when ALL of the following are met:
1. Patient has a diagnosis of chronic hepatitis C infection confirmed by serological markers AND
2. Daklinza (daclatasvir) will be used in a combination antiviral treatment regimen and length of therapy that is supported in FDA approved labeling or in AASLD/IDSA guidelines for the patient's genotype AND
3. The dosing of Daklinza (daclatasvir) is within the FDA labeled dosing or is AASLD/IDSA guideline supported AND
4. The dosing of Sovaldi (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: 12 - 24 weeks based on FDA approved labeling or in AASLD/IDSA guidelines

Other Criteria:

Prior Authorization Group – Diazepam PA

Drug Name(s):

DIAZEPAM soln
diazepam tablet
diazepam conc

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 ONE of:
1. There is evidence of a claim within the 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 a diagnosis of seizure disorder OR
4. Patient has a diagnosis of 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
5. Patient has a diagnosis of skeletal muscle spasms OR
6. Patient has a diagnosis of alcohol withdrawal OR
7. Prescriber has submitted documentation in support of the requested therapeutic use of the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

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:

Required Medical:

Criteria for initial approval are ALL 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 has a BMI greater than 20 kg/m2 AND
6. Patient does not have any FDA labeled contraindications AND
7. Patient is not planning to become pregnant or currently breastfeeding AND
8. Patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of greater than 150 mg/dL AND
9. 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 are ALL the following:
1. Patient has been approved for Egrifta previously through the plan's PA process AND
2. The patient has had and/or maintained an 8% decrease in visceral adipose tissue (VAT) from baseline or maintained or decreased waist circumference AND
3. The 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 has a BMI greater than20 kg/m2 AND
6. Patient does not have any FDA labeled contraindications AND
7. Patient is not planning to become pregnant or currently breastfeeding AND
8. Patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of greater than 150 mg/dL AND
9. 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 – Erythropoietin Stimulating Agents PA - Aranesp

Drug Name(s):

ARANESP

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of:

1. ONE of:
   - A. Erythropoietin Stimulating Agent (ESA) is prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient (pt) AND patient's (pt's) hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL OR
   - B. ESA is prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of:
     - i. Pt's hemoglobin level is less than 10 g/dL for pts initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks) AND
     - ii. Pt is being concurrently treated with chemotherapy, with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
     - iii. Intent of chemotherapy is non-curative OR
   - C. ESA is 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:
     - 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
   - D. ESA is 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
   - E. ESA is prescribed for another indication AND BOTH of:
     - i. There is clinical evidence supporting therapy with an ESA for intended use or prescriber has submitted documentation in support of requested therapeutic use for 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 does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

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

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.

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of:
1. ONE of:
   A. Erythropoietin Stimulating Agent (ESA) is prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient (pt) AND patient's (pt's) hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL OR
   B. ESA is prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of:
      i. Pt's hemoglobin level is less than 10 g/dL for pts initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks) AND
      ii. Pt is being concurrently treated with chemotherapy, with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
      iii. Intent of chemotherapy is non-curative
   OR
   C. ESA is 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:
      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
   D. ESA is prescribed for a pt with anemia due to myelodysplastic syndrome or a pt with anemia resulting from zidovudine treatment of HIV infection AND pt's hemoglobin level is less than 12 g/dL for pts initiating ESA therapy or less than or equal to 12 g/dL for pts stabilized on therapy (measured within the previous four weeks) OR
   E. ESA is prescribed for another indication AND BOTH of:
      i. There is clinical evidence supporting therapy with an ESA for intended use or prescriber has submitted documentation in support of requested therapeutic use for 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 does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

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

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 are ALL of the following:

1. One of the following:
    a. ALL 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 diagnosis that is a CMS-approved compendia accepted indication for the requested medication 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 are ALL of the following:

1. ONE of the following:
    a. ALL 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 diagnosis that is a CMS-approved compendia accepted indication for the requested medication 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 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 are ALL of the following:

1. One of the following:
    a. ALL 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 diagnosis that is a CMS-approved compendia accepted indication for the requested medication

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 – fentanyl Oral PA - Subsys

Drug Name(s):

SUBSYS

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 are ALL of the following:

1. One of the following:
    a. ALL 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 diagnosis that is a CMS-approved compendia accepted indication for the requested medication

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 – Forteo PA

Drug Name(s):

FORTEO

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of the following:

1. Patient has a diagnosis of osteoporosis defined as ONE of the following:
   - A. Patient has severe osteoporosis with a very low BMD defined as a T-score that is –3.5 or lower (3.5 or more standard deviations below the mean (BMD) value for a young adult) OR
   - B. 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
   - C. 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's medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) OR
     - ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM or bisphosphonate (bisphosphonate only if male) AND
2. The patient does NOT have any FDA labeled contraindication(s) AND
3. The patient does not have any of the following conditions where Forteo should not be used: Paget's disease of bone, Unexplained elevations of alkaline phosphatase, Open epiphyses (i.e., pediatric or young adult patient), Prior radiation therapy involving the skeleton, History of skeletal malignancy, Bone metastases, Metabolic bone disease other than osteoporosis, Pre-existing hypercalcemia AND
4. Patient is not receiving concomitant bisphosphonate, SERM, or Prolia (denosumab) therapy AND
5. Total duration of treatment with Forteo has not exceeded 2 years AND
6. Dose requested is within FDA approved labeling

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:

Required Medical:

Criteria for initial approval are 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 AND
4. Patient does not have any FDA labeled contraindications to therapy

Criteria for renewal are ALL of the following:
1. Patient has been previously approved through the plan's PA process AND
2. Patient has had at least a 20% reduction from baseline in PN or IV fluids AND
3. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial approval 6 months. Renewal approval 12 months

Other Criteria:

Prior Authorization Group – Growth Hormone PA

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:

Required Medical:

Criteria for approval of initial Growth Hormone (GH) for children are:

1. ONE of the following:
    - A. Patient (Pt) is 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
    - B. Diagnosis (Dx) is Turner Syndrome, Prader-Willi Syndrome, Noonan Syndrome, or SHOX gene deficiency OR
    - C. Pt has deficiencies in 3 or more pituitary axes (panhypopituitarism) AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy OR
    - D. Dx is chronic renal insufficiency AND BOTH:
        - i. Pt height (ht) is more than 2 standard deviations (SD) below mean (less than 3rd percentile) compared to same age normal children AND
        - ii. Other growth retardation etiologies have been ruled out OR
    - E. Dx is GH deficiency, short stature (SS), or other AND BOTH:
        - i. Pt has ONE of:
            - a) Ht more than 2 SD below the mean for age and sex OR
            - b) Ht more than 1.5 SD below the midparental ht OR
            - c) A decrease in ht SD of more than 0.5 over one year in children greater than 2 years of age OR
            - d) Ht velocity more than 2 SD below mean over 1 yr or more than 1.5 SD sustained over 2 yrs AND
        - ii. Pt has failed at least 2 GH stimulation tests AND
2. Pt does NOT have any FDA labeled contraindication(s) to therapy

Criteria for approval of renewal GH for children are:

1. Pt has been approved for GH previously through the plan's PA process AND
2. ALL of the following:
    - i. Pt doesn't have closed epiphysis and
    - ii. Pt is being monitored for GH therapy side effects and
    - iii. Pt ht has increased or ht velocity has improved since initiation or last renewal of GH AND
3. Pt does NOT have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for approval of initial Growth Hormone (GH) for adults are:

1. ONE of the following:
    A. Diagnosis is childhood GH deficiency (GHD) with genetic/organic origin AND ONE of the following:
        i. Pt has low IGF-1 level without GH replacement OR
        ii. Pt failed at least 1 GH stim test as adult OR
    B. Diagnosis is acquired adult GHD secondary to structural lesions/trauma AND ONE of the following:
        i. Pt deficient in 3 or more pituitary hormones and pt's IGF-1 level is low OR
        ii. Pt failed at least 1 GH stimulation test as adult OR
    C. Other diagnosis (e.g., childhood or adult-onset idiopathic GHD) and pt failed at least 2 GH stimulation tests as adult AND
2. Pt does NOT have any FDA labeled contraindications to therapy

Criteria for approval of renewal (GH) for adults are ALL of:

1. Pt has been approved for GH previously through the plan's PA process AND
2. ALL of the following:
    A. Pt has been evaluated for development of adverse events due to GH therapy AND
    B. Prescriber evaluated pt's serum insulin-like growth factor-1 to confirm appropriateness of current dose AND
    C. GH therapy has shown benefits to pt 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 AND
3. Pt does NOT have any FDA labeled contraindications to therapy

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:

Required Medical:

Criteria for initial approval are ALL of:
1. Patient does not have any FDA labeled contraindications to therapy AND
2. 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:
        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 HAE

AND
3. Medications known to cause angioedema have been evaluated and discontinued when appropriate
AND
4. ONE of:
    a. Requested agent will be used to treat HAE acute attacks OR
    b. Requested agent will be used for prophylaxis against HAE attacks AND BOTH of:
        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. Patient has tried a formulary 17 alpha-alkylated androgen or antifibrinolytic agent OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a formulary 17 alpha-alkylated androgen or antifibrinolytic agent.

