

2010 Medicare High Performance PA Criteria

ACTIQ/FENTORA.....	4
FENTANYL CITRATE	4
ADCIRCA.....	5
ADCIRCA®	5
ALPHA-1 PROTEINASE INHIBITORS	6
ARALAST®	6
PROLASTIN®	6
AMEVIVE.....	7
AMEVIVE®.....	7
ANABOLIC STEROIDS	8
ANADROL-50®.....	8
OXANDROLONE	8
ARANESP.....	10
ARANESP®	10
ARCALYST.....	12
ARCALYST®.....	12
AVONEX.....	13
AVONEX ADMINISTRATION PACK®	13
AVONEX®.....	13
B VS D - PART B VERSUS PART D COVERAGE PA	14
AZASAN®	14
AZATHIOPRINE.....	14
AZATHIOPRINE SODIUM	14
CARIMUNE NF NANOFILTERED®	14
CELLCEPT®.....	14
CYCLOPHOSPHAMIDE	14
CYCLOSPORINE.....	14
DRONABINOL.....	14
EMEND®.....	14
FLEBOGAMMA®	14
GAMASTAN S-D®	14
GAMUNEX®	14
GENGRAF	14
GRANISETRON HCL.....	14
GRANISOL.....	14
METHOTREXATE.....	14
MITOXANTRONE HCL	14
MYCOPHENOLATE MOFETIL	14
MYFORTIC®.....	14
ONDANSETRON HCL	14
ONDANSETRON ODT.....	14
ORTHOCLONE OKT-3®.....	14
POLYGAM S-D®.....	14
PROGRAF®.....	14

RAPAMUNE®	14
SIMULECT®	14
BETASERON.....	15
BETASERON®	15
BOTOX	16
BOTOX®	16
BYETTA.....	18
BYETTA®.....	18
CEREZYME	19
CEREZYME®.....	19
COMBINATION BETA2-AGONIST/CORTICOSTEROID INHALERS.....	20
ADVAIR DISKUS®	20
ADVAIR HFA®	20
SYMBICORT®	20
COPAXONE	21
COPAXONE®	21
DIFLUCAN (FLUCONAZOLE)	22
FLUCONAZOLE	22
ENBREL	23
ENBREL®	23
EPOETIN/PROCRIT	25
PROCRIT®	25
FABRAZYME	27
FABRAZYME®.....	27
FORTEO.....	28
FORTEO®.....	28
GROWTH HORMONES	29
OMNITROPE®.....	29
TEV-TROPIN®.....	29
HUMIRA.....	32
HUMIRA®	32
INCRELEX.....	34
INCRELEX®.....	34
KINERET	35
KINERET®	35
LAMISIL	37
LAMISIL®.....	37
TERBINAFFINE HCL	37
LEUPROLIDE (LONG ACTING)	38
ELIGARD®.....	38
LUPRON DEPOT®	38
LUPRON DEPOT-PED®.....	38
LIDODERM.....	39
LIDODERM®.....	39
NEULASTA.....	40
NEULASTA®.....	40

NEUPOGEN	41
NEUPOGEN®	41
ORENCIA	42
ORENCIA®	42
PEGYLATED INTERFERONS.....	43
PEGASYS®	43
PENLAC	45
CICLOPIROX	45
PROVIGIL.....	46
PROVIGIL®.....	46
REBIF	48
REBIF®.....	48
REGRANEX.....	49
REGRANEX®	49
REMICADE	50
REMICADE®.....	50
REVATIO	52
REVATIO®.....	52
RITUXAN	53
RITUXAN®.....	53
SOMAVERT.....	54
SOMAVERT®	54
SPORANOX	55
ITRACONAZOLE	55
SYMLIN	56
SYMLIN®	56
SYMLINPEN 60®.....	56
TAZORAC.....	57
TAZORAC®	57
TOPAMAX/ZONEGRAN	58
TOPIRAMATE	58
ZONISAMIDE	58
TOPICAL TRETINOIN PRODUCTS	59
TRETINOIN.....	59
TYSABRI	60
TYSABRI®	60
VFEND.....	61
VFEND®	61
XOLAIR.....	62
XOLAIR®	62
ZYVOX.....	64
ZYVOX®	64
INDEX.....	65

ACTIQ/FENTORA

Affected Drugs

FENTANYL CITRATE

Covered Uses

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

Exclusion Criteria

Acute and/or postoperative pain including surgery/post-surgery, trauma/post-trauma, acute medical illness (acute abdominal pain, pelvic pain, muscle spasm). Pre-anesthesia (preoperative anxiolysis and sedation and/or supplement to anesthesia. Coverage is not recommended for circumstances not listed in the Covered Uses.

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

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

ADCIRCA

Affected Drugs

ADCIRCA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D plus Eisenmenger syndrome with pulmonary arterial hypertension (PAH) [men or women]. For Raynaud disease, refer to Levitra.

Exclusion Criteria

Patients taking nitrates. Use of Adcirca for the treatment of erectile dysfunction. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

12 months.

Other Criteria

N/A

ALPHA-1 PROTEINASE INHIBITORS

Affected Drugs

ARALAST®
PROLASTIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Other phenotypes with an alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL (eg, PiSZ phenotype). Alpha-1 antitrypsin (AAT) deficiency-associated panniculitis.

Exclusion Criteria

PiMZ or PiMS phenotype of alpha1-antitrypsin deficiency, unless alpha1-antitrypsin serum concentrations are less than 11 microM (11 micromol/L) or 80 mg/dL. Cystic fibrosis. COPD without alpha1-antitrypsin deficiency. Alpha1-antitrypsin deficiency without lung disease, even if deficiency-induced hepatic disease is present. Bronchiectasis (without alpha1-antitrypsin deficiency). Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

For AAT deficiency and emphysema of other phenotypes that are not FDA-approved (eg, PiSZ, PiMZ or PiMS phenotype), an alpha1-antitrypsin serum concentration of less than 11 microM (11 micromol/L) or 80 mg/dL is required.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

For AAT deficiency and emphysema of other phenotypes that are not FDA-approved (eg, PiSZ, PiMZ or PiMS phenotype), an alpha1-antitrypsin serum concentration of less than 11 microM (11 micromol/L) or 80 mg/dL is required.

AMEVIVE

Affected Drugs

AMEVIVE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus psoriasis of hand and/or foot (may be palmoplantar pustulosis, palmoplantar pustular psoriasis, or palmar plantar pustulosis). Psoriatic arthritis.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

Greater than or equal to 16 years of age.

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist. Psoriasis of hand and/or foot (palmoplantar pustulosis, palmoplantar pustular psoriasis, or palmar plantar pustulosis). Prescribed by a dermatologist.

Coverage Duration

PP/PsA, 12 wk. Hand/ft psor, 16 wk. Approve 2nd 12 or 16 wk, respectively, if pt off Amevive for 12 wk.

