2013 Prior Authorization (PA) Criteria

Certain drugs require prior authorization from EmblemHealth Medicare PDP Medicare Plans. This means that your doctor must contact us to get approval before prescribing the drug to you. If your doctor does not get prior approval, the drug may not be covered.

This list also includes drugs that may be covered under Medicare Part B or Part D depending on how the drugs are used or administered. If your drug is on this list, your doctor should call us and to provide information describing the use and administration of the drug so we can advise on whether the drug will be covered.

To see if your drug is on the list, refer to the table of contents below for the prior authorization criteria you are looking for, or refer to the index located at the end of this document for the medication you are looking for.

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ACTEMRA

Affected Drugs

ACTEMRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on tocilizumab for a Covered Use.

Exclusion Criteria

Tocilizumab should not be given in combination with tumor necrosis factor (TNF) antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), abatacept, anakinra, or rituximab.

Required Medical Information

N/A

Age Restrictions

For indication of systemic-onset JIA [Juvenile Idiopathic Arthritis], may approve for children and adolescents 18 years of age or younger. For rheumatoid arthritis (RA) and Still's disease, approve for adults.

Prescriber Restrictions

Adults with RA [Rheumatoid Arthritis], tocilizumab is to be prescribed by a rheumatologist or in consultation with a rheumatologist. Systemic-onset JIA [Juvenile Idiopathic Arthritis], tocilizumab is to be prescribed by or in consultation with a rheumatologist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Adults with RA [Rheumatoid Arthritis], approve for patients who have tried for at least 2 months or who were intolerant to one of the following TNF [Tumor necrosis factor] antagonists , adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab. Systemic-onset JIA [Juvenile Idiopathic Arthritis], approve for patients who have tried a systemic corticosteroid or MTX [methotrexate], leflunomide, or sulfasalazine or another DMARD [Disease-modifying antirheumatic drug] such as etanercept, adalimumab, infliximab, or anakinra.

ACTHAR

Affected Drugs

H.P. ACTHAR®

Covered Uses

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

Exclusion Criteria

Use in patients with multiple sclerosis (MS) as pulse therapy on a monthly basis.

Required Medical Information

MS [Multiple Sclerosis] exacerbation, history of corticosteroid use.

Age Restrictions

N/A

Prescriber Restrictions

Infantile spasms, prescribed by or in consultation with a neurologist or an epileptologist. MS [Multiple Sclerosis] exacerbation, prescribed by or in consultation with a neurologist or physician that specializes in the treatment of MS [Multiple Sclerosis].

Coverage Duration

Infantile spasms, 12 months. MS [Multiple Sclerosis] exacerbation, approve 1 month.

Other Criteria

For MS [Multiple Sclerosis] exacerbation, approve if the patient cannot use high-dose IV corticosteroids because IV access is not possible or if the patient has tried high-dose corticosteroids administered IV for an acute MS [Multiple Sclerosis] exacerbation and has experienced a severe or limiting adverse effect.

ADHD NON-STIMULANT MEDICATIONS

Affected Drugs

INTUNIV®
KAPVAY®
STRATTERA®

Covered Uses

All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use of Strattera, Kapvay, or Intuniv in patients who have tried a CNS stimulant medication for the treatment of symptoms of ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder]. Patients with ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] and a documented history of addiction to controlled substances, authorize use of Strattera, Intuniv, or Kapvay, without a trial of a CNS stimulant medication. Patients with ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] and a history of seizures, authorize use of Strattera, Intuniv, or Kapvay, without a trial of a CNS stimulant medication. Patients with ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] and co-morbid anxiety, authorize use of Strattera without a trial of a CNS stimulant medication. Patients with ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] and a history of motor tics or a family history or diagnosis of Tourette's syndrome, authorize use of Strattera, Kapvay, or Intuniv without a trial of a CNS stimulant medication.

ALPHA-1 PROTEINASE INHIBITORS

Affected Drugs

ARALAST NP®
GLASSIA®
PROLASTIN C®
ZEMAIRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Alpha-1 antitrypsin (AAT) deficiency-associated panniculitis.

Exclusion Criteria

N/A

Required Medical Information

For AAT [Alpha 1-antitrypsin] deficiency with emphysema (or COPD [Chronic Obstructive Pulmonary Disease]), approve in patients with baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

For all covered uses, the patient is required to try Aralast NP first line. For AAT [Alpha 1-antitrypsin] deficiency with emphysema (or COPD [Chronic Obstructive Pulmonary Disease]), approve in patients with baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL.

AMPYRA

Affected Drugs

AMPYRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on dalfampridine extended-release for Multiple Sclerosis (MS).

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

MS [Multiple Sclerosis]. If prescribed by, or in consultation with, a neurologist or MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

ANABOLIC STEROIDS

Affected Drugs

OXANDROLONE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Duchenne muscular dystrophy, constitutional delay of growth or growth and puberty in prepubertal boys with psychosocial difficulties or psychological distress due to their condition, girls w/Turner's Syndrome or Ullrich-Turner Syndrome, management of protein catabolism w/burns or burn injury, AIDS wasting and cachexia due to a chronic disease, cachexia due to cancer (except oxandrolone), and prevention/prophylaxis of hereditary angioedema (except oxandrolone). Oxymetholone for prevention/prophylaxis of hereditary angioedema, and AIDS wasting and cachexia due to a chronic disease.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Oxandrolone for the management of protein catabolism associated with burns/burn injury. approve for patients who have tried a beta-blocker or who have a contraindication to beta-blocker use. Oxymetholone for the prevention/prophylaxis of hereditary angioedema, approve if the patient has tried danazol.

ANTIDEPRESSANTS- SNRI

Affected Drugs

CYMBALTA®
DESVENLAFAXINE ER®
EFFEXOR XR®
PRISTIQ ER®
SAVELLA®
VENLAFAXINE HCL ER
VENLAFAXINE HCL ER®

Covered Uses

All medically accepted indications not otherwise excluded from Part D. Plus, patients currently taking a selective serotonin and norepinephrine reuptake inhibitor (SNRI) for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use of Cymbalta, Desvenlafaxine Er, Pristiq, Savella, Effexor, Effexor XR, or Venlafaxine Er if the patient has tried a generic selective serotonin reuptake inhibitor (SSRI) or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patients who have taken the SNRI [Selective Norepinephrine Reuptake Inhibitor] being requested at any time in the past and discontinued its use, authorize use without a trial of a generic SSRI [Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patient is a child or adolescent aged 18 years or less, authorize use of Cymbalta, Desvenlafaxine Er, or Pristiq without a trial of a generic SSRI [Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patients with symptoms of suicidal ideation, authorize use of Cymbalta, Desvenlafaxine Er, or Pristiq without a trial of a generic SSRI [Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patients (men or women) with symptoms of stress urinary incontinence, authorize use of Cymbalta without a trial of a generic SSRI

[Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patients with symptoms of fibromyalgia, authorize use of Cymbalta or Savella without a trial of a generic SSRI [Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patients with symptoms of chronic musculoskeletal pain (eg, chronic low back pain or chronic pain due to osteoarthritis), authorize use of Cymbalta without a trial of a generic SSRI [Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor]. Patients with diabetic peripheral neuropathy (DPN), authorize use of Cymbalta without a trial of a generic SSRI [Selective Serotonin Reuptake Inhibitor] or generic SNRI [Selective Norepinephrine Reuptake Inhibitor].

ARANESP

Affected Drugs

ARANESP®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Anemia due to myelodysplastic syndrome (MDS).

Exclusion Criteria

N/A

Required Medical Information

Anemia w/CRF [Chronic Renal Failure]. A hemoglobin (Hb) of less than or equal to 10. 0 g/dL required for start, Hb has to be less than or equal 11. 0 g/dL if previously receiving epoetin alfa (EA) or Aranesp. Anemia due to myelosuppressive chemotherapy, Hb immediately prior start/maintenance of Aranesp is 10. 0 g/dL or less (hematocrit [Hct] is 30% or less). Maintenance of Aranesp is the starting dose if the Hb remains 10. 0 g/dL or less (or Hct remains 30% or less) 4 weeks after therapy start and the rise in Hb is 1. 0 g/dL or more (or Hct rise is 3% or more). patients whose Hb rises less than 1. 0 g/dL (Hct rise less than 3%) compared to pretreatment baseline over 4 weeks of treatment and whose Hb remains less than 10. 0 g/dL after the 4 weeks of treatment (or the Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued Aranesp is not reasonable or necessary if the Hb rises less than 1. 0 g/dL (Hct rise less than 3%) compared to pretreatment baseline by 8 weeks of treatment. Continued Aranesp is not reasonable and necessary if there is a rapid rise in Hb more than 1. 0 g/dL (Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10. 0 g/dL (or the Hct is less than 30%). Continuation and reinstitution of Aranesp must include a dose reduction of 25% from the previously admin dose. MDS [Myelodysplastic syndrome], approve treatment if Hb is 12. 0 g/dL or less. Aranesp treatment is not recommended if Hb is more than 12. 0 g/dL in any situation. If the patient has previously been receiving Aranesp or EA, approve only if Hb is 12. 0 g/dL or less. An additional 6 months of therapy after initial 6 months allowed if Hb is 12. 0 g/dL or less.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Chemo +8 week after last chemo dose. CRF=12 months. MDS=6 months.

Other Criteria

Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition. Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. patients with Hb rise of less than 1. 0 g/dL (or Hct 3% or less) and Hb levels is less than 10. 0 g/dL after 4 weeks therapy, the recommended FDA dose may be increased once by 25%. Continued Aranesp use is not reasonable or necessary if the Hb rise is less than 1. 0 g/dL (or Hct is less than 3%) compared to pretreatment baseline by 8 weeks of treatment. Continued Aranesp administation is not reasonable and necessary if there is a rapid rise in Hb or more than 1. 0 g/dL (or Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10. 0 g/dL (or Hct less than 30%). Continuation and reinstitution of Aranesp must include a dose reduction of 25% from the previously administered dose.

ARCALYST

Affected Drugs

ARCALYST®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on rilonacept for Muckle Wells Syndrome (MWS) or Familial Cold Autoinflammatory Syndrome (FCAS).

Exclusion Criteria

Rilonacept should not be given in combination with tumor necrosis factor (TNF) blocking agents (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), anakinra, or canakinumab.

Required Medical Information

N/A

Age Restrictions

Greater than or equal to 12 years of age.

Prescriber Restrictions

N/A

Coverage Duration

Initial approval of MWS [Muckle-Wells syndrome]/FCAS, 2 months. Subsequent authorization for 12 months if patient had a response.

Other Criteria

Patients already started on rilonacept for MWS [Muckle-Wells syndrome]/FCAS may receive authorization if they have had a response and are continuing therapy to maintain response/remission.

AUBAGIO

Affected Drugs

AUBAGIO®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Aubagio for a Covered Use.

Exclusion Criteria

Concurrent use of Aubagio with other disease-modifying agents used for multiple sclerosis (MS) [eg, Avonex, Rebif, Betaseron, Extavia, Copaxone, Tysabri, or Gilenya].

Required Medical Information

MS [Multiple Sclerosis], patient has a relapsing form of MS [Multiple Sclerosis]. MS [Multiple Sclerosis], previous MS [Multiple Sclerosis] therapies tried.

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or in consultation with a neurologist or MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For use in MS [Multiple Sclerosis], patient must have a relapsing form of MS [Multiple Sclerosis] (includes relapsing-remitting MS [Multiple Sclerosis], secondary-progressive MS [Multiple Sclerosis] with relapses, and progressive-relapsing MS [Multiple Sclerosis]) AND patient must have tried interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron or Extavia), glatiramer acetate (Copaxone), Gilenya, or Tysabri unless the patient is unable to administer injections due to dexterity issues or visual impairment.

AVONEX

Affected Drugs

AVONEX ADMINISTRATION PACK®
AVONEX®

Covered Uses

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

Exclusion Criteria

Concurrent use of Betaseron, Extavia, Copaxone, Rebif, Tysabri, or fingolimod (Gilenya).

Required Medical Information

Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Approve for patients already started on Avonex.