Criteria for renewal approval are ALL of:
1. Patient has been previously approved for therapy through the plan's PA process AND
2. Patient has received benefit from use of the requested agent to prevent or treat HAE acute attacks AND
3. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – HAE PA - Firazyr

Drug Name(s):

FIRAZYR

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient does not have any FDA labeled contraindications to therapy AND
2. 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
3. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND
4. Requested agent will be used to treat HAE acute attacks

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for therapy through the plan's PA process AND
2. Patient has received benefit from use of the requested agent to treat HAE acute attacks AND
3. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – Harvoni PA

Drug Name(s):

HARVONI

Covered Uses:

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

Exclusion Criteria:

Requested agent will not be used in combination with other protease inhibitors used to treat chronic hepatitis C (i.e. boceprevir, simeprevir, or telaprevir) AND Patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent

Required Medical:

Criteria will be approved when ALL of the following criteria are met:

1. Patient has a diagnosis of chronic hepatitis C, genotype 1 confirmed by serological markers AND
2. ONE of the following:
    a. Patient has NOT failed a previous sofosbuvir containing regimen OR
    b. BOTH of the following:
        i. Patient has failed a previous sofosbuvir containing regimen AND
        ii. Patient has advanced fibrosis

AND

3. Dosing of Harvoni (ledipasvir/sofosbuvir) is within the FDA labeled dosage

Age Restrictions:

Prescriber Restrictions:

Prescriber is a specialist (i.e. Gastroenterologist, Hepatologist, or Infectious Disease) or the prescriber has consulted with a specialist

Coverage Duration:

Treatment-experienced with cirrhosis: 24 weeks, All others: 12 weeks

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:

Patient does not have any FDA labeled contraindications to therapy with Hetlioz (tasimelteon) AND Patient does not have severe hepatic impairment (Child-Pugh Class C)

Required Medical:

Criteria for approval require ALL of the following:
1. Patient is legally blind AND
2. Patient has a diagnosis of Non-24-hour sleep-wake disorder

Age Restrictions:

Patients must be 18 years of age or older

Prescriber Restrictions:

Prescriber is a sleep specialist or has consulted with a sleep specialist

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – High Risk Medication PA

Drug Name(s):

amitriptyline
ascomp/codeine
benztropine
butalbital/acetaminophen/caffeine/codeine cap
butalbital/aspirin/caffeine/codeine cap
clemastine 2.68 mg
clomipramine
digox 0.25 mg tab
digoxin 0.25 mg tab
DIVIGEL
doxepin 10 mg, 25 mg, 50 mg, 100 mg, 150 mg cap
DOXEPIN 75 mg cap
doxepin oral conc
ergoloid mesylates
estradiol
estradiol/norethindrone
estropipate 0.75 mg, 1.5 mg
ESTROPIPATE 3 mg
glyburide
GLYBURIDE
glyburide micronized
glyburide/metformin
hydroxyzine soln, syrup, tab
imipramine
lopreeza
megestrol susp, tabs
MENEST
mimvey
mimvey lo
phenergan 12.5 mg, 25 mg supp
phenadoz supp
phenobarbital elixir, soln
PHENOBARBITAL inj
PHENOBARBITAL 15 mg, 30 mg, 60 mg, 100 mg tab
phenobarbital 16.2 mg, 32.4 mg, 64.8 mg, 97.2 mg tab
PREMARIN
PREMPHASE
PREMPRO
promethazine
promethegan supp
SURMONTIL
thioridazine
trimipramine

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-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication AND
    b. Prescriber has completed a risk assessment of the high risk medication for the patient AND
    c. Prescriber has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND
    d. 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 - ketorolac

Drug Name(s):

ketorolac 10 mg tab

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-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication AND
2. Prescriber has completed a risk assessment of the high risk medication for the patient AND
3. Prescriber has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND
4. 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 90 days

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:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH), through ONE of the following:
    A. a genetic test with documented functional mutations in both LDL receptor alleles or alleles known to affect LDL receptor functionality OR
    B. skin fibroblast LDL receptor activity less than 20% normal OR
    C. untreated total cholesterol (TC) greater than 500 mg/dL and triglycerides (TG) less than 300 mg/dL AND both parents with documented untreated TC greater than 250 mg/dL.

AND
2. Patient is on a lipid-lowering regimen (e.g. statins, ezetimibe, nicotinic acid, bile acid sequestrant, or fibrate)
AND
3. Patient will be maintained on a low fat diet with less than 20% of calories from fat AND
4. Patient does NOT have any FDA labeled contraindications to therapy

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for therapy through the plan's PA process AND
2. 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
3. Patient is on a concurrent lipid lowering regimen (e.g. statins, ezetimibe, nicotinic acid, bile acid sequestrant, or fibrate) AND
4. Patient will be maintained on a low fat diet with less than 20% of calories from fat AND
5. Patient does NOT have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – HoFH PA - Kynamro

Drug Name(s):

KYNAMRO

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH), through ONE of the following:
    A. a genetic test confirming two mutated alleles at the LDLr gene locus OR
    B. untreated LDL-C greater than 500 mg/dL AND one of the following:
        i. patient having tendinous and/or cutaneous xanthoma (s) prior to age 10 years
        OR
        ii. both parents with documented untreated LDL-C greater than 190 mg/dL

AND
2. Patient is on a lipid-lowering regimen (e.g. statins, ezetimibe, nicotinic acid, bile acid sequestrant, or fibrate) AND
3. Patient will be maintained on a low fat diet with less than 20% of calories from fat AND
4. Patient does NOT have any FDA labeled contraindications to therapy AND
5. Patient will not be receiving apheresis while on therapy with Kynamro

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for therapy through the plan's PA process
AND
2. 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
3. Patient is on a concurrent lipid lowering regimen (e.g. statins, ezetimibe, nicotinic acid, bile acid sequestrant, or fibrate) AND
4. Patient will be maintained on a low fat diet with less than 20% of calories from fat AND
5. Patient does NOT have any FDA labeled contraindications to therapy AND
6. Patient will not be receiving apheresis while on therapy with Kynamro

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial approval 6 months. Renewal approval 12 months

Other Criteria:

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:

Required Medical:

Criteria for approval are:

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 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) OR
     - b. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to a prerequisite agent
   - OR
   - C. Patient's diagnosis is acute gouty arthritis AND ONE of the following:
     - i. Patient has failed at least 2 conventional first-line agents (prescription oral NSAIDs, colchicine, systemic corticosteroids) OR
     - ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to 2 conventional first-line agents

AND

2. ALL of the following:
   - A. Patient does not have any FDA labeled contraindications to therapy AND
   - B. Patient does not have an active or chronic infection (e.g. tuberculosis, HIV, hepatitis B/C) AND
   - C. If patient is currently being treated with another biologic agent, the agent 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):

ALDARA
imiquimod

Covered Uses:

All FDA-approved 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:
1. Patient has a diagnosis of ONE of the following: external genital and/or perianal warts/condyloma acuminata, actinic keratosis, or superficial basal cell carcinoma
OR
2. Prescriber has submitted documentation in support of therapy for the intended diagnosis