Other Criteria

Plaque psoriasis. Patient has chronic plaque psoriasis AND Patient has tried a systemic therapy (e.g., MTX, azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Enbrel, Remicade, Humira, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician. Hand and/or foot psoriasis, same criteria as plaque psoriasis except all psoriasis types (not just plaque) are allowed. Psoriatic arthritis. Patient has tried Humira, Enbrel, or Remicade for at least 3 months AND the patient will be receiving Amevive in combination with MTX.

ANABOLIC STEROIDS

Affected Drugs

ANADROL-50®
OXANDROLONE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus Oxandrin for inclusion body myositis (IBM) sporadic form. Oxandrin for ALS for maintenance/improvement in muscle strength and/or respiratory capacity. Oxandrin for quadriplegic/tetraplegic patients for maintenance/improvement in respiratory muscle strength, pulmonary function, and/or dyspnea. Oxandrin for Duchenne muscular dystrophy. Oxandrin for constitutional delay of growth or growth and puberty in prepubertal boys with psychosocial difficulties or psychological distress due to their condition. Oxandrin for girls (8 y/o and older) w/Turner's Syndrome or Ullrich-Turner Syndrome. Oxandrin for management of protein catabolism w/burns or burn injury. Oxandrin for AIDS wasting and cachexia due to a chronic disease. Oxandrin for cachexia due to cancer. Oxandrin for alcoholic liver disease (hepatitis). Anadrol-50 for prevention/prophylaxis of hereditary angioedema. Anadrol-50 for AIDS wasting and cachexia due to a chronic disease. Anadrol-50 for antithrombin III deficiency. Anadrol-50 for anemia of chronic kidney disease.

Exclusion Criteria

Coverage of Oxandrin AND Anadrol-50 is not recommended in the following circumstances: Management of weight gain, other than detailed in the FDA-approved indications or other covered uses. Management of weight loss. HIV-associated lipodystrophy. Chronkhite-Canada Syndrome. Heart failure in patients with idiopathic dilated cardiomyopathy (IDC), mitral regurgitation, or aortic regurgitation. Athletic performance (ability) enhancement. Coverage of Anadrol-50 is not recommended in the following circumstances: alcoholic liver disease (hepatitis). Relief of bone pain due to osteoporosis or conditions other than osteoporosis. Coverage of Oxandrin is not recommended in the following circumstances: anemia of chronic kidney disease. Coverage is not recommended for circumstances not listed in the Covered Uses.

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

Oxandrin 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. Anadrol-50 for anemia due to chronic kidney disease. Approve for patients who have tried or are unable to take erythroid-stimulant agents (Procrit, Epogen, Aranesp).

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. Plus anemia due to myelodysplastic syndrome (MDS). Anemia in heart failure.

Exclusion Criteria

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. Anemia associated with the use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products). Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Anemia in patients due to acute blood loss. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Anemia w/CRF. A hemoglobin (Hb) of less than or equal to 11.0 g/dL required for start, Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa (EA) or Aranesp. Deny if Hb exceeds 12.0 g/dL. Anemia due to myelosuppressive chemotx, 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 wks after therapy start and the rise in Hb is 1.0 g/dL or more (or Hct rise is 3% or more). Pts whose Hb rises less than 1.0 g/dL (Hct rise less than 3%) compared to pretx baseline over 4 wks of tx and whose Hb remains less than 10.0 g/dL after the 4 wks 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 pretx baseline by 8 wks 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 wks 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 reinstatement of Aranesp must include a dose reduction of

25% from the previously admin dose. MDS, approve tx if Hb is 12.0 g/dL or less. Aranesp tx is not recommended if Hb is more than 12.0 g/dL in any situation. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. Anemia in HF, approve in pts with New York Heart Association (NYHA) functional class III or IV w/ Hb of 10.0 g/dL or less and according to the MD underlying causes of anemia persist despite transfusions or pt has contraindications to transfusions. Addtl tx allowed if pt has Hb of 12.0 g/dL or less. Aranesp is not recommended if Hb is more than 12.0 g/dL. If pt had previously been receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Chemo course +8 wk after last chemo dose. CRF=12 mos. MDS=6 mos. HF=6 mos. Addtl 6 mos, Hb 12.0 or less.

Other Criteria

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Pts 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 wks 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 administration 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 reinstatement 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.

Exclusion Criteria

Neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA). Juvenile idiopathic arthritis (JIA). Gout. Familial Mediterranean fever (FMF). Arcalyst should not be given in combination with tumor necrosis factor (TNF) blocking agents (Enbrel, Humira, Remicade) or Kineret. Coverage is not recommended for circumstances not listed in the Covered Uses.

Required Medical Information

N/A

Age Restrictions

Greater than or equal to 12 years of age.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

AVONEX

Affected Drugs

AVONEX ADMINISTRATION PACK®
AVONEX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS and prescribed by, or after consultation with, a neurologist or an MS-specialist.

Exclusion Criteria

Concurrent use of Rebif, Betaseron, Copaxone or Tysarbi. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

B VS D - PART B VERSUS PART D COVERAGE PA

Affected Drugs

AZASAN®
AZATHIOPRINE
AZATHIOPRINE SODIUM
CARIMUNE NF NANOFILTERED®
CELLCEPT®
CYCLOPHOSPHAMIDE
CYCLOSPORINE
DRONABINOL
EMEND®
FLEBOGAMMA®
GAMASTAN S-D®
GAMUNEX®
GENGRAF
GRANISETRON HCL
GRANISOL
METHOTREXATE
MITOXANTRONE HCL
MYCOPHENOLATE MOFETIL
MYFORTIC®
ONDANSETRON HCL
ONDANSETRON ODT
ORTHOCLONE OKT-3®
POLYGAM S-D®
PROGRAF®
RAPAMUNE®
SIMULECT®

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

Affected Drugs

BETASERON®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS and prescribed by, or after consultation with, a neurologist or an MS-specialist.

Exclusion Criteria

Concurrent use of Avonex, Rebif, Copaxone or Tysarbi. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

BOTOX

Affected Drugs

BOTOX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus Achalasia. Anal Fissure. BPH. Chronic facial pain/pain associated with TMJ dysfunction. Chronic low back pain. Plantar fasciitis. Tinnitus. Headache (migraine, chronic tension HA, whiplash, chronic daily HA). Palmar/plantar and facial hyperhidrosis. Myofascial pain. Salivary hypersecretion. Spasticity (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm). Essential tremor. Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus). Bladder/voiding/urethral dysfunction. Gastroparesis. Vaginismus. Dysphagia. Interstitial cystitis. Frey's syndrome. Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome. Crocodile tears syndrome. Fibromyalgia.

Exclusion Criteria

Cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the peri-orbital region. Allergic rhinitis. Gait freezing in Parkinsons disease. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Tinnitus if prescribed by ENT. Headache if prescribed by, or after consultation with, a neurologist or HA specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Primary axillary hyperhidrosis after trial with at least 1 topical agent (eg, aluminum chloride). BPH after trial with at least 2 other therapies (eg, alpha1-blocker, 5 alpha-reductase inhibitor, TURP, transurethral microwave heat treatment, TUNA, interstitial laser therapy, stents, various forms of surgery). Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program.