B VS D - PART B VERSUS PART D COVERAGE PA

Affected Drugs

ALBUTEROL SULFATE
ANZEMET®
ASTAGRAF XL®
ATGAM®
AZASAN®
AZATHIOPRINE
AZATHIOPRINE SODIUM
CALCIJEX®
CALCITRIOL
CARNITOR®
CELLCEPT®
CESAMET®
CROMOLYN SODIUM
CUBICIN®
CYCLOPHOSPHAMIDE
CYCLOSPORINE
CYCLOSPORINE MODIFIED
DRONABINOL
EMEND®
GENGRAF
GRANISETRON HCL
GRANISOL
HECTOROL®
HEPARIN SODIUM
HEPARIN SODIUM IN 0.45% NACL
HEPARIN SODIUM IN 0.9% NACL
HEPARIN SODIUM-D5W
IMURAN®
IPRATROPIUM BROMIDE
LEVOCARNITINE
MARINOL®
METHOTREXATE
MIACALCIN®
MITOXANTRONE HCL
MYCOPHENOLATE MOFETIL
MYFORTIC®
NEORAL®
NULOJIX®
ONDANSETRON HCL
ONDANSETRON ODT
PAMIDRONATE DISODIUM
PROGRAF®
PULMOZYME®

RAPAMUNE®
RHEUMATREX®
ROCALTROL®
SANDIMMUNE®
SIMULECT®
TACROLIMUS
THYMOGLOBULIN®
TOBI®
TREXALL®
VANCOMYCIN HCL
ZEMPLAR®
ZOFRAN ODT®
ZOFRAN®
ZORTRESS®

Covered Uses

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

BETASERON/EXTAVIA

Affected Drugs

BETASERON®
EXTAVIA®

Covered Uses

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

Exclusion Criteria

Concurrent use of Avonex, Rebif, Copaxone, Tysabri, or fingolimod (Gilenya).

Required Medical Information

Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

For patients requesting Extavia or Betaseron, approve if the patient has previously tried Avonex, Copaxone, or Rebif.

BONIVA INJECTION

Affected Drugs

BONIVA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Hypercalcemia of malignancy. Prevention of postmenopausal osteoporosis. Treatment of bone metastases in patients with solid tumor (eg, breast cancer, prostate cancer). Osteoporosis disorder related to organ transplantation.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

All osteoporosis uses (treatment or prevention), approve if patient has tried one oral bisphosphonate-containing product AND they had an inadequate response (determined by prescribing physician) or intolerability to oral bisphosphonate, OR patient cannot take an oral bisphosphonate-containing product due to inability to swallow, unable to remain in an upright position for designated period of time following oral bisphosphonate administration, patient has pre-existing GI medical condition in which IV therapy is preferred over oral therapy, or patient has a chronic, complex medication regimen in which oral bisphosphonate may compromise therapy (as determined by prescribing physician), OR patient is currently receiving ibandronate injection for a covered use. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

BOSULIF

Affected Drugs

BOSULIF®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Bosulif for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Bosulif is being used. For chronic myelogenous leukemia (CML), the Philadelphia chromosome (Ph) status of the leukemia must be reported. For CML [Chronic Myeloid Leukemia], prior therapies tried must be reported to confirm resistance or intolerance.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For CML [Chronic Myeloid Leukemia], patient must have Ph-positive CML [Chronic Myeloid Leukemia] and must have resistance or intolerance to prior therapy for approval.

BOTOX

Affected Drugs

BOTOX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus Achalasia. Anal Fissure. BPH [Benign Prostatic Hypertrophy]. Chronic facial pain/pain associated with TMJ [Temporomandibular joint and muscle] dysfunction. Chronic low back pain. Headache (migraine, chronic tension HA [Headache], whiplash, chronic daily HA [Headache]). Palmar/plantar and facial hyperhidrosis. Myofascial pain. Salivary hypersecretion. Spasticity (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS [Multiple Sclerosis], hemifacial spasm). Essential tremor. Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus). Frey's syndrome (gustatory sweating). Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome. Additional indications will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

Exclusion Criteria

Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, rejuvenation of the peri-orbital region), allergic rhinitis, gait freezing in Parkinsons disease, vaginismus, interstitial cystitis, trigeminal neuralgia, or Crocodile tears syndrome.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Headache if prescribed by, or after consultation with, a neurologist or HA [Headache] specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Primary axillary hyperhydrosis after trial with at least 1 topical agent (eg, aluminum chloride). BPH [Benign Prostatic Hypertrophy] after trial with at least 2 other therapies (eg, alpha1-blocker, 5 alpha-reductase inhibitor, TURP [Transurethral resection of the prostate], transurethral microwave heat treatment, TUNA [Transurethral needle ablation], interstitial laser therapy, stents, various forms of surgery). Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID [Non-steroidal

anti-inflammatory drug], antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program. Headache (eg, migraine, chronic tension headache, whiplash, chronic daily headache) after a trial with at least 2 other pharmacologic therapies (eg, anticonvulsants, antidepressants, beta-blockers, calcium channel blockers, non-steroidal anti-inflammatory drugs). Palmar/plantar and facial hyperhidrosis after a trial with at least 1 topical agent (eg, aluminum chloride). Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate). Urinary incontinence after a trial with at least 1 other pharmacologic therapy (eg, oral antimuscarinic agents). Tourette's syndrome if after a trial with at least 1 more commonly used pharmacologic therapy (eg, neuroleptics, clonidine, SSRIs [Selective Serotonin Reuptake Inhibitors], psychostimulants).

CHENODAL

Affected Drugs

CHENODAL®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.

CHORIONIC GONADOTROPINS (HCG)

Affected Drugs

CHORIONIC GONADOTROPIN
NOVAREL
PREGNYL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Preoperative use in male infants/toddlers with hypospadias and chordee.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

Prepubertal cryptorchidism, 4 years or older. Hypospadias, infant or toddler.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless noted otherwise.

Other Criteria

Hypogonadotropic hypogonadism in males. Preoperative use for hypospadias and chordee.

CIALIS

Affected Drugs

CIALIS®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

Indication for which tadalafil is being prescribed.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed to treat the signs and symptoms of BPH [Benign Prostatic Hypertrophy] and not for the treatment of erectile dysfunction (ED) and after a trial of an alpha-1 blocker (eg, doxazosin [Cardura XL], terazosin, tamsulosin [Flomax], alfuzosin extended-release [UroXatral]) or 5 alpha reductase inhibitor (eg, finasteride, dutasteride [Avodart]).

CIMZIA

Affected Drugs

CIMZIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on certolizumab pegol for non-Crohn's disease Covered uses. Crohn's disease (CD) patients already started on certolizumab pegol.

Exclusion Criteria

Concurrent use with tumor necrosis factor (TNF) alpha antagonists (eg, adalimumab, etanercept, golimumab, and infliximab), or anakinra, rituximab, abatacept, natalizumab, tocilizumab.

Required Medical Information

N/A

Age Restrictions

RA [Rheumatoid Arthritis]/CD [Crohn's Disease], Adults.

Prescriber Restrictions

N/A

Coverage Duration

Adult RA [Rheumatoid Arthritis], 12 months. Adult CD [Crohn's Disease], 12 months.

Other Criteria

Adult RA [Rheumatoid Arthritis], approve if the patient has tried Enbrel or Humira. Adult CD [Crohn's Disease], approve if patient has previously tried Humira.

CINRYZE

Affected Drugs

CINRYZE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus for the acute treatment of Hereditary Angioedema (HAE).

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Must be prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

COMETRIQ

Affected Drugs

COMETRIQ®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Cometriq for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of progressive, metastatic medullary thyroid cancer.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

COPAXONE

Affected Drugs

COPAXONE®

Covered Uses

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

Exclusion Criteria

Concurrent use of Avonex, Betaseron, Extavia, Rebif, Tysabri, or fingolimod (Gilenya).

Required Medical Information

Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

DIFLUCAN (FLUCONAZOLE)

Affected Drugs

DIFLUCAN®
FLUCONAZOLE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Prevention of recurrent vulvovaginal or vaginal candidiasis. Tinea corporis and tinea versicolor (pityriasis versicolor). Tinea cruris, manuum, pedis, and faciei. Tinea capitis. Tinea barbae. Treatment or prevention of other superficial, systemic or suspected fungal infections. Continuation therapy for patients started and stabilized on IV or oral fluconazole for systemic infection. Onychomycosis.

Exclusion Criteria

Use of topical ciclopirox 8% solution with Diflucan (fluconazole) is not permitted.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition), by treating physician, and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of topical ciclopirox 8% solution with Diflucan (fluconazole) is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Onychomycosis = 6 months for toenails, 3 months for fingernails. Other conditions = 12 months.

Other Criteria

Criteria only applies to the 50, 100 and 200 mg tablets (not the 150-mg tablet) and oral suspension. Tinea corporis and tinea versicolor after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, manuum, pedis, and faciei after a trial of a topical antifungal agent. Onychomycosis. Approve fluconazole tablets or oral suspension if the patient has tried terbinafine tablets or itraconazole capsules unless the patient has a medical condition or other clinical reason to not utilize these agents (e. g. , drug-drug interactions, heart failure).

DYSPORT

Affected Drugs
DYSPORT®

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

Exclusion Criteria
Use in the management of cosmetic uses.

Required Medical Information
N/A

Age Restrictions
N/A

Prescriber Restrictions
N/A

Coverage Duration
Authorization will be for 12 months.

Other Criteria
N/A

EGRIFTA

Affected Drugs

EGRIFTA®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

Diagnosis is HIV-associated lipodystrophy. Egrifta is prescribed for the reduction of excess abdominal fat. Patient is HIV-infected.

Age Restrictions

Adults.

Prescriber Restrictions

Prescribed by or in consultation with an endocrinologist or a physician specializing in the treament of HIV (eg, infectious disease, oncology).

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

ELIQUIS

Affected Drugs

ELIQUIS®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus use in patients with atrial flutter, Prevention of venous thromboembolism after hip replacement surgery, prevention of venous thromboembolism after knee replacement surgery, prevention of thromboembolic recurrence in patients that do not have atrial fibrillation or atrial flutter and are not post hip or knee replacement surgery, plus patients already started on Eliquis for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

For non-atrial fibrillation/flutter indications, prior therapies.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For the prevention of venous thromboembolism after hip or knee replacement surgery or prevention of thromboembolic recurrence in patients that do not have atrial fibrillation or atrial flutter, approve if the patient has tried one of the following therapies: warfarin, rivaroxaban (Xarelto), dabigatran (Pradaxa), fondaparinux, or a LMWH product (eg, enoxaparin, dalteparin [Fragmin]) or the patient is unable to take one of these medications due to one of the following reasons: allergic, immunologic or inherited disorders, adverse effects (eg, major organ toxicities, major bleeding), ineffectiveness of anticoagulation therapy in a prior setting, drug-drug interactions that cannot be managed, lack of access to proper monitoring, prior heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis (HITT), unable to perform injections or have injections administered to them.

ENBREL

Affected Drugs

ENBREL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept for a Covered Use. Still's disease (SD). Uveitis (noninfectious). Graft versus host disease (GVHD). Behcet's disease. Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, mucous membrane pemphigoid [cicatricial pemphigoid]) (AMBD). Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).

Exclusion Criteria

Concurrent use with adalimumab, alefacept, anakinra, abatacept, certolizumab pegol, ustekinumab, infliximab, rituximab, golimumab, or tocilizumab. Intra-articular injection of etanercept.

Required Medical Information

N/A

Age Restrictions

For use in Still's disease and rheumatoid arthritis (RA), approve for adults. For uveitis (non-infectious), approve for children aged less than 18 years. For juvenile idiopathic arthritis (JIA) approve for children aged 2 years and older.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

RA [Rheumatoid Arthritis], Tried 1 DMARD [Disease-modifying antirheumatic drug] for 2 months or is also receiving MTX [methotrexate]. JIA [Juvenile Idiopathic Arthritis]/JRA [Juvenile Rheumatoid Arthritis], tried 1 other treatment (eg, MTX [methotrexate], sulfasalazine, leflunomide, NSAID [Non-steroidal anti-inflammatory drug], biologic DMARD [Disease-modifying antirheumatic drug]) or will be starting on etanercept concurrently with MTX [methotrexate], sulfasalazine, or leflunomide. Approve without trying MTX [methotrexate] if patient has an absolute contraindication to MTX [methotrexate]. Plaque psoriasis (PP). patient has a minimum BSAof 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. patient has a minimum BSA [Body surface area] of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to a 2-mo trial of either topical therapy (tx) OR localized phototherapy (ultraviolet B [UVB] or

oral methoxsalen plus UVA light [PUVA]), and had inadequate response to 2-mo trial of systemic treatment (with one of the following- MTX [methotrexate], cyclosporine (CSA), acritretin, adalimumab, alefacept, infliximab, or ustekinumab) or has contraindications to all of these. patient has tried a systemic treatment (MTX, CSA, acritretin, adalimumab, alefacept, infliximab, or ustekinumab) or phototherapy (UVB or PUVA) for 2 months. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. SD. Tried a corticosteroid (CS) and 1 non-biologic DMARD [Disease-modifying antirheumatic drug] such as MTX [methotrexate] for at least 2 mo or was intolerant to a non-biologic DMARD [Disease-modifying antirheumatic drug]. GVHD [Graft-Versus-Host disease]. Tried or currently is receiving with etanercept 1 conventional GVHD [Graft-Versus-Host disease] treatment (high-dose SC, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Have not responded to at least 1 conventional treatment (eg, CS, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. AMBD. Tried conventional treatment (systemic CS AND immunosuppressant (eg, AZA, CPM, dapsone, MTX [methotrexate], CSA, MM) or has contraindications to conventional treatment. TRAPS. Tried CS.