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

4 mo ext. genital/perianal warts, actinic keratosis, 2 mo basal 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:
1 Primary immunodeficiency
2 Primary immune defects w/ absent B cells
3 Impaired specific antibody production (normo/hypogammaglobulinemia)
4 Pre solid organ transplant, pt has high risk antibody-mediated rejection (AMR) - highly sensitized pts, those receiving ABO incompatible organ
5 Post solid organ transplant AMR treatment
6 CLL w/ reduced IgG AND hx of infections
7 Prevention of bacterial infections in HIV-treated pts on antiretroviral
8 Adult HIV-associated thrombocytopenia
9 Neonatal sepsis
10 Graves ophthalmopathy
11 ITP, Dermatomyositis, or Polymyositis AND pt failed/intolerant to conventional therapy
12 Severe RA
13 Fetomaternal alloimmune thrombocytopenia
14 Guillain-Barre syndrome (syn)
15 Chronic demyelinating polyneuropathy
16 Multifocal motor neuropathy
17 Paraprotein associated demyelinating neuropathy
18 Lambert-Eaton myasthenia syn
19 Myasthenia Gravis/crisis AND contraindication to plasma exchange
20 Stiff-man syn
21 Monoclonal gammopathy MS
22 Intractable childhood epilepsy
23 Rasmussen syn
24 Kawasaki disease (dis)
25 CMV-induced pneumonitis in solid organ transplant
26 Rotaviral enterocolitis
27 Bacterial infections in lymphoproliferative dis
28 Prevention acute GVHD (BMT)
29 Delayed pressure urticaria
30 Prevention acute humoral rejection in renal transplant
31 Pediatric autoimmune psych disorder w/ strep infections
32 Severe invasive grp A strep dis
33 Severe persistent high-dose asthma
34 Toxic epidermal necrolysis/Stevens-Johnson syn
35 Low serum IgG levels after HSCT
36 Multiple myeloma, pt w/ stable dis, recurrent infections, current chemotherapy
37 Acquired von Willebrand hemophilia AND pt failed/intolerant to conventional therapy

38 Hemolytic dis of newborn AND Rhesus or ABO hemolytic dis
39 Clinical evidence or prescriber submitted documentation supports therapy w/ immunoglobulin for diagnosis

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 3 months for indications in NSH guidelines, 12 months all others

Other Criteria:

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

Indications with 3 month approval duration:
Idiopathic thrombocytopenia purpura (ITP)
Guillain-Barre Syndrome
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

Prior Authorization Group – IPF PA - Esbriet

Drug Name(s):

ESBRIET

Covered Uses:

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

Exclusion Criteria:

Patient does not have severe hepatic impairment (Child-Pugh class C), end-stage liver disease, or a history of end-stage renal disease requiring dialysis AND Patient does not have any FDA labeled contraindication(s) to therapy

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has either the diagnosis of idiopathic pulmonary fibrosis (IPF) or another FDA approved diagnosis 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 less than or equal to 90% AND
    E. ALL of the following:
        a. 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:
                a. Patient has possible UIP patterns on HRCT (i.e. subpleural, basal predominance and reticular abnormality with absent honeycombing) AND
                b. 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. Patient is receiving only one of the listed agents – Esbriet/pirfenidone OR Ofev/nintedanib

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 are ALL of the following:

1. Patient has been approved for the requested agent previously through the plan's PA process AND
2. If IPF, ALL 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% AND
3. Patient is receiving only one of the listed agents – Esbriet/pirfenidone OR Ofev/nintedanib

Prior Authorization Group – IPF PA - Ofev

Drug Name(s):

OFEV

Covered Uses:

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

Exclusion Criteria:

Patient does not have moderate/severe hepatic impairment (Child-Pugh class B or C), end-stage liver disease, or a history of end-stage renal disease requiring dialysis AND Patient does not have any FDA labeled contraindication(s) to therapy

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has either the diagnosis of idiopathic pulmonary fibrosis (IPF) or another FDA approved diagnosis 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 less than or equal to 90% AND
    E. ALL of the following:
        a. 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:
                a. Patient has possible UIP patterns on HRCT (i.e. subpleural, basal predominance and reticular abnormality with absent honeycombing) AND
                b. 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. Patient is receiving only one of the listed agents – Esbriet/pirfenidone OR Ofev/nintedanib

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 are ALL of the following:

1. Patient has been approved for the requested agent previously through the plan's PA process AND
2. If IPF, ALL 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% AND
3. Patient is receiving only one of the listed agents – Esbriet/pirfenidone OR Ofev/nintedanib

Prior Authorization Group – ITP PA

Drug Name(s):

PROMACTA

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:

1. Patient has an FDA labeled diagnosis for requested agent AND
2. Patient does not have any FDA labeled contraindications to therapy AND
3. ONE of:
    - A. If patient has diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP), ONE of:
        - i. Patient's medication history includes use of corticosteroids or immunoglobulins OR patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to treatment with corticosteroids or immunoglobulins OR
        - ii. Patient has had an insufficient response to or is not a candidate for a splenectomy OR
    - B. If patient has diagnosis of hepatitis C (HCV) associated thrombocytopenia, ONE of:
        - i. Patient's platelet count is less than 100 x109 /L AND 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
    - C. If patient has diagnosis of severe aplastic anemia (SAA) and ALL of the following:
        - I. All of the following:
            - A. 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

            - B. 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

        - II. One of the following
            - A. Patient has had an insufficient response to immunosuppressive therapy (defined as failure to antithymocyte globulin (ATG) and cyclosporine) OR
            - B. Patient has an FDA labeled contraindication, intolerance, or hypersensitivity to horse ATG and cyclosporine

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial 8 wk ITP, 12 wk HCV, 16 wk SAA, renewal 12 mos ITP & SAA, 48 wk HCV geno 1/4/6, 24 wk 2/3

Other Criteria:

Criteria for renewal are ALL of the following:

1. Patient has been previously approved for therapy through the plan's prior authorization process AND
2. Patient does not have any FDA labeled contraindications to therapy AND
3. ONE of:
    - A. Patient's diagnosis is ITP AND ONE of:
        - 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's diagnosis is HCV associated thrombocytopenia AND ALL of:
        - i. Patient's HCV genotype is either 1,4,6 or 2,3 AND
        - ii. Patient will be initiating or maintaining HCV therapy with interferon and ribavirin AND
        - iii. ONE of:
            - a. Patient’s platelet count is greater than or equal to 90 x109 /L OR
            - b. Patient's platelet count has increased sufficiently to initiate or maintain interferon based therapy for the treatment of HCV OR
    - C. Patient's diagnosis is SAA and has had a hematological response by week 16 defined as ONE of the following:
        - a. Platelet count increases to 20 x 109/L above baseline OR
        - b. Stable platelet counts with transfusion independence for a minimum of 8 weeks OR
        - c. Hemoglobin increase by greater than 1.5 g/dL OR
        - d. Reduction in greater than or equal to 4 units of Red Blood Cell (RBC) transfusions for 8 consecutive weeks OR
        - e. An Absolute Neutrophil Count (ANC) increase of 100% OR
        - f. An Absolute Neutrophil Count (ANC) increase greater than 0.5 x 109/L

Prior Authorization Group – Kuvan PA

Drug Name(s):

KUVAN

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval of Kuvan require ALL of the following:
1. Patient has a diagnosis of phenylketonuria (PKU) AND
2. Patient has NOT been previously treated with Kuvan (sapropterin) AND
3. Patient is on a phenylalanine (Phe) restricted diet AND
4. 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
5. Prescriber has verified that patient's diet will NOT be modified in any way during the initial 1-month or 2-month trial of Kuvan (sapropterin) therapy AND
6. Patient does not have any FDA labeled contraindications to therapy AND
7. The dose is within the FDA-labeled dose range of 5 to 20 mg/kg/day

Kuvan will be approved for RENEWAL when ALL of the following are met:
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. Prescriber has verified that the patient's diet was NOT modified in any way during the initial 1-month or 2-month trial of Kuvan (sapropterin) therapy AND
3. Patient does not have any FDA labeled contraindications to therapy AND
4. 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 approval 2 months if dose 5-10 mg/kg/day, 1 month if 20 mg/kg/day

Renewal approval 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:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of pulmonary arterial hypertension, WHO Group 1 as determined by right heart catheterization AND
2. The patient's NYHA functional class is II or greater AND
3. The patient's mean pulmonary arterial pressure is greater than 25 mm Hg AND
4. The patient has a pulmonary vascular resistance greater than 3 Wood units AND
5. The patient does not have any FDA labeled contraindications to therapy

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA process and is responding to therapy AND
2. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – Lidocaine transdermal PA

Drug Name(s):

lidocaine transdermal patch
LIDODERM

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 are ALL of the following:
1. 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 that is a CMS-approved compendia accepted indication for the requested medication