Tinnitus after a trial with at least 2 other pharmacologic therapies (eg, lidocaine, antihistamines, antidepressants, anxiolytics, diuretics, anticonvulsants, antispasmodics) and tinnitus retraining therapy and prescribed by an ENT (eg, otolaryngologist). 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) and prescribed by or after consultation with a neurologist/headache specialist. 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). Bladder/Voiding/Urethral dysfunction after a trial with at least 1 other pharmacologic therapy (eg, oral antimuscarinic agents). Gastroparesis after a trial with at least 1 promotility drug (eg, metoclopramide, tegaserod, erythromycin). Vaginismus after a trial with at least 2 other treatment options (eg, behavior therapy, psychotherapy, biofeedback, dilatation techniques, deep muscle relaxation exercises, anesthetic creams, vaginal lubricants, propranolol, alprazolam). Interstitial cystitis after a trial with at least 1 other pharmacologic therapy (eg, pentosan polysulfate, heparin, antihistamines, TCAs, intravesical dimethyl sulfoxide, bacilli Calmette-Guérin). Tourette's syndrome if after a trial with at least 1 more commonly used pharmacologic therapy (eg, neuroleptics, clonidine, SSRIs, psychostimulants). Fibromyalgia if after a trial of at least 2 or more commonly used pharmacologic therapies (eg, TCAs, SSRIs, SNRIs, dopamine agonists, and sedative hypnotics, or lidocaine injection into trigger points).

BYETTA**Affected Drugs**

BYETTA®

Covered Uses

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

Exclusion Criteria

Weight loss treatment. Type 1 diabetes. Coverage not recommended for anything not listed under Covered Uses.

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

CEREZYME

Affected Drugs

CEREZYME®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Type 1 Gaucher disease if being prescribed by, or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders or the patient was referred to a center that specializes in the treatment of Gaucher disease. Type 2 or 3 Gaucher disease if the agent is being prescribed by, or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders or the patient was referred to a center that specializes in the treatment of Gaucher disease.

Exclusion Criteria

Tay-Sachs disease. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Type 1, 2, or 3 Gaucher disease if prescribed by or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

COMBINATION BETA2-AGONIST/CORTICOSTEROID INHALERS

Affected Drugs

ADVAIR DISKUS®
ADVAIR HFA®
SYMBICORT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus COPD. Chronic bronchitis. Emphysema.

Exclusion Criteria

Treatment of symptoms associated with a current rhinovirus infection/cough associated with a current episode of the common cold. Treatment of chronic cough due to GERD. Treatment of symptoms due to an acute respiratory infection (eg, acute bronchitis, sinusitis, pneumonia). Treatment of chronic cough due to NAEB. Treatment of chronic cough due to bronchiolitis. Treatment of chronic cough due to bronchiectasis. Whooping cough/pertussis. ACE inhibitor-induced cough. Psychogenic cough/habit cough/tic cough. Coverage is not recommended for circumstances not listed in the Covered Uses.

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

COPAXONE

Affected Drugs

COPAXONE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS and prescribed by, or after consultation with, a neurologist or an MS-specialist.

Exclusion Criteria

Patient is receiving Avonex, Rebif, Betaseron or Tysabri. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

N/A

DIFLUCAN (FLUCONAZOLE)

Affected Drugs

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

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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 Penlac 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 for if the patient has tried terbinafine tablets or itraconazole capsules unless the patients has a medical condition or other clinical reason to not utilize these agents (e.g., drug-drug interactions, heart failure).

ENBREL

Affected Drugs

ENBREL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patient already on Enbrel. Juvenile spondyloarthropathy. Undifferentiated spondyloarthritis. Reactive arthritis (Reiter's disease). Adult with Still's disease. Uveitis (noninfectious) in children. Scleritis or sterile corneal ulceration. Amyloidosis (primary). Amyloidosis with renal involvement. Chronic inflammatory demyelinating polyneuropathy. Myasthenia gravis. Acute or chronic GVHD. Behcet's disease. Giant cell arteritis. Hidradenitis suppurativa. Polymyalgia rheumatica. Pyoderma gangrenosum. Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, mucous membrane pemphigoid [cicatricial pemphigoid]). Systemic sclerosis (scleroderma) with inflammatory joint involvement. Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).

Exclusion Criteria

Enbrel should not be given in combination with Kineret or Orencia. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist.

Coverage Duration

12 months.

Other Criteria

Adults with RA, approve if patient has tried 1 DMARD for at least 2 months or is concurrently receiving MTX. JIA or JRA, polyarticular course, approve if the patient has tried MTX or will be starting on Enbrel concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Plaque psoriasis. Patient has chronic plaque psoriasis AND Patient has tried a systemic therapy (e.g., MTX, azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Amevive, Remicade, Humira, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions

can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician.

EPOETIN/PROCRIT

Affected Drugs

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). Anemia in HIV-infected pts. Preoperative use in pts undergoing major surgery utilizing hemodilution intraoperatively. Treatment of aplastic anemia. Anemia in heart failure (HF).

Exclusion Criteria

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. To treat orthostatic hypotension in patients with anemia. To treat thalassemia-related anemia. As an adjunct to bone marrow transplantation (BMT) for donors. Use as an adjunct to blood donation for autologous use. Treatment of anemia associated with epidermolysis bullosa. Treatment of anemia in systemic lupus erythematosus. Treatment of anemia in rheumatoid arthritis. Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Treatment of anemia in diabetes mellitus. Hemochromatosis. Anemia in patients due to acute blood loss. Non-anemic pts (Hb more than 13.0 g/dL) prior to surgery. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

CRF anemia. Hemoglobin (Hb) of less than or equal to 11.0 g/dL to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa (EA) or Aranesp. Anemia w/myelosuppressive chemotx. 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 wks

after start and Hb rise is 1.0 g/dL or more (Hct rise is 3% or more). Pts w/Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline over 4 wks of tx and Hb is less than 10.0 g/dL after 4 wks of tx (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 pretx baseline by 8 wks of tx. 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 wks of tx 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, 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. Anemia in HF, approve for New York Heart Association functional class III or IV pts w/Hb 10.0 g/dL or less and per MD underlying anemia causes persist despite transfusions or pt has contraindications to transfusions. Addtl tx allowed if pt has Hb of 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (+/- zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 units/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Anemia due to ribavirin for Hep C, Hb is 10.0 g/dL or less at tx start. Aplastic anemia, Hb is 12.0 g/dL or less. Previously on EA approve if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.

Age Restrictions

N/A

Prescriber Restrictions

For aplastic anemia epoetin alfa has to be prescribed by a hematologist.

Coverage Duration

Chemo course +8 wk. MDS=6mo. HF=6mo. Addtl 6 mo, Hb 12.0 or less. Transfus=3wk. Hemodilut=1 mo. Other=12mo.

Other Criteria

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Pts 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 wks 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 administration 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.