EPOETIN/PROCRIT

Affected Drugs

EPOGEN®
PROCRIT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13. 0 g/dL or less) at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Anemia due to myelodysplastic syndrome (MDS). Anemia associated with use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products with or without the direct-acting antiviral agents Victrelis or Incivek). Anemia in HIV-infected patients. Anemia in heart failure (HF).

Exclusion Criteria

N/A

Required Medical Information

CRF [Chronic Renal Failure] anemia. Hemoglobin (Hb) of less than or equal to 10. 0 g/dL to start. Hb less than or equal to 11. 0 g/dL if previously on epoetin alfa (EA) or Aranesp. Anemia w/myelosuppressive chemotherapy. Hb immediately prior to EA is 10. 0 g/dL or less (or hematocrit [Hct] is 30% or less). EA maintenance is starting dose if Hb level remains 10. 0 g/dL or less (or Hct remains 30% or less) 4 weeks after start and Hb rise is 1. 0 g/dL or more (Hct rise is 3% or more). patients w/Hb rises less than 1. 0 g/dL (Hct rise less than 3%) vs pretreatment baseline over 4 weeks of treatment and Hb is less than 10. 0 g/dL after 4 weeks of treatment (Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued use is not reasonable/necessary if Hb rises less than 1. 0 g/dL (Hct rise less than 3%) vs pretreatment baseline by 8 weeks of treatment. Continued EA is not reasonable/necessary if there is a rapid Hb rise more than 1. 0 g/dL (Hct more than 3%) over 2 weeks of treatment unless Hb remains below or subsequently falls to less than 10. 0 g/dL (or Hct is less than 30%). Continuation/reinstitution of EA must have dose reduction of 25% of previous dose. MDS [Myelodysplastic syndrome], approve if Hb is 12. 0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12. 0 g/dL or less. An additional 6 months allowed after first 6 months if Hb is 12. 0 g/dL or less. Anemia in HIV (with or without zidovudine), Hb is 10. 0 g/dL or less or endogenous erythropoetin levels are 500 munits/mL or less at treatment start. Previously on EA approve if Hb is 12. 0 g/dL or less. Anemia due to ribavirin for Hepatitis C, Hb is 10. 0 g/dL or less at treatment start. All conditions, deny if Hb exceeds 12. 0 g/dL.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Chemo +8 week last chemo dose. MDS=6mo. Transfus=3wk. Start -HF 2mo. Other=12mo.

Other Criteria

Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition. For all covered uses, if the request is for Epogen, then the patient is required to try Procrit or Aranesp first line. Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. patients with Hb rise of less than 1. 0 g/dL (or Hct 3% or less) and Hb levels is less than 10. 0 g/dL after 4 weeks therapy, the recommended FDA dose may be increased once by 25%. Continued epoetin alfa use is not reasonable or necessary if the Hb rise is less than 1. 0 g/dL (or Hct is less than 3%) compared to pretreatment baseline by 8 weeks of treatment. Continued epoetin alfa administation is not reasonable and necessary if there is a rapid rise in Hb or more than 1. 0 g/dL (or Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10. 0 g/dL (or Hct less than 30%). Continuation and reinstitution of epoetin alfa must include a dose reduction of 25% from the previously administered dose. Continuation and reinstitution of Aranesp must include a dose reduction of 25% from the previously administered dose. Anemia in HF, approve initial trial of up to 2 months for patients with more severe HF, Hb of 10. 0 g/dL or less, anemia persists despite transfusions or patient has contraindications to transfusions. Deny if Hb is more than 12. 0 g/dL. Further approval after initial course will be determined on a case-by-case basis after evaluation by a pharmacist and/or physician.

FIRAZYR

Affected Drugs

FIRAZYR®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by, or in consultation with, an allergist/immunologist or a physican that specializes in the treatment of HAE or related disorders.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

FORTEO

Affected Drugs

FORTEO®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Forteo may be approved for the covered osteoporosis indications if the patient has tried an oral or intravenous bisphosphonate (eg, alendronate, risedronate, ibandronate, zoledronic acid [Reclast]), or if the patient has severe renal impairment (eg, creatinine clearance less than 30 mL/min) or chronic kidney disease, or if the patient has multiple vertebral fractures.

GABAPENTIN

Affected Drugs

GRALISE®
HORIZANT®
LYRICA®
NEURONTIN®

Covered Uses

All medically accepted indications not otherwise excluded from Part D. Plus, patients already started on Lyrica, Gralise, Horizant, or Neurontin for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use of Lyrica, Horizant, Gralise, or Neurontin if the patient has tried gabapentin (brand or generic) for the current condition. Patients with symptoms of a seizure disorder, authorize use of Lyrica without a trial of gabapentin. Patients with symptoms of fibromyalgia, authorize use of Lyrica without a trial of gabapentin. Patients with symptoms of GAD, authorize use of Lyrica without a trial of gabapentin in patients who have tried at least two drugs from the following drug classe - tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs) or buspirone. Authorize use of Lyrica in patients who have previously tried Gralise or Horizant.

GILENYA

Affected Drugs

GILENYA®

Covered Uses

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

Exclusion Criteria

Concurrent use of Avonex, Betaseron, Extavia, Rebif, Copaxone or Tysabri.

Required Medical Information

For use in Multiple Sclerosis (MS), patient has a relapsing form of MS [Multiple Sclerosis].

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by a neurologist or an MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For use in MS [Multiple Sclerosis], patient has a relapsing form of MS [Multiple Sclerosis] and patient has tried interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron or Extavia), or glatiramer acetate (Copaxone). Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif) or glatiramer acetate (Copaxone) can be made if the patient is already started on Gilenya or if the patient is unable to administer injections due to dexterity issues or visual impairment. Patients who have tried natalizumab (Tysabri) for MS [Multiple Sclerosis] and have a relapsing form of MS [Multiple Sclerosis] will receive authorization, they are not required to try an interferon beta product or glatiramer acetate.

GILOTRIF

Affected Drugs

GILOTRIF®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

For NSCLC - EGFR exon deletions or mutations.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.

GLEEVEC

Affected Drugs

GLEEVEC®

Covered Uses

All medically-accepted indications not otherwise excluded from Part D. Plus patients already started on Gleevec for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Gleevec is being used. For indications of CML [Chronic Myeloid Leukemia] and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. New patients with CML [Chronic Myeloid Leukemia] and ALL which is Ph-positive may receive authorization for Gleevec.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For CML [Chronic Myeloid Leukemia], new patient must have Ph-positive CML [Chronic Myeloid Leukemia] for approval of Gleevec. For ALL, new patient must have Ph-positive ALL for approval of Gleevec.

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Affected Drugs

BYDUREON®
BYETTA®
VICTOZA 3-PAK®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already on GLP-1 agonist therapy for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

GROWTH HORMONES

Affected Drugs

GENOTROPIN®
HUMATROPE®
NORDITROPIN FLEXPRO®
NORDITROPIN NORDIFLEX®
NUTROPIN AQ NUSPIN®
NUTROPIN AQ®
NUTROPIN®
OMNITROPE®
SAIZEN®
SEROSTIM®
TEV-TROPIN®
ZORBTIVE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Growth hormone (GH) deficiency (DF) (except Serostim and Zorbtive). Non-GH [growth hormone] deficient short stature (idiopathic short stature, ISS) (except Serostim and Zorbtiv). Turner's syndrome (TS) (except Serostim and Zorbtive). SHOX (short stature homeobox-containing gene) deficiency (except Serostim and Zorbtive). Chronic renal insufficiency (CRI) (except Serostim and Zorbtive). Prader-Willi syndrome (PW) (except Serostim and Zorbtive). Noonan syndrome (NS) (except Serostim and Zorbtive). Short bowel syndrome (SBS) (except Serostim). Human Immunodeficiency Virus (HIV) infection with wasting or cachexia (Serostim only). HIV-associated failure to thrive (Serostim only).

Exclusion Criteria

Use in the management of acute critical illness due to complications of surgery, trauma, or with acute respiratory failure, as antiaging therapy, to improve functional status in elderly, somatopause, enhancement of athletic ability, bone marrow transplant (BMT) without total body irradiation, bony dysplasias, burn injury, cardiac transplantation, central precocius puberty, chronic fatigue syndrome, congenital adrenal hyperplasia, constitutional delay of growth and puberty, corticosteroid-induced short stature including a variety of chronic glucocorticoid-dependent conditions, such as asthma, juvenile rheumatoid arthritis, after renal, heart, liver, or BMT [Bone Marrow Transplant], Crohn's disease, cystic fibrosis, dilated cardiomyopathy/heart failure, end-stage renal disease in adults undergoing hemodialysis, Down's syndrome, familial dysautonomia, fibromyalgia, HIV-infected patients with alterations in body fat distribution, infertility, kidney transplant patients (children) with a functional renal allograft, liver transplantation, multiple system atrophy, myelomeningocele, obesity, osteogenesis imperfecta, osteoporosis (postmenopausal, idiopathic in men, glucocorticoid-induced), thalassemia, and X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets).

Required Medical Information

Child/adolesc GH [growth hormone] DF initial treatment, eval by pediatric endocrinologist (PE), documented GH [growth hormone] stim test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) w/GH [growth hormone] response less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile (pct) for gender/age AND pretreatment Ht growth rate (GR) child less than 3 years of less than 7 cm/year and child greater than or equal to 3 years of less than 4 cm/year OR child any age GR less than the 10th pct for age/gender based on min 6 months of data. Child w/brain radiation does not have to meet baseline Ht crit. Congenital hypopituitarism does not have to meet Ht or GR crit. Child w/hypophysectomy, approve. Child/adolesc GH [growth hormone] DF continued treatment, GR increased by 2. 5 cm/year or more in most recent year (MRY) per MD AND epiphyses open (older than 12 years), both crit exclude adolesc w/hypopituitarism. Review GR annually (not applied to hypopituitarism). Adoles/yng adult w/completed linear growth (GR less than 2 cm/yr), review for adult GH [growth hormone] DF. Greater than 18 years, auth not allowed if midparental ht attained. ISS child w/open epiphyses, 6 mo trial if baseline Ht less than 3rd pct (greater than 2 SD below mean for gender/age) AND pretreatment GR child less than 3 years of less than 7 cm/year and child greater than or equal to 3 years of less than 4 cm/year OR child any age GR less than the 10th pct for age/gender based on min 6 months of data AND PE certifies child's basic activities of daily living limited by SS and has condition which GH [growth hormone] is/may be effective AND PE certifies via bone-age x-ray, predicted adult Ht less than 3rd pct. Auth after initial treatment (auth for 12 months) based on adequate clinical response (annualized GR doubles). continued treatment (after 12 to 18 months), GR increased by 2. 5 cm/year or more in MRY per MD AND epiphyses open (older than 12 years). Greater than 18 years, auth not allowed if midparental ht attained. Adult GH [growth hormone] DF or PW/trans adoles, eval by or in consultation w/endocrinologist (start and annually). NS/SHOW/child PW, eval by PE. CRI, eval by PE or nephrologist.

Age Restrictions

TS, children. SHOX/CRI/NS, children/adolescents. HIV failure to thrive, less than 17 years. SBS [Short Bowel Syndrome]/HIV cachexia/wasting, adults.

Prescriber Restrictions

For adults, the endocrinologist must certify that the somatropin is not being prescribed for anti-aging therapy or to enhance athletic ability.

Coverage Duration

GH [growth hormone] DF 12 months. SBS [Short Bowel Syndrome] 4 weeks/year. Non-GH [growth hormone] DF ISS 6 months. HIV wast/cach 24 weeks. HIV failure to thrive 12 weeks.

Other Criteria

Adult GH [growth hormone] DF (start), document diagnosis of GH [growth hormone] DF due to adult-onset (GH alone or multiple hormone deficiencies/hypopituitarism from pituitary dz, hypothalamic dz, surgery, cranial radiation treatment, tumor treatment,

traumatic brain injury, or subarachnoid hemorrhage) or due to childhood-onset (GH not rec in adults who had GH [growth hormone] treatment as child for uses not due to GH [growth hormone] DF) AND negative response to 1 GH [growth hormone] stim test (insulin tolerance [peak less than 5 mcg/L], or glucagon [peak less than 3 mcg/L]) [GHRH plus arginine may be used if available] (exclude stim test for childhood-onset due to mutations, lesions, congenital defects), transition adoles off somatropin 1 mo before retesting, OR 3 or more pituitary hormone deficiencies (TSH, ACTH, LH/FSH, or AVP) AND serum IGF-1 84 microg/L or less using the Esoterix ECB RIA or age/gender adjusted serum IGF-1 SDS below the 2. 5 percentile. TS start, female and has short stature (SS). SHOX start, open epiphyses. CRI w/growth failure (GF), start, approve. Child PW w/GF or adult PW, approve. NS start, baseline ht less than 3rd percentile. TS/SHOX/CRI/child PW/NS, continued treatment, GR increased by 2. 5 cm/year or more in most recent year (MRY) AND epiphyses open. HIV w/wasting or cachexia, HIV-positive AND have 1 of the following, documented unintentional wt loss of greater than or equal to 10% from baseline OR wt less than 90% of the lower limit of ideal body wt OR BMI less than or equal to 20 kg/m2 AND able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body weight AND on antiretroviral treatment greater than or equal to 30 days prior to beginning GH [growth hormone] treatment and will continue antiretroviral treatment throughout GH [growth hormone] treatment. Repeat 12 or 24-week courses of GH [growth hormone] may be authorized after initial 12 or 24-week GH [growth hormone] course for HIV infection w/wasting or cachexia provided that they are off GH [growth hormone] for at least 1 mo and meet all of previous HIV criteria. HIV-associated failure to thrive. Able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body wt AND on antiretroviral treatment for greater than or equal to 30 days prior to beginning GH [growth hormone] treatment and will continue antiretroviral treatment. SBS [Short Bowel Syndrome], receiving specialized nutritional support. SBS [Short Bowel Syndrome] patients eval on case-by-case basis for more than one 4-week course per year.