AND

2. Patient does not have any FDA labeled contraindication(s) to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – linezolid PA

Drug Name(s):

linezolid tab
ZYVOX tabs, susp

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Linezolid will be approved when BOTH of the following are met:
1. Patient does NOT have any FDA labeled contraindication(s)
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 patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin OR
b. Patient has a documented infection due to Staphylococci that are resistant to beta lactams, macrolides, clindamycin, tetracycline, and co-trimoxazole (e.g. MRSA) or patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to beta lactams, macrolides, clindamycin, tetracyclines and co-trimoxazole
AND
ii. Dose is within the FDA labeled dosage

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:

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

Required Medical:

Criteria for approval require ALL 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 treatment 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 treatment 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 – Lorazepam PA

Drug Name(s):

lorazepam

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 ONE of:
1. There is evidence of a claim within the 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 a diagnosis of 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
4. Prescriber has submitted documentation in support of the requested therapeutic use of 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

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of the following:
1. Patient's diagnosis is narcolepsy, obstructive sleep apnea/hypopnea syndrome, or shift work sleep disorder
AND
2. Patient is receiving only one of the listed agents – Nuvigil/armodafinil OR Provigil/modafinil
AND
3. Patient does not have an FDA contraindication to therapy

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

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. ONE of the following:
    A. Patient is not currently being treated with a disease modifying agent (DMA) for the requested indication (multiple sclerosis [MS]) OR
    B. Patient is currently being treated with a DMA for the requested indication AND DMA will be discontinued before starting requested agent

AND

2. 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 patient is using the requested agent AND is at risk if therapy is changed OR
    C. BOTH of the following:
        i. Patient has an FDA labeled diagnosis for the requested agent
        AND
        ii. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for requested therapy through the plan's prior authorization process
AND
2. Patient is NOT currently being treated with an additional DMA for the intended FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – MS PA - Betaseron

Drug Name(s):

BETASERON

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. ONE of the following:
    A. Patient is not currently being treated with a disease modifying agent (DMA) for the requested indication (multiple sclerosis [MS])
    OR
    B. Patient is currently being treated with a DMA for the requested indication AND DMA will be discontinued before starting requested agent
AND
2. 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 patient is using the requested agent AND is at risk if therapy is changed OR
    C. BOTH of the following:
        i. Patient has an FDA labeled diagnosis for the requested agent
        AND
        ii. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for requested therapy through the plan's prior authorization process
AND
2. Patient is NOT currently being treated with an additional DMA for the intended FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – MS PA - glatiramer

Drug Name(s):

COPAXONE
glatopa

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. ONE of the following:
    A. Patient is not currently being treated with a disease modifying agent (DMA) for the requested indication (multiple sclerosis [MS])
    OR
    B. Patient is currently being treated with a DMA for the requested indication AND DMA will be discontinued before starting requested agent
AND
2. 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 patient is using the requested agent AND is at risk if therapy is changed OR
    C. BOTH of the following:
        i. Patient has an FDA labeled diagnosis for the requested agent
        AND
        ii. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for requested therapy through the plan's prior authorization process
AND
2. Patient is NOT currently being treated with an additional DMA for the intended FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – MS PA - Plegridy

Drug Name(s):

PLEGRIDY

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. ONE of the following:
A. Patient is not currently being treated with a disease modifying agent (DMA) for the requested indication (multiple sclerosis [MS]) OR
B. Patient is currently being treated with a DMA for the requested indication AND DMA will be discontinued before starting requested agent
AND
2. 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 patient is using the requested agent AND is at risk if therapy is changed OR
C. BOTH of the following:
i. Patient has an FDA labeled diagnosis for the requested agent
AND
ii. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for requested therapy through the plan's prior authorization process
AND
2. Patient is NOT currently being treated with an additional DMA for the intended FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – MS PA - Tecfidera

Drug Name(s):

TECFIDERA
TECFIDERA STARTER PACK

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. ONE of the following:
    A. Patient is not currently being treated with a disease modifying agent (DMA) for the requested indication (multiple sclerosis [MS]) OR
    B. Patient is currently being treated with a DMA for the requested indication AND DMA will be discontinued before starting requested agent

AND

2. 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 patient is using the requested agent AND is at risk if therapy is changed OR
    C. BOTH of the following:
        i. Patient has an FDA labeled diagnosis for the requested agent
        AND
        ii. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Criteria for renewal are ALL of the following:
1. Patient has been previously approved for requested therapy through the plan's prior authorization process
AND
2. Patient is NOT currently being treated with an additional DMA for the intended FDA labeled indication
AND
3. Patient does not have any FDA labeled contraindications to therapy with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – MS PA - Tysabri

Drug Name(s):

TYSABRI

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of:

1. ONE of:
   - A. Patient (Pt) is not currently being treated with a disease modifying agent (DMA) for requested indication (multiple sclerosis [MS] or Crohn's disease[CD]) OR
   - B. Pt is currently being treated with a DMA for requested indication AND DMA will be discontinued before starting requested agent

AND

2. ONE of the following:
   - A. There is evidence of a claim within the past 90 days that the pt is currently being treated with requested agent OR
   - B. Prescriber states the pt is using requested agent AND is at risk if therapy is changed OR
   - C. ALL of:
     - i. Pt has an FDA labeled diagnosis for requested agent AND
     - ii. Pt does not have any FDA labeled contraindications to therapy AND
     - iii. If request is for MS, ONE of:
       - a. Pt's medication history indicates use of 2 preferred agents (Avonex, Betaseron, glatiramer (i.e. Copaxone, Glatopa), Tecfidera, or Plegridy) OR
       - b. Pt has documented intolerance/FDA labeled contraindication/hypersensitivity to 2 preferred agents (Avonex, Betaseron, glatiramer (i.e. Copaxone, Glatopa), Tecfidera, or Plegridy)

     AND

     - iv. If request is for CD, BOTH of:
       - a. Pt's medication history includes use of a conventional CD therapy (aminosalicylates, metronidazole, ciprofloxacin, corticosteroids (budesonide EC), methotrexate, or immunomodulators such as azathioprine or 6-mercaptopurine) OR pt has documented intolerance/FDA labeled contraindication/hypersensitivity to conventional CD therapy AND
       - b. Pt's medication history includes use of preferred agent Humira OR pt has documented intolerance/FDA labeled contraindication/hypersensitivity to Humira

Criteria for renewal are ALL of:

1. Pt has been previously approved for requested therapy through the plan's PA process AND
2. Pt has shown clinical benefit with Tysabri AND
3. Pt is NOT currently being treated with an additional DMA for the intended FDA labeled indication AND
4. Pt does not have any FDA labeled contraindications to therapy

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:

Prior Authorization Group – Myalept PA

Drug Name(s):

MYALEPT

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of 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 metreleptin therapy AND
3. Patient also has at least one of the following additional diagnosis: diabetes mellitus, hypertriglyceridemia (greater than or equal to 200), and/or high fasting insulin (greater than or equal to 30µU/mL) AND
4. Patient has failed lifestyle modification (i.e. diet modification and exercise) and will continue with lifestyle modification during metreleptin therapy AND
5. Patient has failed maximum tolerable dosing of a conventional agent for the additional diagnosis within the past 90 days AND
6. Patient does not have human immunodeficiency virus (HIV) infection, infectious liver disease and/or acquired lipodystrophy with hematologic abnormalities AND
7. Patient does not have any FDA labeled contraindications to therapy with metreleptin AND
8. The dose is within FDA labeled dosing guidelines

Criteria for renewal are ALL of the following:
1. Patient has been previously approved through the plan's prior authorization process AND
2. Patient has had a reduction in at least one of the following parameters: HbA1C, triglycerides and/or fasting insulin AND
3. Patient will continue with lifestyle modification (i.e. diet and exercise) during therapy with metreleptin AND
4. Patient does not have any FDA labeled contraindications to therapy with metreleptin AND
5. The dose is within FDA labeled dosing guidelines

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

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

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 – Northera PA

Drug Name(s):