FABRAZYME

Affected Drugs

FABRAZYME®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Male patients with a diagnosis of Fabry disease based on clinical symptoms or by genetic testing. Female patients with presumed symptoms of Fabry disease (heterozygous carriers) based on family history and/or genetic testing.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Fabry disease in male patients based on clinical symptoms or by genetic testing. Fabry disease in female patients based on family history and/or genetic testing.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

FORTEO
Affected Drugs
FORTEO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. For the treatment of osteoporosis in patients (women and men) who are at high risk for fracture. Patients at high risk include those with a history of osteoporotic fracture, those with a medical condition that has resulted in bone loss significantly greater than would be expected for the patient's age (eg, chronic liver disease), patients with a very low BMD (defined as (ie, BMD T-score below -2.0) or), and those using medicine that resulted in bone loss (eg, steroids [prednisone]). For use in hypoparathyroidism (primary or secondary) if the patient is under the care of an endocrinologist.

Exclusion Criteria

Prevention of osteoporosis (women and men). Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

T-score below -2.0 may be required for some patients for the treatment of osteoporosis indication.

Age Restrictions

N/A

Prescriber Restrictions

For hypoparathyroidism that patient must be under the care of an endocrinologist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Patients that have tried other medications for the treatment of osteoporosis (eg, bisphosphonates, intranasal calcitonin, raloxifene), are currently receiving such medications, or are intolerant to these agents may receive Forteo regarding of risk status of the treatment of osteoporosis.

GROWTH HORMONES

Affected Drugs

OMNITROPE®

TEV-TROPIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Turner's syndrome. Child with SHOX (short stature homeobox-containing gene) deficiency. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Child, Noonan syndrome. Short bowel syndrome.

Exclusion Criteria

Constitutional delay of growth and puberty. Down's syndrome. Corticosteroid-induced short stature including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation. Kidney transplant patients (children) with a functional renal allograft. Liver transplantation. Cardiac transplantation. Bone marrow transplantation without total body irradiation (cranial radiation). Congenital adrenal hyperplasia. Bony dysplasias (achondroplasia, hypochondroplasia). Osteogenesis imperfecta. X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets). Myelomeningocele. Dilated cardiomyopathy and heart failure. Athletic ability (enhancement). Aging (ie, antiaging) to improve functional status in elderly patients and somatopause. Infertility. Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure. Osteoporosis, postmenopausal or idiopathic in men. Adults with end-stage renal disease undergoing hemodialysis. HIV-infected patients with alterations in body fat distribution (e.g., increased abdominal girth, buffalo hump). Crohn's disease. Chronic fatigue syndrome. Fibromyalgia. Cystic fibrosis. Familial dysautonomia (Riley-Day syndrome, hereditary sensory autonomic neuropathy). Children with severe burn injury. Multiple system atrophy (MSA).

Required Medical Information

Child w/acquired GH deficiency (DF). 1 documented GH stimulation test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) shows diminished serum GH response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile for gender/age AND pretx Ht velocity (VEL) in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 mos of data. Child had brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or growth VEL criteria. Child w/hypophysectomy does not have to meet any criteria. Adolescents (diagnosed as child with GH DF or with idiopathic short stature [ISS]) with prior GH use and aged 16 yrs or older, growth rate (GR) must be at least 2.5 cm/yr in recent yr. Review pts annually for this GR (does not apply

to documented hypopituitarism). Further approval is not recommended if GR is less than 2.5 cm/yr. Adolescents, young adults with ISS who completed linear growth (GR less than 2 cm/year), review for txment of adult GH DF. Non-GH deficient short stature (ISS) child w/open epiphyses. 6 mo trial. Baseline Ht less than 3rd percentile (ie, greater than 2 SD below the mean for gender/age AND pretx Ht VEL in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 mos of data AND pediatric endocrinologist (PE) must certify child's basic activities of daily living is limited by short stature and child has a condition for which GH is effective (or may be effective during the initial trial of tx) AND PE must certify based on bone-age x-ray, predicted adult Ht is less than 3rd percentile. Authorization for cont tx based on adequate clinical response (an annualized GR that doubles in comparison to previous yr).

Age Restrictions

N/A

Prescriber Restrictions

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

Coverage Duration

SBS 4 wks. NonGH def short stat 6 mos Adult with HIV wasting 24 wks. HIV failure to thrive 12 wks.

Other Criteria

Therapy should be discontinued if there is no significant increase in growth rate during the first year. Adult GH deficiency. 1 of the following diagnoses Adult onset (GH alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage) OR Childhood-onset AND must have a negative response to 1 standard GH stimulation test as follows, 1 of the following stimulation tests must be used (insulin tolerance, glucagon, GH releasing hormone (GHRH) plus arginine, or GHRH plus GH releasing peptide (GHRP-6). Arginine alone may be used in non-obese adolescents with childhood onset. Cutoff values for GH peak for each test are For the insulin tolerance or glucagon peak less than 3 mcg/L, For GHRH plus arginine, peak less than 11 mcg/L with BMI less than 25 kg/m² or less than Patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis for more than 4 wks of therapy or more than one 4-wk course per yr. Adults with HIV infection with wasting or cachexia. All of the following, HIV-positive and have wasting or cachexia AND have 1 of the following, documented unintentional weight loss of greater than or equal to 10% from baseline OR weight less than 90% of the lower limit of ideal body weight OR BMI less than or equal to 20

kg/m² AND must be able to consume or be fed through parenteral or enteral feedings greater than or equal to 75% of maintenance energy requirements based on current body weight AND must have been on antiretroviral therapy for greater than or equal to 30 days prior to beginning GH therapy and will continue antiretroviral therapy throughout the course of GH treatment AND Therapy with GH is limited to 24 weeks. Repeat 12 or 24-week courses of GH may be authorized in patients who have received a previous 12 or 24-week course of GH for HIV infection with wasting or cachexia provided that they have been off GH for at least 1 month and meet all of the previous criteria. HIV-associated failure to thrive. Child less than 17 yrs AND must be able to consume or be fed through parenteral or enteral feedings greater than or equal to 75% of maintenance energy requirements based on current body weight AND has been on antiretroviral therapy for greater than or equal to 30 days prior to beginning GH therapy and will continue antiretroviral tx.

HUMIRA

Affected Drugs

HUMIRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab. Undifferentiated spondylarthritis (undifferentiated arthritis). Crohn's disease (induction/remission) in adolescents (15 up to 18 yrs). Uveitis (noninfectious) in children or adults. Uveitis or other systemic manifestations of Behcet's disease in adults. Sarcoidosis, cutaneous. Pyoderma gangrenosum. Hidradenitis suppurativa.

Exclusion Criteria

Humira should not be given in combination with Kineret or Orencia. Children aged less than 15 yrs with Crohn's disease. Osteoarthritis. Ulcerative colitis. Intra-articular injection. Recurrent spontaneous pregnancy loss. In vitro fertiliation (IVF). Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

Crohn's disease adults and adolescents aged 15 to up to 18 yrs. Uveitis or other systemic manifestations of Behcet's disease in adults. No age range specified.

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist.

Coverage Duration

Crohn's disease=12 wks for induction. All other conds=12mos.