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Affected Drugs

ATIVAN®
CLONAZEPAM
CLORAZEPATE DIPOTASSIUM
DIAZEPAM
KLONOPIN®
LORAZEPAM
LORAZEPAM INTENSOL
ONFI®
OXAZEPAM
RESTORIL®
TEMAZEPAM
TRANXENE T-TAB®
VALIUM®

Covered Uses

All medically accepted indications not otherwise excluded from Part D. Plus, patients currently taking the benzodiazepine being requested for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restrictions

N/A

Coverage Duration

Procedure-related sedation = 1mo, All other conditions = 12 months.

Other Criteria

Restless Leg Syndrome, approve clonazepam or temazepam if the patient has tried one other agent for this condition (eg, ropinirole, pramipexole, carbidopa-levodopa [immediate-release or extended-release]). Insomnia, approve lorazepam, oxazepam, or temazepam if the patient has had a trial with one of the following - ramelteon, eszopiclone, zolpidem, or zaleplon.

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Affected Drugs

DIPHENHYDRAMINE HCL
HYDROXYZINE HCL
HYDROXYZINE PAMOATE
PROMETHAZINE HCL
PROMETHAZINE VC
VISTARIL®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Approve promethazine hydrochloride tablets or syrup if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, palonosetron, aprepitant) for the current condition. Approve diphenhydramine (capsules or elixir) if the patient has tried at least two other FDA-approved products for the management of insomnia. Approve hydroxyzine hydrochloride (tablets and syrup) or hydroxyzine pamoate (capsules) if the patient has tried at least two other FDA-approved products for the management of anxiety.

HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS

Affected Drugs

CHLORZOXAZONE
LORZONE®
METHOCARBAMOL
ORPHENADRINE CITRATE
ORPHENADRINE COMPOUND
ORPHENADRINE COMPOUND FORTE
PARAFON FORTE DSC®
SKELAXIN®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 1 month.

Other Criteria

Musculoskeletal conditions/disorders, approve if the patient has tried two other therapies for the current condition.

HUMIRA

Affected Drugs

HUMIRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab for a Covered Use.

Exclusion Criteria

Concurrent use with anakinra, abatacept, rituximab, ustekinumab, certolizumab pegol, etanercept, infliximab, or golimumab.

Required Medical Information

N/A

Age Restrictions

Rheumatoid arthritis (RA), adults. CD [Crohn's Disease], adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

RA [Rheumatoid Arthritis], Tried 1 DMARD [Disease-modifying antirheumatic drug] (brand or generic, oral or injectable) for 2 months (this includes patients who have tried other biologic DMARDs [Disease-modifying antirheumatic drugs] for 2 months), or patient is concurrently receiving methotrexate (MTX). JIA [Juvenile Idiopathic Arthritis]/JRA [Juvenile Rheumatoid Arthritis]. Tried MTX [methotrexate], sulfasalazine, leflunomide or biologic DMARD [Disease-modifying antirheumatic drug] (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX [methotrexate], sulfasalazine, or leflunomide. Approve without trying another agent if patient has absolute contraindication to MTX [methotrexate], sulfasalazine, or leflunomide. Plaque psoriasis (PP). patient has tried a systemic therapy (MTX, CSA, acritretin, etanercept, alefacept, infliximab, or ustekinumab) for 2 months or phototherapy (UVB or PUVA) for 2 months. Rarely, patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. CD [Crohn's Disease]. Tried corticosteroids (CSs) or if CSs are contraindicated or if patient currently on CSs or patient has tried one other agent for CD [Crohn's Disease] (eg, azathioprine, 6-mercaptopurine, MTX [methotrexate], certolizumab, infliximab).

ICLUSIG

Affected Drugs

ICLUSIG®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Iclusig for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Iclusig is being used. For chronic myelogenous leukemia (CML), prior therapies tried must be reported to confirm resistance or intolerance to prior tyrosine kinase inhibitor therapy. For acute lymphoblastic leukemia (ALL), the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies must be reported to document resistance or intolerance to prior tyrosine kinase inhibitor therapy.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For CML [Chronic Myeloid Leukemia], patient must have resistance or intolerance to prior tyrosine kinase inhibitor therapy for approval. For ALL, patient must have Ph-positive ALL and must have resistance or intolerance to prior tyrosine kinase inhibitor therapy for approval.

ILARIS

Affected Drugs

ILARIS®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on canakinumab (Ilaris) for a Covered Use.

Exclusion Criteria

When used in combination with tumor necrosis factor (TNF) blocking agents (e. g. , etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Initial approval for MWS [Muckle-Wells syndrome] or FCAS, one dose. Subsequent auth 12 mo if patient had a response.

Other Criteria

For initial approval for MWS [Muckle-Wells syndrome] or FCAS, authorize one dose. After up to 8 weeks of therapy if the patient has had a response to therapy as determined by prescribing physician an additional 12 months authorization is allowed.

INCIVEK

Affected Drugs

INCIVEK®

Covered Uses

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

Exclusion Criteria

Patients with recurrent hepatitis C after liver (or other organ) transplantation. Patients who have failed therapy with Incivek or another NS3/4A protease inhibitor (e. g. , Victrelis) for HCV.

Required Medical Information

N/A

Age Restrictions

Adults.

Prescriber Restrictions

Must be prescribed by or in consultation with a gastroenterologist or infectious disease physician.

Coverage Duration

Authorization will be for 3 months.

Other Criteria

Must be prescribed in combination with peginterferon alfa and ribavirin.

IVIG

Affected Drugs

CARIMUNE NF NANOFILTERED®
GAMMAGARD LIQUID®
GAMMAPLEX®
GAMUNEX-C®
PRIVIGEN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Idiopathic thrombocytopenic purpura (ITP) or immune thrombocytopenia, acute and chronic treatment. Kawasaki disease (KD). B-cell CLL in patients with hypogammaglobulinemia and previous history of a serious bacterial infection. Chronic inflammatory demyelinating polyneuropathy (CIDP). Allogeneic bone marrow transplant (BMT) or hematopoietic stem cell transplantation (HSCT). HIV-infected infants and children less than 13 years old - prevention of recurrent bacterial infections (PRB) or passive immunization of varicella (chickenpox) [PIV]. Adult Still's disease. Autoimmune hemolytic anemia (AIHA). Autoimmune mucocutaneous blistering diseases (AMBD). CMV interstitial pneumonia in allogeneic BMT [Bone Marrow Transplant] or HSCT patients. Dermatomyositis and polymyositis (DaP). End stage heart failure, ESRD, end stage liver or lung disease, or small bowel transplant awaiting transplant or post-transplant, to lower allosensitization. Epilepsy, pediatric intractable. Evans syndrome (EvS). Guillan-Barre syndrome (GBS). HIV-associated thrombocytopenia (HAT). IgM (or other) paraproteinemic demyelinating neuropathy. Multifocal acquired demyelinating sensory and motor neuropathy or Lewis-Sumner syndrome. Multifocal motor neuropathy (MMN), treatment. Multiple myeloma (MM). Multiple sclerosis (MS), acute severe exacerbations (MSase). MS [Multiple Sclerosis], post-partum to prevent relapses (MSppr). Myasthenia gravis (MG). Neutropenia, immune-mediated (NIM). Opsoclonus myoclonus. Pure red blood cell aplasia (PRCA) secondary to chronic parvovirus B19 infection (infxn). PRCA, immunologic subtype. Pydoderma gangrenosum (PD). Stiff-person syndrome (SPS). Systemic lupus erythematosus (SLE). Thrombocytopenia refractory to platelet transfusion (TRPT). Thrombocytopenia, fetal alloimmune (TFA). Urticaria, chronic autoimmune (CAU). Noninfectious uveitis. Varicella, postexposure prophylaxis (VPP). Vasculitic syndromes, systemic (VSS).

Exclusion Criteria

N/A

Required Medical Information

ITP [Immune thrombocytopenic purpura] acute bleed, tried corticosteroid (CS), if possible, or before surgery/procedure if PC less than 75, 000 for majory surgery or less than 50, 000 for other. Chronic ITP [Immune thrombocytopenic purpura] if patient (pt) tried a CS, if possible. BMT [Bone Marrow Transplant]/HSCT in previous year, 6 months if IgG is less than 500 mg/dL (not applicable to MM, malignant macroglobulinemia). HIV-infected kids PRB, on highly active antiretroviral therapy (HAART), IgG less than 400

mg/dL or functional antibody deficiency (2 or more serious bacterial infections (SBis) in 1 yr-period of HAART and antibiotic prophylaxis or absence of detectable antibody response). HIV-infected kids (PIV), 1 dose if VariZIG unavailable and no history of varicella infection, or seronegative for varicella-zoster virus, or has not received 2 varicella vaccine doses, or is immunized but is moderately/severely immunocompromised, and no IVIG [Intravenous Immune Globulin] dose within 2-3 weeks of varicella exposure. Transplant, high levels of preformed anti-HLA antibodies (peak reactive antibody level greater than 20%) and managed by transplant center. EvS, refer to ITP [Immune thrombocytopenic purpura] or AIHA criteria depending on predominant symptoms. GBS, approve if IVIG [Intravenous Immune Globulin] started within 2 weeks and no longer than 4 weeks of neuropathic symptoms onset or initial response to IVIG [Intravenous Immune Globulin] now having a relapse. Adult HAT, approve 1 mo if significant bleeding or on HAART. Infants/children/adolescents HAT, approve 5 days if on HAART. MM stable disease, recurrent SBis.

Age Restrictions

HIV-infected infants and children less than 13 years old - prevention of recurrent bacterial infxns or passive immunization of varicella (chickenpox). Still's disease, adult. Retractable epilepsy, children. ITP [Immune thrombocytopenic purpura] acute bleed or chronic ITP [Immune thrombocytopenic purpura] less than 17 years old.

Prescriber Restrictions

PID, allergist/immunologist, immunologist, otolaryngologist, or ID MD. ITP [Immune thrombocytopenic purpura], hematologist. KD, ped cardiologist or ped ID MD. B-cell CLL, oncologist, hematologist or ID MD. CIDP/MMN/MG/SPS, neurologist. BMT [Bone Marrow Transplant]/HSCT, oncologist or hematologist. HIV-infected kids, ID MD or immunologist. HIV-infected adults, ID MD. DaP, neurologist or rheumatologist. GBS, neurologist or GBS specialist. MS [Multiple Sclerosis] exac, MSppr, MS [Multiple Sclerosis] specialist. PRCA infxn, ID MD, immunologist, hematologist, transplant MD.

Coverage Duration

12 mo unless otherwise noted. Acute or surgery ITP [Immune thrombocytopenic purpura], 1 mo. CMV, 2 months. TFA, 6 months. Pregnant ITP [Immune thrombocytopenic purpura], 3 months.

Other Criteria

Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home. KD, acute phase, 1 dose, 2nd dose if failed to respond to initial therapy (tx). SD, tried 2 of following: corticosteroid (CS), methotrexate (MTX), and biologic (eg, Enbrel, Remicade or Kineret), if possible. AIHA, tried CS, if possible, or had splenectomy. AMBD, tried conventional txs (eg, systemic CS and immunosuppresive), if possible, or disease rapidly progressive/extensive/debilitating, or inadequate time for treatment to have rapid effect. DaP, tried conventional treatment of systemic CS and immunosuppressive, if possible. Retractable epilepsy, tried an anticonvulsant and CS. MSase, 1 5-day course if not responded to or significant AE from 2 of following: oral/IV CS treatment (if possible), plasma exchange, or adrencorticotropic hormone and

continuing to deteriorate. MSppr, 6 mo in women not currently receiving disease-modifying treatment. MG, 1 5-day course if MG exacerbation, requires stabilization before surgery, has been started on immunosuppressive drug or responded to previous IVIG [Intravenous Immune Globulin] course but weakens/relapses and no response to other drugs. NIM, 1 mo if tried 2 other txs (eg, CS, antibiotic, Neupogen or Neulasta). PRCA from B19 infxn, 3 months if chronic immunodeficient condition and clinically significant anemia or transfusion dependent. PRCA immunologic, tried prednisone and CPA or cyclosporine (CSA). PD, 6 months if tried 2 other systemic txs (eg, systemic/intralesional CS, immunosuppressant, dapsone, Remicade). SPS, tried benzodiazepine or baclofen. SLE [Systemic lupus erythematosus], tried AZA, CPA, MTX [methotrexate], mycophenolate, rituximab, or a CS. CAU, 6 months if tried 2 of following: antihistamine, H2-blocker, a CS, and CSA or Singulair. Uveitis, 6 months if tried CS and an immunosuppressive agent (MTX, CSA, mycophenolate, AZA), 2nd 6 mo if improvement or reduction in CS or immunosuppressive dose. VPP, 1 dose if VariZIG not available and patient immunocompromised. VSS, patient has anti-neutrophil antibody-associated vasculitis, tried a CS and either CPA or AZA.