NORTHERA

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient (pt) has either the diagnosis (dx) of neurogenic orthostatic hypotension (NOH) or another FDA approved dx AND
2. If NOH, ALL of the following
    A. Pt has symptomatic NOH caused by primary autonomic failure [Parkinson's disease (PD), multiple system atrophy, or pure autonomic failure], dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy AND
    B. Prescriber has performed baseline blood pressure (BP) readings while the pt is sitting and also within 3 minutes of standing from a supine (lying face up) position AND
    C. Pt has a decrease of at least 20 mmHg in systolic BP or 10 mmHg diastolic BP within three minutes after standing from a sitting position AND
    D. Pt has persistent and consistent symptoms and the prescriber has determined that the pt has definitive NOH by one of the following:
        i. Prescriber has monitored and evaluated the pt's beat-to-beat BP associated with the Valsalva maneuver and it is determined that the pt has definitive NOH OR
        ii. Prescriber has performed an evaluation of the plasma norepinephrine response to orthostasis and the pt's plasma norepinephrine increases by less than 60% or by less than approximately 1 nmol/L (approximately 150 pg/mL) rather than approximately doubling within 5 minutes of standing OR
        iii. Prescriber has performed measurements of forearm or total peripheral resistance during orthostasis or other stimuli that decrease venous return to the heart and they have failed to increase AND
    E. Prescriber has assessed the severity of the pt's baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND
3. Pt does not have any FDA labeled contraindication(s) to therapy

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:

Criteria for renewal are ALL of the following:
1. Pt has been previously approved for the requested medication through the plan's PA process AND
2. If NOH, BOTH of the following:
    A. Pt has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND

B. Pt had an increase in systolic BP from baseline of at least 10 mmHg upon standing from a supine (laying face up) position AND

3. Pt does not have any FDA labeled contraindication(s) to therapy

Prior Authorization Group – Noxafil PA

Drug Name(s):

NOXAFIL

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are:

1. ONE of:
A. Patient (Pt) has diagnosis (dx) of oropharyngeal candidiasis AND history of fluconazole or alternative antifungal OR has documented intolerance, FDA labeled contraindication, or hypersensitivity to fluconazole or alternative antifungal OR
B. Pt is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or a pt with hematologic malignancy, prolonged neutropenia from chemotherapy, or a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant pt AND requested medication is prescribed for prophylaxis of invasive Aspergillus or Candida OR
C. Pt has an infection caused by Zygomycetes OR
D. Pt has dx of invasive Aspergillus AND pt has history of an alternative antifungal OR documented intolerance, FDA labeled contraindication, or hypersensitivity to an alternative antifungal OR
E. Prescriber has submitted documentation supporting use of requested medication for intended dx AND
2. Pt does not have any FDA labeled contraindications to therapy

Criteria for renewal are ALL of:
1. Pt has been approved for requested medication through the plan's prior authorization process AND
2. Pt does not have any FDA labeled contraindications to therapy AND
3. ONE of:
A. Requested medication is prescribed for prophylaxis of invasive Aspergillus or Candida and pt 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. Pt has dx of invasive Aspergillus or infection caused by Zygomycetes and pt has continued indicators of active disease (for example continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR
C. Prescriber has submitted documentation supporting continued use of requested medication for intended dx

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

One month for oropharyngeal and esophageal candidiasis, 6 months for other indications

Other Criteria:

Prior Authorization Group – Nuvigil PA

Drug Name(s):

NUVIGIL

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of the following:
1. Patient's diagnosis is narcolepsy, obstructive sleep apnea/hypopnea syndrome, or shift work sleep disorder
AND
2. Patient is receiving only one of the listed agents – Nuvigil/armodafinil OR Provigil/modafinil
AND
3. Patient does not have an FDA contraindication to therapy

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 – 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:

Required Medical:

Initial criteria are ALL of the following:
1. Patient has a diagnosis of chronic hepatitis C (Hep C) genotype 1 or 4 infection confirmed by serological markers AND
2. If patient has subtype 1a, must NOT have the NS3 Q80K polymorphism AND
3. Patient does NOT have any FDA labeled contraindications to Olysio (simeprevir) or the other agents used in the combination therapy AND
4. ONE of:
    a. Patient will receive triple drug therapy including Olysio, peginterferon alfa and ribavirin (PR) AND Patient has a compensated liver (no evidence of clinical disease (for example, absence of encephalopathy, ascites, or bleeding)) OR
    b. Olysio (simeprevir) will be used in a combination antiviral treatment regimen with Sovaldi (sofosbuvir) supported by FDA approved labeling or AASLD guidelines AND the dose of Sovaldi is within the FDA labeled dosage of 400 mg daily AND
5. Patient has not attempted a prior course of therapy for hep C with an HCV NS3/4A protease inhibitor AND
6. Dose is within the FDA labeled dosage of 150 mg daily AND
7. Patient has not already had more than 12 weeks of Olysio

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 weeks w/ PR, 12 -24 weeks w/Sovaldi

Other Criteria:

Olysio with Sovaldi with or without ribavirin without cirrhosis is approved for a duration of 12 weeks and with cirrhosis duration of 24 weeks is approved. Treatment of patients with HCV genotype 1 post liver transplantation can be 24 weeks

Prior Authorization Group – Oncology PA

Drug Name(s):

AFINITOR
AFINITOR DISPERZ
bexarotene
BOSULIF
CAPRELSA
COMETRIQ
ERIVEDGE
FARYDAK
GILOTRIF
GLEEVEC
HEXALEN
IBRANCE
ICLUSIG
IMBRUVICA
INLYTA
IRESSA
JAKAFI
LENVIMA
LONSURF
LYNPARZA
MATULANE
MEKINIST
NEXAVAR
ODOMZO
POMALYST
REVLIMID
SPRYCEL
STIVARGA
SUTENT
SYLATRON
TAFINLAR
TARCEVA
TARGRETIN
TASIGNA
THALOMID
tretinoin cap
TYKERB
VOTRIENT
XALKORI
XTANDI
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 for Target Oncology Agents require ALL of the following:
1. ONE of the following:
    A. There is evidence of a claim within the past 180 days that the patient is currently receiving the target agent OR
    B. Prescriber states the patient is using the target agent OR
    C. ALL of the following:
        i. ONE of the following:
            a) Patient has an FDA approved diagnosis for the target agent OR
            b) Use of the target agent is for an indication that is supported by compendia or prescriber has submitted additional documentation supporting the requested therapeutic use
        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 target agent and results indicate therapy with the target agent is appropriate AND
            b) Patient does NOT have any FDA labeled contraindication(s) AND
            c) Patient has tried and failed the first line agent for the intended indication (if applicable) OR patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first line agent
        AND
        iii. Patient does not have any FDA labeled limitations of use

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – Onfi PA

Drug Name(s):

ONFI

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 includes ONE of:
1. There is evidence of a claim within the 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 a diagnosis of seizure disorder OR
4. Prescriber has submitted documentation in support of the requested therapeutic use of the requested agent

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:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of pulmonary arterial hypertension, WHO Group 1 as determined by right heart catheterization AND
2. The patient's NYHA functional class is II or greater AND
3. The patient's mean pulmonary arterial pressure is greater than 25 mm Hg AND
4. The patient has a pulmonary vascular resistance greater than 3 Wood units AND
5. The patient does not have any FDA labeled contraindications to therapy

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA process and is responding to therapy AND
2. Patient does not have any FDA labeled contraindications to therapy

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:

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 Grastek: Timothy grass or cross-reactive grass OR
    B. Pollen specific antibodies to ONE of the pollen extracts included in Grastek: Timothy grass or cross-reactive grass

AND
3. ONE of the following:
    A. Patient has tried and failed at least two traditional 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 traditional allergy therapies, one of which was an intranasal corticosteroid

AND
4. Patient is not currently using subcutaneous injectable immunotherapy AND
5. Patient is not taking a beta blocker AND
6. Grastek 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 AND
9. Patient does not have any FDA labeled contraindications to therapy

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:

Traditional 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:

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 Ragwitek: Short Ragweed OR
    B. Pollen specific antibodies to ONE of the pollen extracts included in Ragwitek: Short Ragweed

AND
3. ONE of the following:
    A. Patient has tried and failed at least two traditional 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 traditional allergy therapies, one of which was an intranasal corticosteroid

AND
4. Patient is not currently using subcutaneous injectable immunotherapy AND
5. Patient is not taking a beta blocker AND
6. Ragwitek 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 AND
9. Patient does not have any FDA labeled contraindications to therapy

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:

Traditional 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:

1. 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
2. Patient has another FDA approved indication for the requested agent

Criteria for renewal approval are BOTH of the following:

1. Patient has been approved previously for the requested agent through the plan's PA process AND
2. If cystic fibrosis, the patient has shown improvement or stabilization in FEV1 from pre-therapeutic/baseline levels with the requested agent

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

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:

Required Medical:

Criteria for approval are BOTH of:

1. ONE of the following:
   - A. Peginterferon (PEG) is prescribed for treatment of chronic myelogenous leukemia (CML) OR
   - B. Use of requested agent is for an oncology indication supported by compendia or prescriber has submitted documentation supporting requested use OR
   - C. Patient (Pt) has chronic hepatitis B AND BOTH of:
     - i. Chronic hepatitis B infection confirmed by serological markers AND
     - ii. Pt has not had PEG for more than 18 months for this indication OR
   - D. Pt has acute or chronic hepatitis C (Hep C) and ONE of:
     - i. Double therapy (PEG/ ribavirin [RBV]) is requested and ALL of:
       - a) Hep C infection confirmed by serological markers AND
       - b) PEG is not being used as a maintenance dose for hep C infection AND
       - c) Pt has not had PEG for more than 24 months for this indication OR
     - ii. Triple therapy (PEG/RBV and oral NS3/4A protease inhibitor) is requested and ALL of:
       - a) Patient has chronic hep C genotype 1 (for boceprevir, simeprevir, telaprevir) or genotype 4 (for simeprevir) infection confirmed by serological markers AND
       - b) Pt will receive triple therapy including an oral NS3/4A protease inhibitor and PEG/RBV AND
       - c) Pt has not had PEG for more than 48 weeks for this indication OR
     - iii. Triple therapy (PEG/RBV and sofosbuvir) is requested and ALL of:
       - a) Pt has chronic hep C infection, any genotype, confirmed by serological markers AND
       - b) Pt will receive triple therapy including PEG/RBV and sofosbuvir AND
       - c) Pt will NOT be receiving an oral NS3/4A protease inhibitor at the same time as this regimen with sofosbuvir AND
       - d) ONE of:
         - 1) Pt is NOT a nonresponder of previous therapy with PEG/RBV and boceprevir or telaprevir AND has not had PEG for more than 12 weeks of triple therapy for this indication OR
         - 2) Pt is a nonresponder of previous therapy with PEG/RBV and boceprevir or telaprevir AND has not had PEG for more than 24 weeks of triple therapy for this indication AND
2. Pt does not have FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months for cancer/pre-cancer, 18 months for hep B, hep C see Other Criteria

Other Criteria:

24 months for confirmed hepatitis C virus infection for double therapy

48 weeks for confirmed hepatitis C virus genotype 1 or genotype 4 (for simeprevir only) infection for triple therapy with PEG/RBV and oral NS3/4 A protease inhibitor

12 weeks for confirmed hepatitis C virus infection for triple therapy with PEG/RBV and sofosbuvir in patient who is NOT a nonresponder of previous therapy with PEG/RBV and boceprevir or telaprevir

24 weeks for confirmed hepatitis C virus genotype 1a or 1b, for triple therapy with PEG/RBV and sofosbuvir in a nonresponder of previous therapy with PEG/RBV and boceprevir or telaprevir

Prior Authorization Group – Prolia PA

Drug Name(s):

PROLIA

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for approval are ALL of the following:

1. ONE of:
    - A. Patient (pt) is postmenopausal woman or man with diagnosis (dx) of osteoporosis defined as ONE of:
        - i. Patient has history (hx) of vertebral fracture(s) or low trauma or fragility fracture(s) [for example, prior fracture from minor trauma such as falling from standing height or less] within the past 5 years OR
        - ii. Pt has T-score that is –2.5 or lower (2.5 or more SD below mean bone mineral density (BMD) value for a young adult) AND ONE of:
            - a) Pt's medication (med) hx includes use of a bisphosphonate or SERM (bisphosphonate only if male) OR
            - b) Pt has documented intolerance, FDA labeled contraindication, or hypersensitivity to bisphosphonates or SERMs (bisphosphonates only if male)

    OR

    - B. Pt is woman with dx of breast cancer receiving aromatase inhibitor therapy AND ONE of:
        - i. Pt meets criteria above for use in postmenopausal women

        OR

        - ii. Pt has T-score of -1 to -2.5 AND ONE of:
            - a) Pt's med hx includes use of a bisphosphonate OR
            - b) Pt has documented intolerance, FDA labeled contraindication, or hypersensitivity to bisphosphonates

    OR

    - C. Pt is man with prostate cancer receiving androgen deprivation therapy AND ONE of:
        - i. Pt meets criteria above for osteoporosis OR
        - ii. ALL of:
            - a) ONE of:
                - i) Pt is at least 70 years of age OR
                - ii) Pt is less than 70 years of age AND either T-score of -1 or lower OR hx of osteoporotic fracture AND
            - b) ONE of:
                - i) Pt's med hx includes use of a bisphosphonate OR
                - ii) Pt has documented intolerance, FDA labeled contraindication, or hypersensitivity to bisphosphonates

AND

2. Pt does not have any FDA labeled contraindication(s) AND
3. Pt is not receiving concomitant bisphosphonate, SERM, or teriparatide AND
4. Dose requested is within FDA approved labeling

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:

Required Medical:

Criteria for approval are ALL of the following:

1. Patient has ONE of the following diagnoses:
    a. Patient has opioid-induced constipation (OIC), and advanced illness and is receiving palliative care OR
    b. Patient has opioid-induced constipation (OIC) and chronic non-cancer pain AND
2. Patient has chronic use of an opioid agent in the past 90 days AND
3. ONE of the following:
        i. Patient has tried at least one standard laxative treatment 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 treatment for constipation – lactulose or polyethylene glycol 3350

AND

4. Patient does not have any FDA labeled contraindications to therapy

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:

Required Medical:

Criteria for approval are 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. Patient does not have any FDA labeled contraindications AND
4. Patient has no underlying liver disease, including cirrhosis AND
5. Medications known to cause hyponatremia have been evaluated and discontinued when appropriate AND
6. Patient has not already received 30 days of Samsca therapy following the most recent hospitalization for initiation of therapy AND
7. 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:

Required Medical:

Criteria for approval are BOTH of the following:

1. ONE of the following:
    - A. Patient has a diagnosis of hypercalcemia due to parathyroid carcinoma OR
    - B. Patient has a diagnosis of primary hyperparathyroidism with severe hypercalcemia defined as serum calcium greater than 12.5 mg/dL and is unable to undergo parathyroidectomy OR
    - C. Patient has a diagnosis of secondary hyperparathyroidism due to chronic kidney disease and the patient is on dialysis and BOTH of the following:
        - i. Patient has an intact PTH (iPTH) level greater than 300 pg/mL AND
        - ii. Patient's medication history includes a formulary prerequisite agent (calcium acetate, Fosrenol, or sevelamer) or patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to a formulary prerequisite agent

    OR
    - D. Use of Sensipar is for an indication that is supported by compendia or prescriber has submitted additional documentation supporting the requested therapeutic use AND
2. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 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.

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. Patient has a diagnosis of Cushing's disease AND
2. ONE of the following:
    A. Patient has had recurrence or persistence of symptoms after pituitary surgical resection
    OR
    B. Patient is not a candidate for pituitary surgical resection

AND
3. Patient does not have severe hepatic impairment (e.g. Child Pugh C)

Criteria for renewal are ALL of the following:
1. Patient has been previously approved through the plan's PA approval process AND
2. ALL of the following:
    A. Patient has had a 15% or greater decrease in urinary free cortisol levels AND
    B. Patient has shown improvement in at least ONE of the following clinical signs and symptoms: fasting plasma glucose, hemoglobin A1c, hypertension, or weight

AND
3. Patient does not have severe hepatic impairment (e.g. Child Pugh C)

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial approval will be for 3 months, renewal 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.