Other Criteria

Adults with RA, approve if the patient has tried 1 DMARD or is concurrently receiving MTX. Adults with Crohn's disease to induce remission. Approve if patient has tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids. Adults with Crohn's disease to maintain remission. Patient has received 2 doses or 12 wks of adalimumab and has responded or if has not received adalimumab for induction of remission then authorize if patient has tried azathioprine, 6-mercaptopurine, or MTX or if patient has tried infliximab or certolizumab pegol. Plaque psoriasis in patients without psoriatic arthritis. Pt has chronic (greater than or equal to 1 year) plaque psoriasis AND pt has tried a systemic therapy (e.g., MTX, azathioprine, cyclosporine, Soriatane, Prograf, Enbrel, Raptiva, Amevive, Remicade, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a pt may

have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician. JIA or JRA, polyarticular course. Approve if the patient has tried MTX or will be starting on Humira concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias).

INCRELEX

Affected Drugs

INCRELEX®

Covered Uses

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

Exclusion Criteria

Patients with primary IGFD with height standard deviation score greater than -3.0 and IGF-1 standard deviation score of greater than -3.0. Idiopathic short stature, growth hormone deficiency. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Children diagnosed with severe Primary IGFD must meet the following criteria Height standard deviation score is less than or equal to -3.0 AND Age adjusted Basal IGF-1 standard deviation score is less than or equal to -3.0 AND Growth hormone concentration is normal or increased.

Age Restrictions

Children age not specified.

Prescriber Restrictions

pediatric endocrinologist or after consultation with pediatric endocrinologist.

Coverage Duration

12 months.

Other Criteria

N/A

KINERET

Affected Drugs

KINERET®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus Patient already started on anakinra. Juvenile idiopathic arthritis (JIA) or juvenile rheumatoid arthritis (JRA), polyarticular course (regardless of type of onset). Systemic onset JIA. Ankylosing spondylitis. Adult with Still's disease. Muckle-Wells syndrome. Familial cold autoinflammatory syndrome (FCAS). Neonatal Onset Multisystem Inflammatory disease (NOMID) or Chronic infantile neurological cutaneous and articular (CINCA) syndrome. Schnitzler's syndrome. Acute gout. Familial Mediterranean fever. Tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS).

Exclusion Criteria

Osteoarthritis, symptomatic. Lupus arthritis. Type 2 diabetes mellitus. Anakinra should not be given in combination with TNF blocking agents (Enbrel, Humira, Remicade, Cimzia) or with Orencia. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Acute gout, approve 3 doses. Approve 12 months for all other conditions/uses.

Other Criteria

Adults with RA. Approve if the patient has tried Humira, Enbrel, or Remicade for at least 2 months. JIA, JRA (regardless of onset), approve if pt has tried Enbrel, Humira, or Orencia. Systemic onset of JIA, approve if pt has tried a systemic corticosteroid. Ankylosing spondylitis, approve if the pt has tried Enbrel, Remicade, or Humira. Adult with Still's disease, approve if pt has tried one DMARD or is currently receiving MTX. MWS, approve if pt has tried two other drugs (Aralyst, colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, CellCept). FCAS, approve if pt has tried two other drugs (eg, colchicine, corticosteroids, antihistamines, azathioprine, Cellcept, Aralyst). Schnitzler's syndrome, approve if pt has tried one other prescription medication used in Schnitzler's syndrome. Acute gout, pt has tried 2 standard therapies for

acute gout (eg, NSAIDs, colchicine, corticosteroid) or pt cannot tolerate or has contraindications to standard therapies. FMF, approve in pts who have tried colchicine. TRAPS, approve in patients who have tried colchicine.

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. Eumycetoma/mycetoma.

Exclusion Criteria

Tinea versicolor (pityriasis versicolor). Systemic fungal infections. Oral, esophageal or vaginal candidiasis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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 Penlac with Lamisil is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

Physician must consider onychomycosis to be medically significant.

Coverage Duration

Ony=6wks fingernails, 12 wks 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 azole antifungal. Other superficial fungal skin infections after a trial of a topical antifungal agent or an oral antifungal agent.

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 (Lupron Depot), Uterine leiomyomata (Lupron 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). Premenstrual syndrome (Lupron Depot, Lupron Depot Ped). Menstrual migraine (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). Lymphangi leiomyomatosis (Lupron Depot, Lupron Depot Ped).

Exclusion Criteria

Polycystic ovarian syndrome (PCOS). Hirsutism. Benign prostatic hyperplasia (BPH). Functional bowel syndrome/irritable bowel syndrome. Orchitis/epididymo-orchitis. Coverage not recommended for anything not listed under Covered Uses.

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 mos.

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, 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 neuropathic pain. Myofascial pain. Low back pain. Carpal tunnel syndrome.

Exclusion Criteria

RA. Fibromyalgia. Coverage is not recommended for circumstances not listed in the Covered Uses.

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

Myofascial pain as adjunctive therapy. Approve if being used in combination with a standard myofascial trigger point (MTP) treatment modalities (e.g., physical therapy, MTP injections of local anesthetic, relaxation techniques). Low back pain. Approve after trying at two other pharmacologic therapies commonly used to treat low back pain (e.g., acetaminophen, nonsteroidal anti-inflammatory agents [NSAIDs], muscle relaxants, opioids, cyclooxygenase-2 [COX-2] inhibitors, tramadol, gabapentin, tricyclic antidepressants [amitriptyline]). Carpal tunnel syndrome. Approve after a trying one other pharmacological therapy used to treat carpal tunnel syndrome (e.g., steroids [oral or injectable], NSAIDs).

NEULASTA

Affected Drugs

NEULASTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D but worded more broadly as cancer patients receiving chemotherapy. Patients undergoing peripheral blood progenitor cell mobilization/autologous stem cell transplantation.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

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

NEUPOGEN

Affected Drugs

NEUPOGEN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving chemotherapy, patients with AML receiving chemotherapy, cancer patients receiving BMT, patients undergoing peripheral blood progenitor cell collection and therapy, and patients with severe chronic neutropenia (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with HIV or AIDS. Treatment of myelodysplastic syndromes. Drug induced agranulocytosis or neutropenia. BMT patients with delayed or inadequate neutrophil engraftment after PBPC transplantation. Hematopoietic stem cell transplant patients (for promotion of myeloid engraftment). Aplastic anemia with neutropenia.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

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

ORENCIA

Affected Drugs

ORENCIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on Orencia.

Exclusion Criteria

Orencia should not be given in combination with a TNF α antagonist (e.g., etanercept, adalimumab, infliximab) or with anakinra. Psoriasis. Systemic lupus erythematosus. Multiple sclerosis. Prevention of RA. Coverage not recommended for anything not listed under Covered Uses.

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

Adults with rheumatoid arthritis approve if the patient has tried one DMARD (oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs for at least 2 months] OR approve if the patients is concurrently receiving MTX. Juvenile idiopathic arthritis (JIA) [or JRA], polyarticular course approve if the patient has tried MTX or will be starting on abatacept concurrently with MTX, approve without trying MTX if the patient has an absolute contraindication to MTX.