KINERET

Affected Drugs

KINERET®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patient already started on anakinra for a covered use. Still's disease (SD). Chronic infantile neurological cutaneous and articular (CINCA) syndrome.

Exclusion Criteria

Anakinra should not be given in combination with TNF [Tumor necrosis factor] blocking agents (etanercept, adalimumab, infliximab, certolizumab pegol, and golimumab), or abatacept, rituximab, or tocilizumab.

Required Medical Information

N/A

Age Restrictions

Rheumatoid arthritis (RA) and Still's disease, adults.

Prescriber Restrictions

N/A

Coverage Duration

Approve 12 months.

Other Criteria

Adults with RA [Rheumatoid Arthritis]. Tried adalimumab, certolizumab pegol, golimumab, etanercept, or infliximab for at least 2 months or was intolerant to one of these therapies. SD, approve if patient has tried a CS and has had an inadequate response to 1 non-biologic DMARD [Disease-modifying antirheumatic drug] (eg, methotrexate) for at least 2 months or was intolerant to this therapy.

LAMISIL

Affected Drugs

LAMISIL®
TERBINAFINE HCL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Tinea corporis. Tinea cruris, faciei, manuum, pedis, and imbricate. Plantar- or moccasin-type dry tinea pedis. Black piedra. Tinea capitis. Tinea barbae. Cutaneous (skin) candidiasis. Other superficial fungal skin infections.

Exclusion Criteria

N/A

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) by the treating physician and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of topical ciclopirox 8% solution with terbinafine is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Ony=6wks fingernails, 12 weeks toenails. Other conds=12mos.

Other Criteria

Tinea corporis if the patient has trial a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, pedis, and imbricate after a trial of a topical antifungal agent. Cutaneous (skin) candidiasis after a trial of a topical antifungal agent and an oral azole antifungal. Other superficial fungal skin infections after a trial of a topical antifungal agent or an oral antifungal agent.

LETAIRIS/TRACLEER

Affected Drugs

LETAIRIS®
TRACLEER®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Patients currently on Letairis or Tracleer for treatment of pulmonary arterial hypertension. Chronic thromboembolic pulmonary hypertension (CTEPH) (Tracleer).

Exclusion Criteria

N/A

Required Medical Information

For the FDA-approved indication of pulmonary arterial hypertension, patients not currently on Letairis or Tracleer are required to have had a right-heart catheterization to confirm the diagnosis of PAH [Pulmonary Arterial Hypertension] to ensure appropriate medical assessment. For the FDA-approved indication of pulmonary arterial hypertension, patients currently on Letairis or Tracleer may continue therapy if they have a diagnosis of PAH [Pulmonary Arterial Hypertension].

Age Restrictions

N/A

Prescriber Restrictions

For treatment of pulmonary arterial hypertension, Letairis or Tracleer must be prescribed by or in consultation with a cardiologist or a pulmonologist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

LEUPROLIDE (LONG ACTING)

Affected Drugs

ELIGARD®
LUPRON DEPOT®
LUPRON DEPOT-PED®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D but specific to the following drugs as follows: Prostate cancer (Lupron Depot OR Eligard), Endometriosis (Lupon Depot), Uterine leiomyomata (Lupon Depot), Treatment of central precocious puberty (Lupron Depot Ped). Ovarian cancer (Lupron Depot, Lupron Depot Ped). Breast cancer (Lupron Depot, Lupron Depot Ped). Preserve ovarian function/fertility in women undergoing chemotherapy (Lupron Depot, Lupron Depot Ped). Induce amenorrhea during bone marrow transplant (Lupron Depot, Lupron Depot Ped). Premenstral syndrome (Lupron Depot, Lupron Depot Ped). Catamenial pneumothorax (Lupron Depot, Lupron Depot Ped). Paraphilias or other inappropriate sexual behaviors or disorders (Lupron Depot, Lupron Depot Ped). Dysfunctional uterine bleeding (Lupron Depot, Lupron Depot Ped).

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

For dysfunctional uterine bleeding approve for up to 6 months and all other indications x 12 months.

Other Criteria

Premenstrual syndrome (PMS) for patients that have tried two other therapies (e. g. , selective serotonin reuptake inhibitors [SSRIs], oral contraceptives [OCs]). Menstrual migraine approve if the patient has tried two other therapies for the treatment of acute migraine (e. g. , NSAIDs [Non-steroidal anti-inflammatory drugs], triptans, ergotamines) or prophylaxis of migraine (e. g. , beta-blockers, amitriptyline, divalproex).

LIDODERM

Affected Drugs

LIDODERM®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus diabetic neuropathic pain.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

MEKINIST

Affected Drugs

MEKINIST®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Mekinist for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Mekinist is being used. For unresectable or metastatic melanoma must have documentation of BRAF V600E or V600K mutations.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For unresectable or metastatic melanoma must be used in patients with BRAF V600E or V600K mutations.

NEULASTA

Affected Drugs

NEULASTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D but worded more broadly as cancer patients receiving myelosuppressive chemotherapy.

Exclusion Criteria

Use after undergoing peripheral blood progenitor cell (PBPC) transplantation.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

NEUPOGEN

Affected Drugs

NEUPOGEN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e. g. , congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL).

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Cancer/AML [Acute Myeloid Lymphoma], PBPC, MDS [Myelodysplastic syndrome], AA, ALL, oncologist or a hematologist. SCN, hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

NUEDEXTA

Affected Drugs
NUEDEXTA®

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

Exclusion Criteria
N/A

Required Medical Information
N/A

Age Restrictions
N/A

Prescriber Restrictions
N/A

Coverage Duration
Authorization will be for 12 months.

Other Criteria
N/A

NUVIGIL/PROVIGIL

Affected Drugs

MODAFINIL
NUVIGIL®
PROVIGIL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with multiple sclerosis (MS) - Provigil only. Excessive daytime sleepiness (EDS) due to myotonic dystrophy - Provigil only. Attention-deficit hyperactivity disorder (ADHD) and attention-deficit disorder (ADD) - Provigil only. Adjunctive/augmentation for treatment of depression in adults - Provigil only.

Exclusion Criteria

N/A

Required Medical Information

For the FDA-approved indication of excessive sleepiness due to obstructive sleep apnea/hypoapnea syndrome (OSAHS) patients must have tried continuous positive airway pressure (CPAP). For the FDA-approved indication of excessive sleepiness due to shift-work sleep disorder (SWSD), patients must be working at least 5 overnight shifts per month.

Age Restrictions

ADHD [Attention Deficit Hyperactive Disorder] or ADD [Attention Deficit Disorder]. Adjunctive augmentation treatment for depression must be in adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Excessive sleepiness due to OSAHS [Obstructive sleep apnea/hypoapnea syndrome] if the patient has tried CPAP [Continuous positive airway pressure]. Excessive sleepiness due to SWSD [Shift work sleep disorder] if the patient is working at least 5 overnight shifts per month. ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] for patients who have tried two alternative medications for ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] from two different classes as follows: methylphenidate products (e. g. , methylphenidate, dexmethylphenidate), amphetamines (e. g. , mixed amphetamine salts, dextroamphetamine), atomoxetine, alpha agonists (e. g. , Kapvay, Intuniv), bupropion or tricyclic antidepressants (TCAs e. g. , imipramine, desipramine).

Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression.

ORENCIA

Affected Drugs

ORENCIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on abatacept for a covered use.

Exclusion Criteria

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (e. g. , etanercept, adalimumab, certolizumab pegol, golimumab, or infliximab) or with anakinra, rituximab, or tocilizumab.

Required Medical Information

N/A

Age Restrictions

Rheumatoid arthritis (RA), adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

RA [Rheumatoid Arthritis], approve if the patient has tried one of the following biologic DMARDs [Disease-modifying antirheumatic drugs], adalimumab, etanercept, certolizumab pegol, golimumab, or infliximab for at least 2 months, or was intolerant to one of these therapies. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], polyarticular course, approve Orencia IV only if the patient has tried one of the following biologic DMARDs [Disease-modifying antirheumatic drugs], adalimumab, etanercept, or infliximab for at least 2 months or was intolerant to one of these therapies (Orencia SC is not FDA-approved for the treatment of JIA [Juvenile Idiopathic Arthritis]/JRA).

PEGYLATED INTERFERONS

Affected Drugs

PEGASYS PROCLICK®
PEGASYS®
PEGINTRON REDIPEN®
PEGINTRON®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Pediatric patients who have not been previously treated with interferon alfa or peginterferon alfa AND who are not HIV co-infected. Hep B. Acute Hepatitis C. Retreatment of Hepatitis C. Recurrent Hepatitis C. Chronic Hepatitis C. Any indication besides Hepatitis C.

Exclusion Criteria

N/A

Required Medical Information

Hepatitis C. depending on genotype, response in HCV RNA, liver fibrosis, HIV status, and HIV RNA. Chronic Hepatitis C, on waiting list for liver transplant. Recurrent Hepatitis C, after liver transplant, grade II fibrosis or greater. Hep B, coinfected with Hepatitis C.

Age Restrictions

For acute hepatitis, coinfection w/hepatitis B and C, retreatment in patients previously treated for Hepatitis C with interferon alfa or pegylated interferon alfa, recurrent Hepatitis C after liver transplant, or chronic Hepatitis C on waiting list for liver tranplant, approve for adults. For hepatitis C in children (txment, re-txment), approve Pegasys if aged 5 to 17 years, approve PegIntron if aged 3 to 17 years.

Prescriber Restrictions

For all patients with hepatitis C, must be prescribed by an infectious disease MD, gastroenterologist, hepatologist, or a transplant MD or in consultation with one of these MDS [Myelodysplastic syndrome].

Coverage Duration

Hepatitis C. 12, 24, 48, 72 weeks Acute Hepatitis C. 6 to 12 mo Chronic Hepatitis C liver transplant 12 weeks non-Hepatitis C 12 mo.

Other Criteria

Adult not previously treated for chronic hepatitis C (HC) with interferon alfa (IA)/peginterferon alfa (PA) and not HIV co-infected, HC genotype 2/3 authorize 24 weeks initial treatment, or HC genotype 3 with high level of HCV RNA (per MD) or advanced fibrosis authorize 48 weeks (total), or HC genotypes 1/4 authorize 12 weeks initial treatment (document baseline HCV RNA) and reassess viral titer at 12 weeks, if decreased by 2log10 or more and virus is undetectable, authorize 36 weeks (total 48

weeks), or if not decreased by 2log 10, authorize 12 weeks and reassess at 24 weeks, or genotype 1 with viral titer decrease of 2log10 but virus still detectable, authorize 12 weeks and reassess at 24 weeks. At 24 week, if advanced fibrosis (via liver bx) and undetectable virus, authorize 24 weeks (48 weeks total), or if advanced fibrosis and detectable HCV RNA MD and patient to decide whether to continued with another 24 weeks OR If no advanced fibrosis and do not have greater than or equal to 2 log10 decrease or virus undetectable, no further authorization, or if genotype 1 with 2log10 decrease AND detectable virus at week 12 but no detectable virus at week 24, then authorize for 48 weeks (72 weeks total, retreatment). HC viral genotype 5/6 use genotype 1/4 criteria above. Coinfected with HIV/HC (genotype 1, 2, 3, 4) and not previously treated for HC, authorize up to 48 weeks (total). Child 2 to 17 years w/HC (genotypes 1, 2, 3, 4) not been previously treated for HC w/IA/PA AND not HIV co-infected, authorize 24 weeks initial treatment. At 24 week, if viral titer undetectable after 24 weeks or if viral titer decreased by 2log10 or more after 12 weeks of treatment, authorize 24 weeks (48 weeks total), or if viral titer still detectable after 24 weeks of treatment, then no further authorization. Coinfected with HC and Hep B, authorize 48 weeks. Acute Hepatitis C (ie, infection within 6 months of exposure), authorize 6 to 12 months of treatment if at least 2 to 4 months after acute onset. Retreatment of patients who have been previously treated for HC with IA or PA, authorize 48 weeks. Retreatment of patients who failed to attain a sustained virologic response (SVR) [undetectable HCV RNA at the end of treatment and 24 weeks after treatment completion] with PA and ribavirin is not recommended unless specific factors that contributed to the nonresponse are identified and corrected before retxment. Recurrent Hepatitis C after liver transplant and grade II fibrosis, authorize 48 weeks if PA prescribed by hepatologist or liver transplant MD affiliated with liver transplant program. HC on waiting list for liver transplantation, authorize initial 12 weeks if administered in liver clinic affiliated with liver transplant program. At 12 weeks, genotype 2/3 and viral titer decreased by 2log10 or more and virus undetectable authorize 24 weeks total from the time patient has achieved an optimal dose of PA and ribavirin, for genotype 1 and viral titer decreased by 2log10 or more and virus undetectable authorize 52 weeks total from the time patient has achieved an optimal dose of PA and ribavirin, or genotype 1/2/3 and viral titer not decreased by 2log10, then no further authorization.