Exclusion Criteria:

Patient does NOT have severe hepatic impairment (i.e. Child Pugh C)

Required Medical:

Criteria for initial approval are BOTH of the following:
1. Patient has a diagnosis of acromegaly AND
2. ONE of the following:
    a. The use of requested agent is for adjunctive therapy with irradiation to alleviate acromegaly symptoms OR
    b. Patient had an inadequate response to surgery or pituitary irradiation defined by ONE of the following:
        i. Growth hormone level greater than 5 ng/mL OR
        ii. IGF-1 level greater than 1.9 U/mL for males or greater than 2.2 U/mL for females OR
    c. Patient is NOT a candidate for both surgical resection AND pituitary irradiation

Criteria for renewal are BOTH of the following:
1. Patient has been previously approved through the plan's PA approval process AND
2. 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)

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 – sildenafil PA

Drug Name(s):

sildenafil

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are ALL of the following:
1. ONE of the following:
    A. Patient has a diagnosis of pulmonary arterial hypertension, WHO Group 1 as determined by right heart catheterization OR
    B. Prescriber has submitted documentation in support of the use of the prescribed agent for the intended diagnosis (erectile dysfunction is not a covered diagnosis)

AND
2. The patient's mean pulmonary arterial pressure is greater than 25 mm Hg AND
3. The patient has a pulmonary vascular resistance greater than 3 Wood units AND
4. Patient's NYHA functional class is II or greater AND
5. Patient is not concurrently taking oral erectile dysfunction agents (e.g. Cialis, Viagra, Levitra) AND
6. Patient does not have any FDA labeled contraindications to therapy

Criteria for renewal require BOTH of the following:
1. Patient has been previously approved for therapy through the plan's PA process and is responding to therapy AND
2. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group – Sivextro PA

Drug Name(s):

SIVEXTRO

Covered Uses:

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

Exclusion Criteria:

Patient does NOT have any FDA labeled contraindication(s) to the requested agent

Required Medical:

Criteria for approval require ONE of the following:

1. If Requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient AND BOTH of the following:
    a. ONE of the following:
        i. Patient 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
        ii. Use of requested agent is for an indication that is supported by compendia or the prescriber has submitted additional documentation supporting the requested therapeutic use AND
    b. Dose is within the FDA labeled dosage

OR

2. 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 patient AND ALL of the following:
    a. Patient 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
    b. ONE of the following:
        i. Infection is due to Staphylococci that are resistant to beta lactams, macrolides, clindamycin, tetracycline, and co-trimoxazole, or vancomycin (e.g. MRSA) or patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to beta lactams, macrolides, clindamycin, tetracyclines, and co-trimoxazole, or vancomycin
        OR
        ii. Infection is due to vancomycin-resistant Enterococcus faecalis or patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin
    AND
    c. Dose is within the FDA 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

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 initial approval are ALL of:
1. ONE of:
    A. There is evidence of a claim within past 90 days that patient (Pt) is currently receiving requested agent OR
    B. Prescriber states pt is using requested agent AND is at risk if therapy is changed OR
    C. Pt has acromegaly and ONE of:
        i. Pt is not a candidate for both surgical resection AND pituitary irradiation OR
        ii. Requested agent is for adjunctive therapy with irradiation OR
        iii. Pt had inadequate response to surgery or pituitary irradiation defined by growth hormone(GH) level greater than 5 ng/mL OR IGF-1 level greater than 1.9 U/mL for males or 2.2 U/mL for females
    OR
    D. Pt has carcinoid tumor, meningioma, lung neuroendocrine tumor, neuroendocrine tumor poorly differentiated (high-grade)/large or small cell, pancreas islet cell neuroendocrine tumor, vasoactive intestinal polypeptidoma, thymoma, or thymic carcinoma AND ONE of:
        i. Pt has had an inadequate response to or is not a candidate for surgical resection OR
        ii. Pt is not a candidate for radiation therapy
    OR
    E. Pt has dumping syndrome AND BOTH of:
        i. Pt has had an inadequate response to dietary management AND
        ii. Pt has tried acarbose or has documented intolerance, FDA labeled contraindication, or hypersensitivity to acarbose
    OR
    F. Use of target agent is for indication supported by compendia or prescriber has submitted documentation supporting requested use
AND
2. Pt does not have FDA labeled contraindications to therapy AND
3. Dose is within FDA labeled dosage

Criteria for renewal are ALL of:
1. Pt has been previously approved for therapy through the plan's PA process and is responding to therapy AND
2. If pt has acromegaly, ONE of:
    A. GH 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. Pt does not have FDA labeled contraindications to therapy AND
4. Dose is within FDA labeled dosage

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 – 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 include ONE of:
1. There is evidence of a claim within past 180 days that patient (Pt) is currently receiving requested agent OR
2. Prescriber states patient is using requested agent OR
3. ALL of the following:
    i. ONE of the following:
        A. Pt has acromegaly and ONE of:
            a. Pt is not a candidate for both surgical resection AND pituitary irradiation OR
            b. Requested agent is for adjunctive therapy with irradiation OR
            c. Pt had inadequate response to surgery or pituitary irradiation defined by growth hormone(GH) level greater than 5 ng/mL OR IGF-1 level greater than 1.9 U/mL for males or 2.2 U/mL for females OR
        B. Pt has carcinoid tumor, locally advanced/metastatic gastroenteropancreatic neuroendocrine tumor or poorly differentiated (high-grade)/large or small cell neuroendocrine tumor, pancreas islet cell neuroendocrine tumor, vasoactive intestinal polypeptidoma AND ONE of:
            a. Pt has had an inadequate response to or is not a candidate for surgical resection OR
            b. Pt is not a candidate for radiation therapy OR
        C. Pt has dumping syndrome AND BOTH of:
            a. Pt has had an inadequate response to dietary management AND
            b. Pt has tried acarbose or has documented intolerance, FDA labeled contraindication, or hypersensitivity to acarbose OR
        D. Use of target agent is for indication supported by compendia or prescriber has submitted documentation supporting requested use AND
    ii. Pt does not have FDA labeled contraindications to therapy AND
    iii. Dose is within FDA labeled dosage

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial approval will be for 6 months, renewal approval will be for 12 months

Other Criteria:

Criteria for renewal approval are:
1. There is evidence of a claim within past 180 days that pt is currently receiving requested agent OR

2. Prescriber states pt is using requested agent OR
3. Pt has been previously approved for therapy through the plan's PA process and is responding to therapy AND
    i. If pt has acromegaly, ONE of:
        A. GH 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
    ii. Pt does not have FDA labeled contraindications to therapy AND
    iii. Dose is within FDA labeled dosage

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:

Required Medical:

Criteria for initial approval are ALL of:
1. ONE of:
    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 patient is using the requested agent AND is at risk if therapy is changed OR
    C. Patient has acromegaly and BOTH of the following:
        i. ONE of:
            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 2.2 U/mL for females
        AND
        ii. ONE of:
            a. Patient has tried and failed a formulary prerequisite agent (octreotide or Somatuline Depot (lanreotide)) OR
            b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to formulary prerequisite agents OR
            c. Patient will be using requested agent as adjunctive therapy AND is currently on a prerequisite agent (octreotide or Somatuline Depot (lanreotide))

AND
2. Patient does not have any FDA labeled contraindications to therapy AND
3. Dose is within the FDA labeled dosage

Criteria for renewal are ALL of:
1. Patient has been previously approved for therapy through the plan's prior authorization process and is responding to therapy AND
2. If patient has acromegaly, ONE of:
    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. Patient does not have any FDA labeled contraindications to therapy AND
4. Dose is within the FDA labeled dosage

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:

Required Medical:

Criteria for approval are ALL of the following:
1. Patient has a diagnosis of chronic hepatitis C (Hep C) infection confirmed by serological markers AND
2. Sovaldi (sofosbuvir) will be used in a combination antiviral treatment regimen supported by FDA approved labeling or the AASLD guidelines AND
3. Patient does NOT have any FDA labeled contraindications to Sovaldi (sofosbuvir) or the other agents used in the combination therapy AND
4. Patient will NOT be receiving Incivek (telaprevir) or Victrelis (boceprevir) concomitantly with Sovaldi (sofosbuvir) AND
5. If patient has hepatocellular carcinoma (HCC) the following are met:
    a. Patient has either a single tumor 5 cm or less in diameter OR patient has up to 3 tumors with each being 3 cm or less in diameter AND
    b. Patient has NO extrahepatic manifestations of cancer or evidence of vascular invasion of tumor

AND
6. Dose of Sovaldi (sofosbuvir) is within the FDA labeled dosage (400 mg daily) AND
7. If treatment regimen includes Olysio (simeprevir), the dose of Olysio (simeprevir) is within the FDA labeled dosage (150 mg daily)

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

48 wks HCC/cirrhotics, Hep C 24 wks Sovaldi + RBV/post transplant, 12 wks triple therapy/geno 2