PEGYLATED INTERFERONS

Affected Drugs

PEGASYS®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D (note all are in patients with hep C). Pediatric patients aged 3 to 17 years who have not been previously txd with interferon alfa or peginterferon alfa AND who are not HIV co-infected. Adult patient coinfectd with hep C and hep B. Acute hep C. Retreatment of hep C. Recurrent Hep C after liver transplant and grade II fibrosis or greater. Chronic hep C on waiting list for liver transplant. Any indication besides hep C.

Exclusion Criteria

Maintenance tx of hep C extending tx to 72 wks or longer (one exception for 72 wks for genotype 1 hep C). Therapy for 72 weeks is not recommended in prior nonresponders and relapsers. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Hepatitis C. depending on genotype, response in HCV RNA, liver fibrosis, CD4 count, and HIV RNA. See Other Criteria and Covered Uses for details. Chronic hep C on waiting list for liver transplant. Response assessed after 12 wks. In genotype 2 and 3 if HCVRNA has decreased by greater than or equal to 2 log₁₀ or virus undetectable, then authorize for a total of 6 months of therapy from the time the patient has achieved an optimal dose of both peginterferon and ribavirin OR In genotype 1, if the HCV RNA has decreased by greater than or equal to 2 log₁₀ (or undetectable), then authorize for a total of 12 months of therapy from the time that the patient has achieved an optimal dose of both peginterferon and ribavirin OR In genotype 1, 2 or 3, if the HCV RNA has not decreased by greater than or equal to 2 log₁₀ (or virus undetectable), then further authorization not recommended.

Age Restrictions

Children less than 3 years old for hepatic C. Children less than 18 years old for all other conditions/circumstances.

Prescriber Restrictions

For all pts 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.

Coverage Duration

Hep C. 12, 24, 48, 72 wks Acute hep C. 6 to 12 mo Chronic hep C lvr trnplnt
12 wks non-hep C 12 mo.

Other Criteria

A. Patient not previously treated for hep C with interferon/peginterferon alfa. Obtain Hep C genotype and HCV RNA titer before starting therapy (HCV RNA not required for genotype 2/3). A1. Chronic hep C (genotype 2/3) not coinfecting with HIV and not previously treated for hepatitis C. Approve 24 wks. OR A2. Chronic hep C genotype 3 not coinfecting with HIV and not previously treated for hep C and a high level of HCV RNA (determined by physician) or advanced fibrosis. Authorize 48 wks of therapy (total). OR A3. Chronic hep C (genotype 1 or 4) who is not coinfecting with HIV and not previously treated for hep C. Authorize 12 wks and reassess again in 12 wks. Record baseline HCV RNA. After 12 wks assess and if HCV RNA has decreased by greater than or equal to 2 log₁₀ (or undetectable) authorize for 36 wks OR If HCV RNA has not decreased by greater than or equal to 2 log₁₀ (or undetectable) authorize for 12 wks more and reassess again after total of 24 wks OR If genotype 1 and HCV RNA has decreased by greater than or equal to 2 log₁₀ and virus is still detectable, then authorize for 12 more wks and reassess after 24 wks (if undetectable at wk 24, authorize 48 more wks, total 72 wks using non FDA approved indication). A3 continues. After 24 wks if advanced fibrosis and HCV RNA undetectable then authorize 24 more wks (48 total) OR If advanced fibrosis and detectable HCV RNA physician and patient will decide whether to continue with another 24 wks OR If does not have advanced fibrosis and do not have a greater than or equal to 2 log₁₀ decrease or virus undetectable, no further authorization. OR A4. Chronic hep C viral genotype 5 or 6 not coinfecting with HIV and not previously treated for hep C use criteria for genotype 1 and 4 above. OR A5. Coinfecting with HIV and chronic hep C genotype 2 or 3 and not previously treated for hep C. If HCV RNA is detectable and CD4 count is greater than or equal to 200 cells/microL authorize 48 wks. OR If HCV RNA is detectable and CD4 count is 100 - 199 cells/microL and HIV RNA is less than 5000 copies/mL authorize 48 wks. OR If HCV RNA is undetectable or CD4 count is less than 100 cells/microL no authorization. OR A6. Coinfecting with HIV and chronic hep C genotype 1 and not previously treated for hep C. If HCV RNA is detectable and CD4 count is greater than or equal to 200 cells/microL authorize 24 wks and reassess after wk 24. OR If HCV RNA is detectable and CD4 count is 100 - 199 cells/microL and HIV RNA is less than 5000 copies/mL authorize 24 wks and reassess after 24 wks. OR If HCV RNA is undetectable or CD4 count is less than 100 cells/microL or HIV RNA is less than 5000 copies/mL with CD4 count less than 100 cells/microL no authorization. A6 continues. After 24 wks if HCV RNA is decreased by greater than or equal to 2 log₁₀ or virus undetectable authorize 24 more wks OR If HCV RNA has not decreased by greater than or equal to 2 log₁₀ or virus undetectable no authorization.

PENLAC

Affected Drugs

CICLOPIROX

Covered Uses

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

Exclusion Criteria

Tx with other systemic antifungal agents used for the treatment of onychomycosis (fluconazole, itraconazole, terbinafine). Prophylactic therapy for onychomycosis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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 Penlac with Lamisil is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

Physician must consider onychomycosis to be medically significant.

Coverage Duration

Authorization will be for up to 48 weeks.

Other Criteria

N/A

PROVIGIL

Affected Drugs

PROVIGIL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with MS. Excessive daytime sleepiness (EDS) due to myotonic dystrophy. ADHD and ADD. Adjunctive/augmentation for treatment of depression in adults. EDS in Parkinson's. Idiopathic hypersomnia. Spasticity due to cerebral palsy. Cancer-related fatigue.

Exclusion Criteria

Alcoholic organic brain syndrome. Enhancement of performance in situations of induced sleep deprivation. Fibromyalgia. Chronic fatigue syndrome. EDS associated with primary insomnia. ALS. Adjunctive therapy in the treatment of schizophrenia. Seasonal affective disorder. Post-stroke sleep-wake disorders or sleep disorders. Bipolar disorder, including bipolar depression. Hypersomnia, fatigue, or sleepiness due to other specific conditions or of unknown etiology. Fatigue and EDS in chronic traumatic brain injury. Fatigue in post-polio patients. Coverage is not recommended for circumstances not listed in Covered Uses.

Required Medical Information

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

Age Restrictions

Adjunctive augmentation treatment for depression must be in adults.

Prescriber Restrictions

Idiopathic hypersomnia must have the diagnosis confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Excessive sleepiness due to OSAHS if the patient has tried CPAP. Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. ADHD/ADD for patients who have tried two alternative medication for ADHD/ADD from two different classes as follows: methylphenidate products (e.g., methylphenidate, dexamethylphenidate), amphetamines (e.g., mixed amphetamine salts, dextroamphetamine), atomoxetine, 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. Idiopathic hypersomnia if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center). Spasticity due to cerebral palsy, approve if pateint has tried one other agent for spasticity (eg, benzos, baclofen, dantrolene, tizanidine, or botulinum toxin).

REBIF**Affected Drugs**

REBIF®

Covered Uses

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

Exclusion Criteria

Concurrent use of Avonex, Betaseron, Copaxone or Tysabri. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by or after consultation with a neurologist or an MS specialist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

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.

Exclusion Criteria

Prevention of ulcers/wounds. First-line therapy for the treatment of Stage II ulcers/wounds. Treatment of wounds/ulcers classified as Stage I. Coverage is not recommended for circumstances not listed in the Covered Uses.

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).

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 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 [papain-urea]) for at least 4 weeks.

REMICADE

Affected Drugs

REMICADE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus current Remicade therapy. Undifferentiated spondyloarthritis/spondyloarthritis. JRA or JIA. Behcet's disease. Adult with Still's disease. Uveitis. Sarcoidosis. Amyloidosis with renal involvement. Pyoderma gangrenosum. Hidradenitis suppurativa. Graft-versus-host disease, treatment. Indeterminate colitis. Enterovesical fistulas in patients with Crohn's disease. Macular edema in type 2 diabetes. Orbital myositis (chronic idiopathic orbital inflammation). SAPHO (synovitis, acne, pustulosis, hyperostosis, osteitis) syndrome. Familial Mediterranean fever. Cogan's syndrome.

Exclusion Criteria

Primary Sjorgren's syndrome. Sciatica. Fistulas in pts without Crohn's disease. MDS. COPD. Asthma. Atopic dermatitis. Wegener's granulomatosis. Systemic vasculitis. Giant cell arteritis. Takayasu's arteritis. Primary sclerosing cholangitis. Inflammatory myopathies (polymyositis, dermatomyositis, inclusion body myositis). Diffuse cutaneous systemic sclerosis (scleroderma, SSc). Concurrent with Kineret or Orencia. Intra-articular injection. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist.

Coverage Duration

CD (w/ or w/out fistulas)=12 wks for induction. All other conds=12mos.

Other Criteria

Adults with RA, approve if patient has tried 1 DMARD for at least 2 months or is concurrently receiving MTX. Crohn's disease to induce remission. Approve if patient has tried a corticosteroid or if corticosteroids are contraindicated or if patient currently on a corticosteroid. Crohn's disease to maintain remission. Patient has received 3 doses of infliximab and has responded or if has not received infliximab for induction of remission then authorize if patient has tried azathioprine, 6-mercaptopurine, or MTX or if patient has tried adalimumab or certolizumab pegol. Fistulizing Crohn's disease to induce remission, approve. Fistulizing Crohn's disease to maintain remission. Patient has received 3 doses

of infliximab and has responded. JIA or JRA, polyarticular course, approve if the patient has tried MTX or will be starting on Remicade concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Plaque psoriasis. Patient has chronic plaque psoriasis AND pt has tried a systemic therapy (e.g., MTX, azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Enbrel, Amevive, Humira, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis AND patient has a minimum body surface area (BSA) of 5% or more. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Exceptions allowed for patients with less than 5% BSA if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to either topical therapy OR localized phototherapy, AND had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician. Ulcerative colitis. Patient has tried 1 other oral or IV therapy for UC.

REVATIO

Affected Drugs

REVATIO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus Eisenmenger syndrome with pulmonary arterial hypertension (PAH) [men or women]. For Raynaud disease, refer to Viagra.

Exclusion Criteria

Patients taking nitrates. Use of Revatio for the treatment of erectile dysfunction. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

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 RA.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Adult with RA. Prescribed by a rheumatologist or in consultation with a rheumatologist.

Coverage Duration

RA.Approve 2 doses.6 mos or more after, approve 2 more doses if response per MD.Other conds=12 mos.

Other Criteria

Adult with RA. Patient has tried at least 1 of the following biologic DMARDs, Enbrel, Remicade, or Humira for at least 2 months.

SOMAVERT

Affected Drugs

SOMAVERT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus treatment of excessive growth hormone associated with McCune-Albright Syndrome.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Acromegaly and treatment of excess growth hormone associated with McCune-Albright syndrome. Prescribed by an endocrinologist or in consultation with an endocrinologist.

Coverage Duration

12 months.

Other Criteria

N/A

SPORANOX

Affected Drugs

ITRACONAZOLE

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 IV itraconazole therapy or oral itraconazole for a systemic infection and it is being used as continuation therapy.

Exclusion Criteria

Candidiasis hypersensitivity syndrome. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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 Penlac with Sporanox is not permitted. Sporanox should not be given for the treatment of onychomycosis in patients with CHF. Itraconazole is permitted for the treatment of patients with a culture positive for Candida.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Ony=12wks toenails, 8wks fingernails. 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 candidiasis after a trial of oral fluconazole.

SYMLIN**Affected Drugs**

SYMLIN®

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

Weight loss treatment. Coverage not recommended for anything not listed under Covered Uses.

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

TAZORAC
Affected Drugs
TAZORAC®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus psoriasis of fingernails or toenails. Oral lichen planus. Congenital ichthyoses (X-linked recessive ichthyosis, non-erythrodermic autosomal recessive lamellar ichthyosis, autosomal dominant ichthyosis vulgaris). Basal cell carcinoma. Mycosis fungoides lesions/cutaneous T-cell lymphomas. Keratosis pilaris (atrophicans). Treatment of other non-cosmetic conditions (eg, actinic keratoses, skin neoplasms, warts, dermatitis/eczema, folliculitis, acne rosacea, cystic acne, comedonal acne).

Exclusion Criteria

Cosmetic skin conditions (eg, alopecia, hyperpigmentation, liver spots, melasma/cholasma, seborrheic keratosis, stretch marks, scarring, wrinkles, premature aging, photo-aged or photo-damaged skin, mottled hyper- and hypopigmentation, benign facial lentigines, roughness, telangiectasia, skin laxity, keratinocytic atypia, melanocytic atypia, dermal elastosis). Coverage not recommended for anything not listed under Covered Uses.

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). For the treatment of other non-cosmetic conditions exceptions can be made if the patient has tried at least 1 other therapy (eg, actinic keratoses, skin neoplasms, warts, dermatitis/eczema, folliculitis, acne rosacea, cystic acne, comedonal acne).

TOPAMAX/ZONEGRAN

Affected Drugs

TOPIRAMATE
ZONISAMIDE

Covered Uses

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

Exclusion Criteria

Weight loss treatment except if patient is being treated for seizures, bipolar disorder, migraine prevention, bulimia nervosa, binge-eating disorder, etc with topiramate or zonisamide (exceptions are not recommended for patients with seizures, bipolar disorder, migraine headache, bulimia nervosa, binge-eating disorder, etc who are using topiramate or zonisamide only for weight loss OR for patients who are using topiramate or zonisamide to prevent weight gain or produce weight loss caused by other medications such as antipsychotics [eg, clozapine, olanzapine, quetiapine, risperidone, thioridazine] or antidepressants). Smoking cessation therapy (exceptions are not recommended for patients with psychiatric conditions who are using topiramate or zonisamide only for smoking cessation OR patients who have successfully stopped smoking and are using topiramate or zonisamide to prevent relapse). Coverage not recommended for anything not listed under Covered Uses.

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 TRETINOIN PRODUCTS

Affected Drugs

TRETINOIN

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Acne rosacea. Actinic keratosis/treatment of precancerous skin lesions. Ichthyosis. Diabetic foot ulcers. Mucositis. Warts. Keloids. Lichen planus. Lichen sclerosus. Pseudofolliculitis. Oral leukoplakia. Molluscum contagiosum. Darier's disease (keratosis follicularis). Treatment of other non-cosmetic conditions therapy (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis). Coverage of the combination of clindamycin plus tretinoin (Ziana) is recommended for acne vulgaris ONLY.

Exclusion Criteria

Cosmetic conditions (e.g., liver spots, stretch marks, scarring, solar elastosis, premature aging, treatment of photo-aged or photo-damaged skin, solar lentigines, skin roughness, mottled hyperpigmentation, age spots, wrinkles, geographic tongue, hyperpigmentation caused by folliculitis, acne, or eczema, melasma/cholasma, alopecia androgenetic, alopecia areata, seborrheic keratosis). Psoriasis. Coverage of Ziana is not recommended for any non-FDA approved indication. Coverage not recommended for anything not listed under Covered Uses.

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 other non-cosmetic conditions exceptions can be made if the patient has tried at least 1 other therapy (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis). Coverage of the combination clindamycin plus tretinoin (Ziana) is recommended for acne vulgaris ONLY and all other indications are not recommended.

TYSABRI

Affected Drugs

TYSABRI®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Concurrent use of another immunomodulator (eg, Rebif, Betaseron, Copaxone or Avonex) in MS patients. MS patients with chronic progressive MS. Concurrent use with immunosuppressants (eg, 6MP, azathioprine, CSA, MTX) or TNF alfa inhibitors (eg, Remicade, Humira, Cimzia) in CD patients. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

Adults.

Prescriber Restrictions

MS. Prescribed by a neurologist or an MS specialist registered with the TOUCH prescribing program. CD. Prescribed by a physician registered with the TOUCH program.

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Adults with MS. Patient has a relapsing form of MS and has had an inadequate response to, or is unable to tolerate, other MS therapies. Adults with CD. Patient has moderately to severely active CD with evidence of inflammation and has had an inadequate response to, or is unable to tolerate, conventional CD therapies (eg, 6MP, AZA, CSA, MTX) and TNF alfa inhibitors (Remicade, Humira, Cimzia).

VFEND

Affected Drugs

VFEND®

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 IV or oral voriconazole for a systemic infection.

Exclusion Criteria

Onychomycosis. Treatment or prevention of vaginal or vulvovaginal candidiasis. Tinea cruris, manuum, pedis, faciei, capitis, barbae, corporis and versicolor (pityriasis versicolor). Other superficial fungal infections.

Required Medical Information

Esophageal candidiasis 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

N/A

XOLAIR
Affected Drugs
XOLAIR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients with seasonal or perennial allergic rhinitis.

Exclusion Criteria

For treatment of peanut allergy. For the treatment of latex allergy in health care workers with occupational latex allergy. For the treatment of atopic dermatitis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Moderate to severe persistent asthma and SAR/PAR, 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/PAR, 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). For EG/EE/eosinophilic colitis, biopsy with at least 15 eosinophils/HPF.

Age Restrictions

Moderate to severe persistent asthma, patient is at least 6 y/o. SAR/PAR, patient is at least 12 y/o.

Prescriber Restrictions

Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. SAR/PAR if prescribed by an allergist, immunologist, or pulmonologist.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Pts with moderate to severe persistent asthma must meet all criteria prescribed by or in consultation with an allergist, immunologist, or pulmonologist AND baseline IgE of at least 30 IU/mL AND pt has a positive skin test or in vitro testing AND/OR for 1 or more seasonal aeroallergens AND patient's asthma symptoms have not been adequately controlled by inhaled corticosteroids AND patient is at least 6 y/o. Pts with SAR/PAR must meet the following criteria

prescribed by an allergist, immunologist, or pulmonologist AND baseline IgE level at least 30 IU/mL AND pt has positive skin testing and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for 1 or more relevant allergens AND the patient is at least 12 y/o.

ZYVOX
Affected Drugs
ZYVOX®

Covered Uses

Exclusion Criteria

Pseudomembranous colitis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

VRE, cultures must be done. Methicillin-resistant Staphylococcus, cultures must be done.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for one fill up to one month.

Other Criteria

N/A

Index

ADCIRCA®, 5
ADVAIR DISKUS®, 20
ADVAIR HFA®, 20
AMEVIVE®, 7
ANADROL-50®, 8
ARALAST®, 6
ARANESP®, 10
ARCALYST®, 12
AVONEX ADMINISTRATION
PACK®, 13
AVONEX®, 13
AZASAN®, 14
AZATHIOPRINE, 14
AZATHIOPRINE SODIUM, 14
BETASERON®, 15
BOTOX®, 16
BYETTA®, 18
CARIMUNE NF NANOFILTERED®,
14
CELLCEPT®, 14
CEREZYME®, 19
CICLOPIROX, 45
COPAXONE®, 21
CYCLOPHOSPHAMIDE, 14
CYCLOSPORINE, 14
DRONABINOL, 14
ELIGARD®, 38
EMEND®, 14
ENBREL®, 23
FABRAZYME®, 27
FENTANYL CITRATE, 4
FLEBOGAMMA®, 14
FLUCONAZOLE, 22
FORTEO®, 28
GAMASTAN S-D®, 14
GAMUNEX®, 14
GENGRAF, 14
GRANISETRON HCL, 14
GRANISOL, 14
HUMIRA®, 32
INCRELEX®, 34
ITRACONAZOLE, 55
KINERET®, 35
LAMISIL®, 37
LIDODERM®, 39
LUPRON DEPOT®, 38
LUPRON DEPOT-PED®, 38
METHOTREXATE, 14
MITOXANTRONE HCL, 14
MYCOPHENOLATE MOFETIL, 14
MYFORTIC®, 14
NEULASTA®, 40
NEUPOGEN®, 41
OMNITROPE®, 29
ONDANSETRON HCL, 14
ONDANSETRON ODT, 14
ORENCIA®, 42
ORTHOCLONE OKT-3®, 14
OXANDROLONE, 8
PEGASYS®, 43
POLYGAM S-D®, 14
PROCRIT®, 25
PROGRAF®, 14
PROLASTIN®, 6
PROVIGIL®, 46
RAPAMUNE®, 14
REBIF®, 48
REGRANEX®, 49
REMICADE®, 50
REVATIO®, 52
RITUXAN®, 53
SIMULECT®, 14
SOMAVERT®, 54
SYMBICORT®, 20
SYMLIN®, 56
SYMLINPEN 60®, 56
TAZORAC®, 57
TERBINAFINE HCL, 37
TEV-TROPIN®, 29
TOPIRAMATE, 58
TRETINOIN, 59
TYSABRI®, 60
VFEND®, 61
XOLAIR®, 62
ZONISAMIDE, 58
ZYVOX®, 64