PENLAC

Affected Drugs

CICLOPIROX

Covered Uses

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

Exclusion Criteria

Treatment with other systemic antifungal agents used for the treatment of onychomycosis (fluconazole, itraconazole, terbinafine).

Required Medical Information

Treatment for onychomycosis must be considered non-cosmetic by the treating physician and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of topical ciclopirox 8% solution with terbinafine, itraconazole, or fluconazole (for onychomycosis use) is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for up to 48 weeks.

Other Criteria

N/A

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Affected Drugs

ADCIRCA®
REVATIO®
SILDENAFIL

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

For initial approval for use in pulmonary arterial hypertension (PAH), approve if patient has had a right-heart catheterization to confirm diagnosis of PAH [Pulmonary Arterial Hypertension] to ensure appropriate medical assessment. For patients currently receiving sildenafil or tadalafil, approve if patient has a diagnosis of PAH [Pulmonary Arterial Hypertension].

Age Restrictions

N/A

Prescriber Restrictions

For PAH [Pulmonary Arterial Hypertension], if prescribed by, or in consultation with, a cardiologist or a pulmonologist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

PRADAXA

Affected Drugs

PRADAXA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus use in patients with atrial flutter. Treatment of acute venous thromboembolism. Prevention of venous thromboembolism after hip replacement surgery. Prevention of venous thromboembolism after knee replacement surgery. Additional indications will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use of Pradaxa for patients with non-valvular atrial fibrillation or flutter. Authorization may be given for treatment of acute venous thromboembolism (VTE), prevention of VTE after hip or knee replacement surgery, or additional indications evaluated by a pharmacist and/or a physician on a case-by-case basis, if the patient has tried one of the following therapies for the condition: warfarin (Coumadin), rivaroxaban (Xarelto), fondaparinux (Arixtra), or a low molecular weight heparin (LMWH) product (enoxaparin [Lovenox], tinzaparin [Innohep], dalteparin [Fragmin]), OR if the patient is unable to take one of these medications listed for the condition for one of the following reasons: patient has allergic, immunologic or inherited disorder, patient had adverse effect (eg, major organ toxicity, major bleeding), the patient has experienced ineffectiveness to the agent in a prior setting, the patient has drug-drug interactions that cannot be managed (warfarin), the patient lacks access to proper monitoring (warfarin), the patient has experienced prior heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis (HITT) (fondaparinux [Arixtra] or LMWH), or the patient is unable to perform injections or have injections administered to them (fondaparinux [Arixtra] or LMWH).

PROLIA

Affected Drugs

PROLIA®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Prolia may be approved for treatment of postmenopausal osteoporosis if the patient has tried an oral or intravenous bisphosphonate (eg, alendronate, risedronate, ibandronate, zoledronic acid [Reclast]), or if the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has multiple osteoporotic fractures in the setting of T-scores less than -3. 5.

PROMACTA

Affected Drugs

PROMACTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.
Thrombocytopenia due to hepatitis C virus (HCV)-related cirrhosis.

Exclusion Criteria

Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).

Required Medical Information

Cause of thrombocytopenia.

Age Restrictions

N/A

Prescriber Restrictions

Treatment of thrombocytopenia due to chronic immune (idiopathic) thrombocytopenic purpura (ITP), approve if prescribed by, or after consultation with, a hematologist. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, either a gastroenterologist or a physician who specializes in infectious disease.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy.

REBIF

Affected Drugs

REBIF®

Covered Uses

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

Exclusion Criteria

Concurrent use of Avonex, Betaseron, Extavia, Copaxone, Tysabri, or fingolimod (Gilenya).

Required Medical Information

Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

RECLAST

Affected Drugs

RECLAST®
ZOLEDRONIC ACID

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Reclast for an FDA-approved indication.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Reclast may be approved for the covered osteoporosis indications if 1) the patient has tried one oral bisphosphonate or oral bisphosphonate-containing product AND the patient has an inadequate response as determined by the prescribing physician or the patient has intolerability to an oral bisphosphonate, or 2) the patient cannot take an oral bisphosphonate product because they cannot swallow, or because they cannot remain in an upright position post oral bisphosphonate administration, or because the patient has a chronic and complex existing medication regimen in which an oral bisphosphonate agent will likely compromise therapy as determined by the prescribing physician, this exception will be evaluated by a pharmacist and/or physician on a case-by-case basis, or because the patient has a pre-existing gastrointestinal medical condition (eg, esophageal lesions, esophageal ulcers, etc.) in which intravenous bisphosphonate therapy may be medically preferred over oral therapy.

REGRANEX

Affected Drugs

REGRANEX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus any granulating ulcer/wound (eg, pressure ulcers, venous stasis ulcers) that is classified as NPUAP Stage III or IV. Any clean and granulating ulcer/wound classified as NPUAP Stage II.

Exclusion Criteria

N/A

Required Medical Information

Diabetic neuropathic ulcer(s) that is/are classified as NPUAP Stage III or IV. Any clean and granulating ulcer/wound classified as Stage II (e. g. , Stage II diabetic neuropathic ulcers and pressure ulcers), III or IV.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Diabetic neuropathic ulcer(s) that is/are classified as NPUAP Stage III or IV. Any granulating ulcer/wound classified as Stage III or IV. Any clean and granulating ulcer/wound classified as Stage II (e. g. , Stage II diabetic neuropathic ulcers and pressure ulcers), if the patient has tried other standard ulcer/wound care therapies (eg, debridement, topical therapies [collagenase]) for at least 4 weeks.

REMICADE

Affected Drugs

REMICADE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on infliximab for non-Crohn's disease covered uses. Crohn's disease (CD) patients already on infliximab (IFB) and continuing therapy for maintenance of remission (MR). Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Sarcoidosis (Sarc). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Enterovesical fistulas (EF) in patients with Crohn's disease. SAPHO (synovitis, acne, pustulosis, hyperostosis, osteotis) syndrome. Crohn's disease after ileocolonic resection, to reduce the chance of recurrence.

Exclusion Criteria

Concurrent use with anakinra, abatacept, alefacept, rituximab, ustekinumab, certolizumab pegol, etanercept, adalimumab, golimumab, or tocilizumab. Intra-articular injection of IFB.

Required Medical Information

N/A

Age Restrictions

Rheumatoid arthritis (RA), SD, Fistulizing CD [Crohn's Disease], Adults. CD [Crohn's Disease] (induce, maintain remission), UC [Ulcerative colitis], patients aged 6 years or more.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

RA [Rheumatoid Arthritis], Tried 1 DMARD [Disease-modifying antirheumatic drug] for 2 months or also receiving MTX [methotrexate]. CD [Crohn's Disease]. Tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other agent for CD [Crohn's Disease] (eg, azathioprine, 6-MP, MTX [methotrexate], certolizumab, adalimumab). Fistulizing CD [Crohn's Disease] (FCD), approve. Plaque psoriasis (PP). Tried systemic treatment (MTX, CSA, acritretin, etanercept, alefacept, adalimumab, or ustekinumab) for 2 months or phototx for 2 months. If contraindications to nearly all other txs, exceptions to be evaluated by RPh or MD on case-by-case basis. Ulcerative colitis (UC). Tried 2-mo trial of systemic CS, 6-MP, AZA, CSA or tacrolimus. SD. Tried CS AND 1 non-biologic DMARD [Disease-modifying antirheumatic drug] (eg, MTX [methotrexate]) for 2 months, or was intolerant.

UV. Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX [methotrexate], MM, CSA, AZA, CPM), etanercept, adalimumab. Sarc. Tried CS and immunosuppressant (eg, MTX [methotrexate], AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG). Tried 1 systemic treatment (eg, systemic CS, immunosuppressant (eg, AZA, 6MP, CSA, CPM, chlorambucil), etanercept or adalimumab) for 2 months, or 2-mo trial of intralesional CS or CSA for localized PG. Tried one systemic CS or 1 other immunosuppressant (eg, mycophenolate, CSA) for 2 months. Hidradenitis suppurativa (HS). Tried 1 treatment (eg, intralesional/oral CS, systemic antibiotic, isotretinoin). GVHD [Graft-Versus-Host disease]. Tried 1 treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.) or receiving IFB concurrently. CD [Crohn's Disease] enterovesical fistulas (EF). Tried 1 treatment (eg, AZA, 6-MP, MM, CSA, tacrolimus). SAPHO. Tried NSAID [Non-steroidal anti-inflammatory drug] and MTX [methotrexate], systemic CS, sulfasalazine, or CSA.

REMODULIN

Affected Drugs

REMODULIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Patients currently on Remodulin for treatment of pulmonary arterial hypertension.

Exclusion Criteria

N/A

Required Medical Information

For the FDA-approved indication of pulmonary arterial hypertension, patients not currently on Remodulin are required to have had a right-heart catheterization to confirm the diagnosis of PAH [Pulmonary Arterial Hypertension] to ensure appropriate medical assessment. For the FDA-approved indication of pulmonary arterial hypertension, patients currently on Remodulin may continue therapy if they have a diagnosis of PAH [Pulmonary Arterial Hypertension].

Age Restrictions

N/A

Prescriber Restrictions

For treatment of pulmonary arterial hypertension, Remodulin must be prescribed by or in consultation with a cardiologist or a pulmonologist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

RITUXAN

Affected Drugs

RITUXAN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D. Patients already started on Rituxan for rheumatoid arthritis (RA).

Exclusion Criteria

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), or anakinra, abatacept, or tocilizumab.

Required Medical Information

N/A

Age Restrictions

RA [Rheumatoid Arthritis], adults.

Prescriber Restrictions

Adult with RA [Rheumatoid Arthritis] (initial and repeat courses). Prescribed by a rheumatologist or in consultation with a rheumatologist. Non-RA [Rheumatoid Arthritis] indications, if prescribed by or in consultation with an oncologist, hematologist, neurologist, multiple sclerosis (MS) specialist, rheumatologist, dermatologist, or immunologist, or who are being managed by a transplant center.

Coverage Duration

RA [Rheumatoid Arthritis]. Approve 2 doses. 16 weeks or more after, approve 2 more doses if response per doctor. Othr=12 months.

Other Criteria

Adult with RA [Rheumatoid Arthritis] (initial course), approve if patient has tried at least 1 of the following biologic DMARDs [Disease-modifying antirheumatic drugs], etanercept, certolizumab pegol, golimumab, infliximab, or adalimumab, for at least 2 months. Adult with RA [Rheumatoid Arthritis] (repeat course), approve if 16 weeks or more after the first dose of the previous rituximab regimen and the patient has responded (eg, less joint pain, morning stiffness, or fatigue, or improved mobility, or decreased soft tissue swelling in joints or tendon sheaths) as determined by the prescribing physician.

SAMSCA

Affected Drugs

SAMSCA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on tolvaptan for the treatment of hyponatremia.

Exclusion Criteria

N/A

Required Medical Information

Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For the treatment of clinically significant hypervolemic and euvolemic hyponatremia with serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).

SIGNIFOR

Affected Drugs

SIGNIFOR®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Signifor is being used.

Age Restrictions

Cushing's, 18 years of age and older.

Prescriber Restrictions

Initial course, prescribed by or in consultation with an endocrinologist.

Coverage Duration

Initial therapy, approve for 3 months. Continuation therapy, approve for 12 months.

Other Criteria

Cushing's disease, approve if according to the prescribing physician the patient is not a candidate for surgery or surgery has not been curative. Patients who have already been started on Signifor for Cushing's disease will be approved if the patient has had a response, as determined by the prescribing physician and the patient is continuing therapy to maintain response.

SIMPONI

Affected Drugs

SIMPONI®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on golimumab for a covered use.

Exclusion Criteria

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (e. g. , adalimumab, certolizumab pegol, etanercept, infliximab), or anakinra, rituximab, abatacept, or tocilizumab.

Required Medical Information

N/A

Age Restrictions

Rheumatoid arthritis (RA), adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Adults with rheumatoid arthritis (RA), approve if the patient has tried Enbrel or Humira one disease-modifying antirheumatic drug [DMARD] (brand or generic, oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs [Disease-modifying antirheumatic drugs] for at least 2 months] AND the patient will be receiving methotrexate (MTX) in combination with golimumab. Adult RA [Rheumatoid Arthritis] patients are not required to use MTX [methotrexate] concurrently with golimumab if there are contraindications to MTX [methotrexate] or the patient has a history of intolerance to MTX [methotrexate]. Psoriatic arthritis and ankylosing spondylitis, approve if the patient has tried Enbrel or Humira.

SIMPONI ARIA

Affected Drugs

SIMPONI ARIA®

Covered Uses

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

Exclusion Criteria

Concurrent use with another biologic (for example, tocilizumab, certolizumab, etanercept, adalimumab, anakinra, abatacept, infliximab, rituximab) or tofacitinib.

Required Medical Information

Diagnosis for which Simponi Aria is being prescribed, concurrent medications, previous therapies tried.

Age Restrictions

RA [Rheumatoid Arthritis] - adults.

Prescriber Restrictions

RA [Rheumatoid Arthritis] - Prescribed by or in consultation with a rheumatologist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For RA [Rheumatoid Arthritis] - in patients who have not been receiving Simponi or Simponi Aria, approve if they will be taking Simponi Aria in combination with MTX [methotrexate] or one other traditional disease-modifying antirheumatic drug (DMARD) [e. g. , leflunomide, sulfasalazine, hydroxychloroquine], unless intolerant or contraindicated AND meets one of the following criteria: i. Patient has tried one DMARD [Disease-modifying antirheumatic drug] (brand or generic, oral or injectable) for at least 3 months, (this includes patients who have tried other biologic DMARDs [Disease-modifying antirheumatic drugs] for at least 3 months) OR ii. Patient has a contraindication or intolerance to MTX [methotrexate] and leflunomide, as determined by the prescribing physician OR iii. Patient has early RA [Rheumatoid Arthritis] (defined as disease duration of less than 6 months) with at least one of the following features of poor prognosis - functional limitation (e. g. , based on health assessment questionnaire disability index (HAQ-DI) score), extraarticular disease such as rheumatoid nodules, RA [Rheumatoid Arthritis] vasculitis, or Felty's syndrome, positive rheumatoid factor or anti-cyclic citrullinated peptide (CCP) antibodies, or bony erosions by radiograph.

SOLARAZE

Affected Drugs

SOLARAZE®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise noted.

Other Criteria

For Bowen's disease, approve Solaraze after a trial of at least one other therapy used for the management of Bowen's disease (eg, topical 5-fluorouracil [5-FU], imiquimod, cryotherapy, photodynamic therapy, curettage, excision, laser, or radiotherapy). For DSAP, approve Solaraze after a trial of at least two other therapies used for the management of DSAP (eg, topical 5-FU, imiquimod, topical corticosteroid, topical vitamin D3 analogues, topical or oral retinoid, cryotherapy, photodynamic therapy, and laser).

SPORANOX

Affected Drugs

ITRACONAZOLE
SPORANOX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Tinea corporis. Tinea cruris, faciei, manuum, imbricata, and pedis (nonmoccasin or chronic type). Plantar- or moccasin-type dry tinea pedis. Tinea or pityriasis versicolor. Tinea capitis. Tinea barbae. Treatment of vaginal candidiasis. Prevention of recurrent vulvovaginal or vaginal candidiasis. Treatment or prevention of other superficial, systemic or suspected fungal infections. Patient has been started and stabilized on intravenous (IV) itraconazole therapy or oral itraconazole for a systemic infection and it is being used as continuation therapy. Candida onychomycosis.

Exclusion Criteria

Itraconazole should not be administered for the treatment of onychomycosis in patients with congestive heart failure (CHF). Use of topical ciclopirox 8% solution with itraconazole is not permitted.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) by the treating physician and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of topical ciclopirox 8% solution with itraconazole is not permitted. Itraconazole should not be given for the treatment of onychomycosis in patients with CHF [Congestive Heart Failure]. Itraconazole is permitted for the treatment of patients with Candida onychomycosis if they have a culture positive for Candida.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Ony=12wks toenails, 8wks fingernails. Candida ony, 4 months. Other conds=12mos.

Other Criteria

Tinea corporis after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, imbricata, and pedis (nonmoccasin or chronic type) after a trial of a topical antifungal agent. Tinea or pityriasis versicolor after trial of a

topical antifungal agent, except for extensive conditions. Treatment of vaginal candidasis after a trial of oral fluconazole.

SPRYCEL

Affected Drugs

SPRYCEL®

Covered Uses

All medically-accepted indications not otherwise excluded from Part D. Plus patients already started on Sprycel for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Sprycel is being used. For indications of CML [Chronic Myeloid Leukemia] and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. New patients with CML [Chronic Myeloid Leukemia] and ALL which is Ph-positive may receive authorization for Sprycel.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For CML [Chronic Myeloid Leukemia], new patient must have Ph-positive CML [Chronic Myeloid Leukemia] for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel.

STELARA

Affected Drugs

STELARA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plust patients already started on ustekimumab for a covered use.

Exclusion Criteria

Ustekinumab should not be given in combination with a tumor necrosis factor (TNF) antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), with anakinra, or with alefacept.

Required Medical Information

N/A

Age Restrictions

Adults.

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist or in consultation with a dermatologist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Plaque psoriasis in adults. Patient has tried at least one of the following agents: an oral therapy (eg, MTX [methotrexate], cyclosporine, or acritretin), oral methoxsalen plus PUVA, or a biologic agent (eg, adalimumab, etanercept, infliximab). Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be evaluated by a pharmacist and/or physician on a case-by-case basis.

STIVARGA

Affected Drugs

STIVARGA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Stivarga for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Stivarga is being used. For metastatic colorectal cancer (CRC), prior therapies tried. For metastatic CRC, KRAS mutation status.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For metastatic CRC, patient must have previously been treated with each of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, irinotecan, anti-VEGF therapy (eg, Avastin, Zaltrap). For metastatic CRC with no detected KRAS mutations (ie, KRAS wild-type), patient must have previously been treated with each of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, irinotecan, anti-VEGF therapy (eg, Avastin, Zaltrap), anti-EGFR therapy (eg, Eribitux, Vectibix).

SUBOXONE

Affected Drugs

BUPRENORPHINE-NALOXONE
SUBOXONE®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

SYMLIN

Affected Drugs

SYMLINPEN 120®
SYMLINPEN 60®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as patient has type 1 or 2 diabetes mellitus.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

TAFINLAR

Affected Drugs

TAFINLAR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Tafinlar for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Tafinlar is being used. For unresectable or metastatic melanoma must have documentation of BRAF V600E mutation.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For unresectable or metastatic melanoma must be used in patients with BRAF V600E mutation.

TASIGNA

Affected Drugs

TASIGNA®

Covered Uses

All medically-accepted indications not otherwise excluded from Part D. Plus patients already started on Tasigna for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Tasigna is being used. For indication of CML [Chronic Myeloid Leukemia], the Philadelphia chromosome (Ph) status of the leukemia must be reported. New patients with CML [Chronic Myeloid Leukemia] which is Ph-positive may receive authorization for Tasigna. For indication of gastrointestinal stromal tumor (GIST), prior therapies tried.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For CML [Chronic Myeloid Leukemia], new patient must have Ph-positive CML [Chronic Myeloid Leukemia] for approval of Tasigna. For GIST, patient must have tried sunitinib (Sutent) and imatinib (Gleevec).

TAZORAC

Affected Drugs

TAZORAC®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Congenital ichthyoses (X-linked recessive ichthyosis, non-erythrodermic autosomal recessive lamellar ichthyosis, autosomal dominant ichthyosis vulgaris). Basal cell carcinoma.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).

TECFIDERA

Affected Drugs

TECFIDERA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tecfidera for a Covered Use.

Exclusion Criteria

Concurrent use with other disease-modifying agents used for multiple sclerosis (MS) [eg, Avonex, Rebif, Betaseron, Extavia, Copaxone, Tysabri, Gilenya, or Aubagio].

Required Medical Information

MS [Multiple Sclerosis], patient has a relapsing form of MS [Multiple Sclerosis]. MS [Multiple Sclerosis], previous MS [Multiple Sclerosis] therapies tried.

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or in consultation with a neurologist or MS [Multiple Sclerosis] specialist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For use in MS [Multiple Sclerosis], approve if the patient has a relapsing form of MS [Multiple Sclerosis] (includes relapsing-remitting MS [Multiple Sclerosis], secondary-progressive MS [Multiple Sclerosis] with relapses, and progressive-relapsing MS [Multiple Sclerosis]) and the patient has tried interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron or Extavia), or glatiramer acetate (Copaxone) OR the patient has tried glatiramer acetate but cannot take an interferon beta therapy due to any of the following reasons: depression, suicidality, severe psychiatric disorder, woman who is pregnant or plans to become pregnant, or active liver disease or a history of significant liver disease, history of seizures. Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif), or glatiramer acetate (Copaxone) can be made if the patient is unable to administer injections due to dexterity issues or visual impairment.

TOPAMAX/ZONEGRAN

Affected Drugs

TOPAMAX®
TOPIRAMATE
ZONEGRAN®
ZONISAMIDE

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

TOPICAL IMMUNOMODULATORS

Affected Drugs

ELIDEL®
PROTOPIC®

Covered Uses

All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use of Elidel or Protopic in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Atopic dermatitis or eczema, authorize use of Elidel or Protopic in patients who have tried a prescription strength topical corticosteroid in the past 60 days. Dermatologic condition on or around the eyes, eyelids, or genitalia, authorize use of Elidel or Protopic without a trial of a prescription strength topical corticosteroid.

TOPICAL RETINOID PRODUCTS

Affected Drugs

ADAPALENE
ATRALIN®
AVITA
AVITA®
DIFFERIN®
EPIDUO®
RETIN-A MICRO®
RETIN-A®
TRETINOIN
TRETIN-X®
VELTIN®
ZIANA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. For topical tretinoin products (examples include Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X, and generic topical tretinoin), additional covered uses include: Ichthyosis, Keloids, Lichen planus, Oral leukoplakia, Confluent and reticulated papillomatosis.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise noted.

Other Criteria

N/A

TOPICAL TESTOSTERONE PRODUCTS

Affected Drugs

ANDRODERM®
ANDROGEL®
AXIRON®
FORTESTA®
STRIANT®
TESTIM®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

TRANSMUCOSAL FENTANYL DRUGS

Affected Drugs

ABSTRAL®
ACTIQ®
FENTANYL CITRATE
FENTORA®
LAZANDA®
ONSOLIS®
SUBSYS®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate).

TYKERB

Affected Drugs

TYKERB®

Covered Uses

All medically-accepted indications not otherwise excluded from Part D. Plus patients already started on Tykerb for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Tykerb is being used. For indication of breast cancer, the HER2 status must be reported. New patients with breast cancer which is HER2-positive may receive authorization for Tykerb.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For breast cancer, new patient must have HER2-positive breast cancer for approval of Tykerb.

TYSABRI

Affected Drugs

TYSABRI®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tysabri for a Covered Use.

Exclusion Criteria

Concurrent use of another immunomodulator (eg, Rebif, Betaseron, Extavia, Copaxone or Avonex) or fingolimod (Gilenya) in multiple sclerosis (MS) patients. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) or tumor necrosis factor (TNF) alfa inhibitors (eg, infliximab, adalimumab, certolizumab pegol) in Crohn's disease (CD) patients.

Required Medical Information

Adults with MS [Multiple Sclerosis]. Patient has a relapsing form of MS [Multiple Sclerosis]. Adults with CD [Crohn's Disease]. Patient has moderately to severely active CD [Crohn's Disease] with evidence of inflammation (eg, elevated C-reactive protein).

Age Restrictions

Adults.

Prescriber Restrictions

MS [Multiple Sclerosis]. Prescribed by a neurologist or an MS [Multiple Sclerosis] specialist registered with the TOUCH prescribing program. CD [Crohn's Disease]. Prescribed by a physician registered with the TOUCH program.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Adults with MS [Multiple Sclerosis]. Patient has a relapsing form of MS [Multiple Sclerosis] and has had an inadequate response to, or is unable to tolerate, therapy with at least two of the following MS [Multiple Sclerosis] medications: interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone), or fingolimod (Gilenya). Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif) can be made if the patient has depression or a mood disorder. In these cases, the patient should try glatiramer acetate (Copaxone) or fingolimod (Gilenya), but is not required to try an interferon beta-1a or -1b. Adults with CD [Crohn's Disease]. Patient has moderately to severely active CD [Crohn's Disease] with evidence of inflammation (eg, elevated C-reactive protein) and has had an inadequate response to treatment with corticosteroids (systemic), azathioprine, 6-mercaptopurine, or methotrexate, and patient has tried two TNF [Tumor necrosis factor] antagonists for CD [Crohn's Disease] for at least 2 months each,

adalimumab, certolizumab pegol, or infliximab, and had an inadequate response or was intolerant to the TNF [Tumor necrosis factor] antagonists. Exception to the CD [Crohn's Disease] criteria of treatment with corticosteroids (systemic) are allowed if steroids are contraindicated or not desired, then azathioprine, 6-mercaptopurine, or methotrexate must be tried if they are not contraindicated.

VFEND

Affected Drugs

VFEND®
VORICONAZOLE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as invasive aspergillosis, esophageal candidiasis, treatment of fungal infections caused by Scedosporium apiospermum and Fusarium spp. , and treatment of candidemia in nonneutropenic patients and the following Candida infections: disseminated infections in skin and infections in the abdomen, kidney, bladder wall, and wounds, treatment/prevention of other serious systemic or suspected systemic fungal infections. Continuation therapy for patients started/stabilized on intravenous (IV) or oral voriconazole for a systemic infection.

Exclusion Criteria

N/A

Required Medical Information

Esophageal candidasis requires a trial of one other systemic agent (eg. , fluconazole, IV amphotericin B, itraconazole).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

For safety reasons, if there is insufficient information available to make a determination regarding coverage and the prescribing physician or representative of the physician cannot be contacted, then approve 14-day course.

VICTRELIS

Affected Drugs

VICTRELIS®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus adult patients with Hepatitis B virus (HBV)/chronic HCV genotype 1 co-infection.

Exclusion Criteria

Recurrent hepatitis C after liver (or other organ) transplantation in patients who have failed therapy with boceprevir or another NS3/4A protease inhibitor for HCV (e. g. , telaprevir).

Required Medical Information

HCV RNA titers. Tx-naïve patients with chronic HCV-1 monoinfection without cirrhosis and retx of patients with chronic HCV-1 monoinfection who have been previously treated with interferon/peginterferon alfa without cirrhosis, greater or equal to 1 log10 reduction in HCV RNA at TW 4 required, TW 12 if HCV RNA less than 100=addl 12wks if HCV RNA greater or equal to 100=no addl, TW 24 if early responder with undetectable HCV RNA and patient non-black and for tx-naive patient with chronic HCV-1 monoinfection without cirrhosis=addl 4wks, TW 24 if early responder with undetectable HCV RNA and patient non-black and for retx in patient with chronic HCV-1 monoinfection previously treated for HCV with interferon/peginterferon alfa without cirrhosis=addl 12wks, TW 24 if early responder with undetectable HCV RNA and patient black=addl 24wks, TW 24 if late responder with undetectable HCV RNA and patient non-black=addl 12wks if patient black=addl 24wks, TW 24 if early or late responder with detectable HCV RNA=no addl. Retx in patients with chronic HCV-1 monoinfection previously treated with interferon/peginterferon alfa without cirrhosis null-responder documentation required, TW 12 if HCV RNA less than 100=addl 12wks if HCV RNA greater or equal to 100=no addl, TW 24 if HCV RNA undetectable=addl 24wks if HCV RNA detectable=no addl. Poor interferon response with chronic HCV-1 monoinfection and less than 1 log10 reduction HCV RNA after TW 4 without cirrhosis, TW 12 if HCV RNA less than 100=addl 12wks if HCV RNA greater or equal to 100=no addl, TW 24 if HCV RNA undetectable=addl 24wks if HCV RNA detectable=no addl. Chronic HCV-1 monoinfection and advanced fibrosis/compensated cirrhosis, TW 12 if HCV RNA less than 100=addl 12 weeks if HCV RNA greater or equal to 100=no addl, TW 24 if HCV RNA undetectable=addl 24wks if HCV RNA detectable=no addl.

Age Restrictions

Adults.

Prescriber Restrictions

All FDA-approved indications. Prescribed by or in consultation with a gastroenterologist or infectious disease physician.

Coverage Duration

Authorization=8wks withTW 12, 24 assessment.

Other Criteria

HCV RNA titers not available but sent approve until available. For all FDA-approved indications, patient must have completed or will be completing a 4-week lead-in with peginterferon alfa and ribavirin prior to initiating boceprevir and boceprevir must be prescribed in combination as triple-drug therapy with peginterferon alfa and ribavirin.

VIMPAT

Affected Drugs

VIMPAT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Diabetic neuropathic pain. Seizure disorders.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Diabetic neuropathic pain (DPN), approve if the patient has tried at least two other therapies for DPN - tricyclic antidepressants (eg, nortriptyline), serotonin and norepinephrine reuptake inhibitors (SNRIs) (eg, Cymbalta, venlafaxine extended-release [Effexor XR]), gabapentin, Lyrica, sodium valproate, dextromethorphan, morphine, tramadol, oxycodone, capsaicin, or Lidoderm.

XALKORI

Affected Drugs

XALKORI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus, patients with non-small cell lung cancer (NSCLC) already started on crizotinib.

Exclusion Criteria

N/A

Required Medical Information

For the FDA-approved indication of NSCLC for patients new to therapy, ALK status required.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

NSCLC, patient new to therapy must be ALK-positive for approval.

XARELTO

Affected Drugs

XARELTO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus, patients with non-valvular atrial flutter. Treatment of acute venous thromboembolism or long-term use for thromboprophylaxis in medically-ill patients.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For non-FDA approved indications, non atrial flutter indications patient must try one of the following therapies for the condition: warfarin, dabigatran, fondaparinux, or a low molecular weight heparin (LMWH) product (ie, enoxaparin, tinzaparin, dalteparin) OR the patient must be unable to take one of the medications listed due to one of the following reasons: allergic, immunologic or inherited disorders, adverse effects (eg, major organ toxicities, major bleeding), or patient has experienced ineffectiveness in a prior setting, or patient has drug-drug interactions that cannot be managed (warfarin), or the patient lacks access to proper monitoring (warfarin), or patient has experienced prior heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis (HITT) [fondaparinux and LMWH], or the patient is unable to perform injections or have injections administered to them (fondaparinux and LMWH).

XELJANZ

Affected Drugs

XELJANZ®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xeljanz for a Covered Use.

Exclusion Criteria

Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab) or a TNF [Tumor necrosis factor] inhibitor (eg, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].

Required Medical Information

N/A

Age Restrictions

Rheumatoid Arthritis (RA), adults.

Prescriber Restrictions

RA [Rheumatoid Arthritis], prescribed by or in consultation with a rheumatologist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

RA [Rheumatoid Arthritis], patient has tried MTX [methotrexate] or another traditional DMARD [Disease-modifying antirheumatic drug] (eg, leflunomide, sulfasalazine) for at least 3 months unless the patient has been shown to be intolerant AND the patient has tried at least one biologic DMARD [Disease-modifying antirheumatic drug] for RA [Rheumatoid Arthritis] (eg, tocilizumab, anakinra, abatacept, rituximab) or a TNF [Tumor necrosis factor] inhibitor (eg, certolizumab, etanercept, adalimumab, infliximab, golimumab) for at least 3 months unless intolerant.

XENAZINE

Affected Drugs

XENAZINE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, Xenazine must be prescribed by or after consultation with a neurologist. For TD, Xenazine must be prescribed by or after consultation with a neurologist or psychiatrist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

XEOMIN

Affected Drugs

XEOMIN®

Covered Uses

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

Exclusion Criteria

Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, rejuvenation of the peri-orbital region), allergic rhinitis, gait freezing in Parkinsons disease, vaginismus, dysphagia (upper esophageal sphincter dysfunction), interstitial cystitis, Crocodile tears syndrome, or fibromyalgia.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Blepharospasm, approve if the patient has tried onabotulinumtoxinA (Botox).

XOLAIR

Affected Drugs

XOLAIR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Seasonal or perennial allergic rhinitis (SAR or PAR [Perennial allergic rhinitis]).

Exclusion Criteria

N/A

Required Medical Information

Moderate to severe persistant asthma and SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis], baseline IgE level of at least 30 IU/mL. For asthma, patient has a positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). For SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis], patient has positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach).

Age Restrictions

Patients aged 12 years and older.

Prescriber Restrictions

Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] if prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Moderate to severe persistent asthma must meet all criteria patient's asthma symptoms have not been adequately controlled by concomitant use of at least 2 months of inhaled corticosteroid and a long-acting beta-agonist (LABA) or LABA alternative, if LABA contraindicated or patient has intolerance then alternatives include sustained-release theophylline or a leukotriene modifier (eg, montelukast), AND inadequate control demonstrated by hospitalization for asthma, requirement for systemic corticosteroids to control asthma exacerbation(s), or increasing need (eg, more than 4 times a day) for short-acting inhaled beta2 agonists for symptoms (excluding

preventative use for exercise-induced asthma). SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] must meet the following criteria - patient has tried concurrent therapy with at least one drug from 2 of the following classes, a non-sedating or low-sedating anthistamine/nasal antihistamine, a nasal corticosteroid, or montelukast or patient has tried at least one drug from all 3 of these classes during one allergy season AND patient has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy, AND for patients with allergies to animals, these animals must be removed from the patient's immediate environment (eg, work, home).

XTANDI

Affected Drugs

XTANDI®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Xtandi for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis for which Xtandi is being used. For metastatic castration-resistant prostate cancer, prior therapies tried.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

For prostate cancer, patient must have metastatic, castration-resistant prostate cancer for approval. For metastatic, castration-resistant prostate cancer, patient must have previously received therapy with docetaxel for approval.

ZELBORAF

Affected Drugs

ZELBORAF®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus, patients with melanoma already started on vemurafenib.

Exclusion Criteria

N/A

Required Medical Information

For the FDA-approved indication of melanoma, for patients new to therapy, BRAFV600E status required.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Melanoma, patient new to therapy must have BRAFV600E mutation for approval.

ZETIA

Affected Drugs

ZETIA®

Covered Uses

All medically accepted indications not otherwise excluded from Part D.

Exclusion Criteria

N/A

Required Medical Information

Patients with severe renal impairment, CrCl 30 mL/min or less.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Authorize use in patients who have tried a statin or statin-containing product (brand or generic) or if being initiated in combination with a statin or statin-containing product. Patients taking a medication that has a significant drug interaction with any of the statins (eg, cyclosporine, fibrates, niacin more than 1 g/day, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV protease inhibitors, nefazodone, amiodarone, and verapamil), authorize use without a trial of a statin. Patients with severe renal impairment (CrCl of 30 mL/min or less), authorize use without a trial of a statin. Homozygous familial sitosterolemia, authorize use without a trial of a statin. Pregnancy, authorize use without a trial of a statin. Patients with active liver disease or unexplained persistent elevations of serum transaminases, authorize use without a trial of a statin. Patients previously diagnosed with myopathy or rhabdomyolysis (either medication-related or not medication-related) OR patients with an underlying muscle/muscle-metabolism-related disorder (eg, myositis, McArdle disease), pharmacist will review on a case-by-cases basis for authorization without a trial of a statin.

ZYVOX

Affected Drugs

ZYVOX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patient already started on linezolid or intravenous vancomycin for a Covered Use.

Exclusion Criteria

N/A

Required Medical Information

For indication of vancomycin-resistant enterococcus (VRE) infection, cultures must be done to confirm. Methicillin-resistant Staphylococcus, cultures must be done to confirm. For patients already started on linezolid, approve oral linezolid for patients already started in hospital, or other inpatient facility, or as an outpatient on intravenous linezolid (which is now being switched to oral linezolid for continuation of therapy). For patients already started on linezolid, approve oral linezolid for patients already started in hospital or other inpatient facility on oral linezolid (to allow continuation of therapy).

Age Restrictions

N/A

Prescriber Restrictions

For non-FDA-approved indications, linezolid must be prescribed by, or after consultation with, an infectious disease physician.

Coverage Duration

Authorization will be for one fill up to one month.

Other Criteria

Approve linezolid for use in other infections that are resistant to other antibiotics, but the identified organism(s) is/are susceptible to linezolid. For safety reasons, if there is insufficient information available to make a determination regarding coverage and the prescribing physician or representative of the physician cannot be contacted, then approve.

HIP Health Plan of New York (HIP) is a Medicare Advantage organization with a Medicare contract. Group Health Incorporated (GHI) is a Medicare Advantage organization and a standalone prescription drug plan with a Medicare contract. HIP and GHI are EmblemHealth companies.

Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take.

Beneficiaries must use network pharmacies to access their premium and/or copayment/coinsurance may change on January 1, 2014.

This document includes EmblemHealth Medicare PDP partial formulary as of November 1, 2013. For a complete, updated formulary, please visit our Web site at http://www.emblemhealth.com/medicare or call the Customer Service number below:

For alternative formats or language, please call Customer Service toll free at:
EmblemHealth Medicare PDP: 1-800-585-5786, 24 hours a day, 7 days a week

TTY/TDD users should call 1-800-899-2114, 24 hours a day, 7 days a week

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