Other Criteria:

Olysio with Sovaldi with or without ribavirin without cirrhosis is approved for a duration of 12 weeks and with cirrhosis duration of 24 weeks is approved

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:

Patient does NOT have cirrhosis AND
Patient does NOT have decompensated liver disease (e.g. bleeding varices, ascites, encephalopathy, jaundice) AND
Patient does NOT have severe hepatic impairment (Child-Pugh C) AND
Technivie (ombitasvir/paritaprevir/ritonavir) will not be used in combination, with a treatment regimen containing a direct acting antiviral (DAA) indicated for chronic hepatitis C [e.g. Daklinza (daclatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), or Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir)] AND Patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent

Required Medical:

Criteria will be approved when ALL of the following are met:
1. Patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND
2. Technivie (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 genotype AND
3. The dosing of Technivie (ombitasvir/paritaprevir/ritonavir) 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: 12 weeks based on FDA approved labeling or in AASLD/IDSA guidelines

Prior Authorization Group – Viekira PA

Drug Name(s):

VIEKIRA

Covered Uses:

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

Exclusion Criteria:

Requested agent will not be used in combination with other protease inhibitors used to treat chronic hepatitis C (i.e. boceprevir, simeprevir, or telaprevir) AND
Patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent AND Patient does NOT have decompensated liver disease AND Patient has NOT been previously treated with Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir)

Required Medical:

Criteria will be approved when ALL of the following criteria are met:
1. Patient has a diagnosis of chronic hepatitis C, genotype 1 confirmed by serological markers AND
2. If liver transplant recipient, patient must have normal hepatic function and mild fibrosis (Metavir fibrosis score less than or equal to 2) AND
3. Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir) will be used in a combination antiviral treatment regimen supported by FDA approved labeling if applicable AND
4. Patient's subtype has been identified and provided AND
5. Dosing of Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir) is within the FDA labeled dosage

Age Restrictions:

Prescriber Restrictions:

Prescriber is a specialist (i.e. Gastroenterologist, Hepatologist, or Infectious Disease) or the prescriber has consulted with a specialist

Coverage Duration:

Geno 1a & 1b no cirrhosis (CS) 12 wks 1a, CS 24 wks 1b, CS 12 wks Liver transplant pts 24 wks

Other Criteria:

Prior Authorization Group – Voriconazole PA

Drug Name(s):

VFEND
voriconazole

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Criteria for initial approval are BOTH of:
1. ONE of the following:
   A. Patient (Pt) has diagnosis (dx) of invasive Aspergillus, Scedosporium apiospermum, or Fusarium OR
   B. Pt has dx of esophageal candidiasis or candidemia in nonneutropenic pt AND pt has history of fluconazole or alternative antifungal or documented intolerance, FDA labeled contraindication, or hypersensitivity to fluconazole or alternative antifungal OR
   C. Pt has dx of blastomycosis AND pt has history of itraconazole OR documented intolerance, FDA labeled contraindication, or hypersensitivity to itraconazole OR
   D. Pt is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or a pt with a hematologic malignancy, prolonged neutropenia from chemotherapy, or a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant pt OR
   E. Prescriber has submitted documentation supporting the use of requested medication for intended dx

AND

2. Pt does not have any FDA labeled contraindications to therapy

Criteria for renewal are ALL of:
1. Pt has been approved for requested medication through the plan's Prior Authorization process AND
2. Pt does not have any FDA labeled contraindications to therapy AND
3. ONE of the following:
   A. Pt has dx of invasive Aspergillus, Scedosporium apiospermum, Fusarium, esophageal candidiasis, candidemia in nonneutropenic pt or blastomycosis and pt has continued indicators of active disease (e.g. continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR
   B. Requested medication is being prescribed for prophylaxis and pt 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. Prescriber has submitted documentation supporting continued use of requested medication for intended dx

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

One month for oropharyngeal and esophageal candidiasis, 6 months for other indications

Other Criteria:

Prior Authorization Group – Xenazine PA

Drug Name(s):

tetrabenazine
XENAZINE

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Xenazine will be approved when ALL of the following are met:
1. ONE of the following:
    A. Patient has a diagnosis of chorea associated with Huntington's disease OR
    B. Prescriber has submitted documentation supporting the requested agent for the intended diagnosis

AND
2. If the patient has a diagnosis of depression or suicidal ideation, the patient is being treated for depression AND
3. Patient is not receiving a monoamine oxidase inhibitor (MAOI) AND
4. Patient is not receiving reserpine or the patient's reserpine will be discontinued at least 20 days before starting Xenazine therapy AND
5. Patient does not have impaired hepatic function

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:

Initial

1. Dx is asthma or chronic idiopathic urticaria (CIU) AND
2. If asthma ALL of:
    - A. Pretreatment IgE more than/equal to 30 IU but less than/equal to 700 IU AND
    - B. Patient (Pt) weight (wt) more than/equal to 30 kg but less than/equal to 150 kg AND
    - C. Allergic asthma confirmed by skin or RAST test AND
    - D. Baseline FEV1 less than 80% predicted AND
    - E. Claim w/in past 90 days of inhaled corticosteroid (ICS) OR documented intolerance, FDA labeled contraindication, or hypersensitivity to ICS AND
    - F. Claim w/in past 90 days of long-acting beta-2 agonist (LABA), leukotriene modifier (LM), or theophylline OR documented intolerance, FDA labeled contraindication, or hypersensitivity to LABA, LM, or theophylline AND
    - G. Asthma symptom exacerbations AND
    - H. Dose w/in dosing parameters (IgE, wt) in FDA label or does not exceed 375mg every 2 wks

AND

3. If CIU ALL of:
    - A. 6 mo history of CIU w/ hives/itching AND
    - B. ONE of:
        - i. Pt on max tolerable H1 antihistamine therapy w/in past 90 days OR
        - ii. Documented intolerance, FDA labeled contraindication, or hypersensitivity to H1 antihistamines

    AND
    - C. Dose w/in FDA label not to exceed 300mg every 4 wks

Renewal

1. Pt previously approved through plan's PA process AND
2. Dx is asthma or CIU AND
3. If asthma ALL of:
    - A. Pt wt more than/equal to 30 kg but less than/equal to 150 kg AND
    - B. Pt does not have clinical worsening defined as ONE of: Increased ICS or rescue drug use, therapy w/ systemic corticosteroids, unscheduled care visits due to exacerbations AND
    - C. Claim w/in past 90 days of standard therapy (e.g. combination of ICS, LABA, LM, theophylline, oral corticosteroid or oral beta-2 agonist) OR documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies AND
    - D. Dose w/in dosing parameters (IgE, wt) in FDA label or does not exceed 375mg every 2 wks

AND

4. If CIU ALL of:
    - A. Symptom improvement (e.g. number/size of hives, less itching) AND
    - B. Dose w/in FDA label not to exceed 300mg every 4 wks

Age Restrictions:

Patient must be 12 years of age or older

Prescriber Restrictions:

Coverage Duration:

Initial approval 16 weeks for asthma, 24 weeks for CIU, renewal approval 12 months

Other Criteria:

Prior Authorization Group – Xyrem PA

Drug Name(s):

XYREM

Covered Uses:

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

Exclusion Criteria:

Required Medical:

Xyrem will be approved when ALL of the following are met:

1. ONE of the following:
    - A. Patient has a diagnosis of narcolepsy with cataplexy OR
    - B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND ONE of the following:
        - i. Patient's medication history includes a standard stimulant agent OR
        - ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to a standard stimulant agent

AND

2. Prescriber has documented that the patient is enrolled in the Xyrem Success Program AND
3. Patient does not have any FDA labeled contraindications to therapy

Age Restrictions:

Patient must be 18 years of age or older.

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

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:

Required Medical:

Criteria for approval are ALL 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 are met:
        i. Prescriber provides documentation of a formal, consultative evaluation including diagnosis AND a complete medical history which includes previous pharmacological and non-pharmacological therapy

AND

2. Zohydro ER is not prescribed as an as-needed (prn) analgesic AND
3. Patient does not have any FDA labeled contraindications to Zohydro ER therapy AND
4. 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:

Prescriber is a specialist in, or patient has been evaluated by a specialist in, the area of practice related to the source of the chronic non-cancer pain

Coverage Duration:

Approval will be for 12 months

Other Criteria: