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ACTEMRA

Affected Drugs

ACTEMRA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Must be prescribed by a rheumatologist or under consult of a rheumatologist.

Coverage Duration

Authorization will be for 12 months unless requested by prescriber for a period of less than 12 months.

Other Criteria

Patients that have tried other medications for the treatment of rheumatoid arthritis including at least one tumor necrosis factor (TNF) antagonist, are currently receiving such medications, or are intolerant to these agents may receive Actemra with or without methotrexate.

ACTIQ/FENTORA

Affected Drugs

ACTIQ®
FENTANYL CITRATE
FENTORA®
ONSOLIS®

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 patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take at least 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events.

AMEVIVE

Affected Drugs

AMEVIVE®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Amevive will not be covered in patients diagnosed with HIV.

Required Medical Information

Plaque psoriasis involvement requirement for greater than or equal to 5% BSA [Body surface area] except in instances where (i or ii): i. Plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia OR ii. Patient meets ALL 3 of the following conditions: 1) Patient has had an inadequate response to either topical therapy OR localized phototherapy AND 2) Patient has had an inadequate response to systemic therapy AND 3) Patient has significant disability or impairment in physical or mental functioning according to the treating physician.

Age Restrictions

Greater than or equal to 16 years of age.

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist.

Coverage Duration

Plaque psoriasis or PsA [Psoriatic arthritis], 12 weeks of treatment. May get 2nd 12 weeks if other conditions met.

Other Criteria

Plaque psoriasis. Patient has chronic plaque psoriasis AND Patient has tried a systemic therapy (e. g. , MTX [methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Enbrel, Remicade, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, 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.

ANABOLIC STEROIDS

Affected Drugs

ANADROL-50®
ANDROXY®
OXANDROLONE

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage of Oxandrin AND Anadrol-50 is not recommended in the following circumstances: Anorexia. Management of weight loss. HIV-associated lipodystrophy. Chronkhite-Canada Syndrome. Antithrombin III deficiency. Heart failure in patients with idiopathic dilated cardiomyopathy (IDC), mitral regurgitation, or aortic regurgitation. Alcoholic liver disease. Athletic performance (ability) enhancement. Anadrol is contraindicated in patients with severe hepatic dysfunction, women who are or have the ability to become pregnant, carcinoma of the breast in females with hypercalcemia, and carcinoma of the breast or prostate in males.

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

ARANESP

Affected Drugs

ARANESP®

Covered Uses

All FDA approved indications not otherwise excluded from Part D worded as anemia associated with CRF [Chronic Renal Failure], including patients on dialysis and not on dialysis, if hemoglobin (Hb) is less than or equal to 11.0 g/dL for therapy initiation. If the patient has previously been receiving darbepoetin or epoetin alfa, approve only if Hb is less than or equal to 12.0 g/dL. Deny darbepoetin if hemoglobin exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia in cancer due to chemotherapy approve for 4 months if the patient has a Hb less than or equal to 10.0 g/dL or Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL and the physician anticipates a Hb decrease or the patient has comorbidities that require higher Hb levels. Also, deny darbepoetin if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia due to myelodysplastic syndrome (MDS) but do not approve if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation).

Exclusion Criteria

Anemia associated with cancer. Anemia associated with AML [Acute Myeloid Lymphoma], CML [chronic myelogenous leukemia] or other myeloid cancers. Anemia associated with radiotherapy in cancer. To enhance athletic performance. Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Anemia in patients due to acute blood loss. Anemia in heart failure. Anemia associated with the use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products). Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Hb value of less than or equal to 11.0 g/dL required for initiation of therapy in chronic renal failure (CRF). Also, in CRF [Chronic Renal Failure] Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa or darbepoetin. CRF [Chronic Renal Failure] indication should be denied if Hb exceeds 12.0 g/dL for this condition and in any situation (continuation or initiation). For anemia in cancer patients due to chemotherapy a Hb of less than or equal to 10.0 g/dL is required or if Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL the physician must anticipate a Hb decrease or the patient has comorbidities that require higher Hb levels. Deny darbepoetin in any situation that Hb is greater than 12.0 g/dL in cancer due to

chemotherapy. For MDS [Myelodysplastic syndrome], deny darbepoetin if hemoglobin is greater than 12.0 g/dL.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 3 months unless requested by prescriber for a period less than 3 months.

Other Criteria

Anemia due to myelodysplastic syndrome (MDS) but treatment with darbepoetin is not allowed if Hb greater than 12.0 g/dL at anytime point.

ARZERRA

Affected Drugs

ARZERRA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.

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 requested by prescriber for a period of less than 12 months.

Other Criteria

Physician documentation of either Rituximab non response or contraindication required.

B VS D - PART B VERSUS PART D COVERAGE PA

Affected Drugs

AZASAN®
AZATHIOPRINE
CARIMUNE NF NANOFILTERED®
CELLCEPT®
CYCLOPHOSPHAMIDE
CYCLOSPORINE
CYCLOSPORINE MODIFIED
EMEND®
FLEBOGAMMA®
GAMASTAN S-D®
GAMMAGARD LIQUID®
GAMUNEX®
GENGRAF
GRANISETRON HCL
GRANISOL
METHOTREXATE
MYCOPHENOLATE MOFETIL
MYFORTIC®
OCTAGAM®
ONDANSETRON HCL
ONDANSETRON ODT
POLYGAM S-D®
PRIVIGEN®
PROGRAF®
RAPAMUNE®
TACROLIMUS ANHYDROUS

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.

BOTOX

Affected Drugs

BOTOX®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

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 [Headache] specialist.

Coverage Duration

Authorization will be for 3 months unless requested by prescriber for a period less than 3 months.

Other Criteria

Primary axillary hyperhidrosis 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. 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 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. 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 [Tricyclic Antidepressants], 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 [Selective Serotonin Reuptake Inhibitors], psychostimulants). Fibromyalgia if after a trial of at least 2 or more commonly used pharmacologic therapies (eg, TCAs [Tricyclic Antidepressants], SSRIs [Selective Serotonin Reuptake Inhibitors], SNRIs [Selective Norepinephrine reuptake inhibitors], dopamine agonists, and sedative hypnotics, or lidocaine injection into trigger points).

CELEBREX

Affected Drugs

CELEBREX®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

For diagnosis other than the treatment to reduce the number of adenomatous colorectal polyps in a FAP, celebrex will not be approved if patient has tried fewer than 2 other NSAIDs [Non-steroidal anti-inflammatory drugs] or is currently on a daily aspirin regiment. Patients with any of the following risk factors will be allowed Celebrex without the NSAID [Non-steroidal anti-inflammatory drug] failure requirement: History of GI bleed/ulcer, Active peptic ulcer disease, Current daily or every other day use of oral corticosteroids, Current stable use of anticoagulants, or over the age of 65.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months unless requested by prescriber for a period of less than 12 months.

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

CIMZIA

Affected Drugs

CIMZIA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

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

26 weeks/induce remission or 12 months for maint of remission.

Other Criteria

N/A

DRONABINOL

Affected Drugs

DRONABINOL

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Dronabinol is indicated for nausea and vomiting associated with chemotherapy where the patient has failed to respond to other conventional antiemetics. Marinol is also indicated in the treatment of anorexia associated with weight loss in patients with AIDS. According to the National Comprehensive Cancer Network antiemetic guidelines Marinol is recommended for breakthrough treatment (failure) of chemotherapy induced nausea and vomiting. NCCN guidelines recommend a different class of medications than previously tried.

Exclusion Criteria

Coverage may not be allowed in patient with history of psychiatric illnesses or other chemical dependency due to the abuse potential of the medication. 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

EMSAM

Affected Drugs

EMSAM®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Emsam needs to be prescribed and monitored by a practitioner experienced in psychiatry (psychiatrist or NP with a specialty in GeriPsych) and The prescriber must obtain a release from the patient to share information with the PCP.

Coverage Duration

Authorization will be for 12 months unless requested by prescriber for a period of less than 12 months.

Other Criteria

Emsam is only allowed if failed/intolerant to at least 1 SSRI [Selective Serotonin Reuptake Inhibitor] OR at least 1 TCA [Tricyclic Antidepressant] OR bupropion OR venlafaxine. Patient must have a minimum washout period of 1 week after taking any of the following medications: Antidepressants [SSRIs, eg, Zoloft® (sertraline), Paxil® (paroxetine): SNRIs [Selective Norepinephrine reuptake inhibitors], eg, Effexor® (venlafaxine), Cymbalta® (duloxetine): TCAs [Tricyclic Antidepressants], eg, Tofranil® (imipramine), Elavil® (amitriptyline): MAOIs, eg, Marplan® (isocarboxazid), Nardil® (phenelzine), Parnate® (tranylcypromine): Remeron® (mirtazapine): Wellbutrin® (bupropion)]; other medicines that contain selegiline (eg, Eldepryl®): the herbal supplement St. John's wort: certain pain medicines [eg, Demerol® (meperidine), Ultram® (tramadol), Dolophine® (methadone), Talwin® (pentazocine), or Darvon® (propoxyphene)]; Flexeril® or other medicines that contain cyclobenzaprine, a medicine used to treat muscle spasms: BuSpar® (buspirone), an anxiety medicine (if used with transdermal patch): certain seizure medicines [eg, Tegretol® (carbamazepine) and

Trileptal«* (oxcarbazepine)]: Zyban«* (bupropion): and amphetamines, Cold/cough preparations and over-the-counter diet pills or herbal weight loss products containing pseudoephedrine, phenylephrine, phenylpropanolamine, dextromethorphan, or ephedrine: herbal or dietary supplements that contain tyramine. Patient must have a minimum washout period of 2 weeks after taking any of the following medications: BuSpar«* (buspirone), an anxiety medicine and Prozac«*(fluoxetine), an SSRI [Selective Serotonin Reuptake Inhibitor] antidepressant. A washout period up to 5 weeks may be required for certain patients.

ENBREL

Affected Drugs

ENBREL®

Covered Uses

All FDA approved indications not otherwise excluded from Part D plus patient already on Enbrel. Juvenile spondyloarthritis. Patient has tried at least 1 other DMARD [Disease-modifying antirheumatic drug]. Undifferentiated spondyloarthritis. Reactive arthritis. Patient has tried an NSAID [Non-steroidal anti-inflammatory drug] and at least 1 DMARD [Disease-modifying antirheumatic drug]. Adult with Still's disease. Patient has tried 1 DMARD [Disease-modifying antirheumatic drug] or is currently on MTX [methotrexate]. Uveitis (noninfectious) in children. Patient has tried topical (ophthalmic) or systemic corticosteroids, MTX [methotrexate] or cyclosporine. Amyloidosis(primary). Patient has tried 1 other therapy. Amyloidosis with renal involvement. Patient has tried 1 DMARD [Disease-modifying antirheumatic drug] or is currently receiving MTX [methotrexate]. Chronic inflammatory demyelinating polyneuropathy. Patient has tried 2 of the following, IVIG [Intravenous Immune Globulin], a corticosteroid, plasmapheresis, azathioprine, cyclosporine, cyclophosphamide, interferon alfa. Scleritis or Sterile Corneal Ulceration. Patient has tried 1 other therapy (eg, oral, topical(ophthalmic) or IV corticosteroids, MTX [methotrexate], topical(ophthalmic)NSAID, cyclosporine, cyclophosphamide). Myasthenia gravis. Patient is receiving corticosteroids and at least 1 other immunosuppressant (eg, azathioprine, cyclosporine, cyclophosphamide, Cellcept). Acute or chronic GVHD [Graft-Versus-Host disease]. Patient is being managed in a transplant center and has tried 1 conventional therapy (eg, highdose corticosteroid, Cellcept, list) or is concurrently receiving at least 1 of the medications with Enbrel. Behcet's disease. Patient has not responded to at least one conventional therapy(eg, corticosteroids, immunosuppressives(list), RoferonA). Hidradenitis suppurativa. Patient has tried 1 other therapy (eg, intralesional or oral corticosteroids, antibiotics, isotretinoin). Dermatomyositis or polymyositis. Patient has not responded to 2 conventional therapies(IVIG, steroids, immunosuppressants(list)or if these therapies are contraindicated or not tolerated. Inclusion body myositis. Pyoderma gangrenosum. Patient has 1 other systemic therapy(eg, intralesional corticosteroids or cyclosporine(for local), systemic corticosteroids or immunosuppressants(list). Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, mucous membrane pemphigoid [cicatricial pemphigoid]). Patient has tried conventional therapy (systemic corticosteroids AND immunosuppressive agents(list)) or has contraindications. Systemic sclerosis (scleroderma). Patient has inflammatory joint involvement and has tried an NSAID [Non-steroidal anti-inflammatory drug] and at least 1 DMARD [Disease-modifying antirheumatic drug].

Exclusion Criteria

Pulmonary sarcoidosis ocular sarcoidosis prevention of peri-prosthetic osteolysis primary sclerosing cholangitis ITP [Immune thrombocytopenic purpura] Sjogren's syndrome MDS [Myelodysplastic syndrome] Hepatitis C Sciatica Wegener's granulomatosis Immune mediated cochleovestibular disorders Graves ophth Not with anakinra or abatacept other indications* Coverage not recommended for anything not listed under Covered Uses Alopecia areata, Alopecia totalis, alopecia universalis. Asthma. Crohn's disease. Graves ophthalmopathy. Hepatitis C. Immune-mediated cochleovestibular disorders (autoimmune sensorineural hearing loss, autoimmune inner ear disease, immune-mediated Meniere's disease). Immune thrombocytopenic purpura (ITP). Myelodysplastic syndrome (MDS). Prevention of peri-prosthetic osteolysis. Primary sclerosing cholangitis. Sarcoidosis, ocular. Sarcoidosis, pulmonary. Sciatica. Sjogren's syndrome. Wegener's granulomatosis. Enbrel should not be given in combination with Kineret or Orencia. Intra-articular injection. Cancer anorexia/weight loss syndrome. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Plaque psoriasis: Patient has minimum BSA [Body surface area] involvement with plaque psoriasis of greater than or equal to 5% except if (i or ii): i. Patients with plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia OR ii. The patient meets all 3 of the following conditions: 1) Patient has had an inadequate response to either topical therapy OR localized phototherapy AND 2) Patient has had an inadequate response to systemic therapy and 3) Patient has significant disability or impairment in physical or mental functioning according to the treating physician.

Age Restrictions

N/A

Prescriber Restrictions

Plaque psoriasis. Prescribed by a dermatologist.

Coverage Duration

12 months.

Other Criteria

Adults with RA [Rheumatoid Arthritis]. Approve if the patient has tried 1 DMARD [Disease-modifying antirheumatic drug] for at least 2 months or is concurrently receiving MTX [methotrexate]. Other agents (eg. Humira, Remicade) should be tried first, this is in

addition to having tried a DMARD [Disease-modifying antirheumatic drug] such as auranofin, aurothioglucose, azathioprine, cyclosporine, d-penicillamine, gold sodium thiomalate, hydroxychloroquine, leflunomide, MTX [methotrexate] or sulfasalazine. Some patients with unfavorable prognostic factors (eg, early age of disease onset, high titer of rheumatoid factor, increased ESR, swelling of greater than 20 joints, extraarticular manifestations of RA [Rheumatoid Arthritis]) or with joint erosions may be started early on biologic agents patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis. Plaque psoriasis: Patient has chronic plaque psoriasis AND Patient has tried at least 1 systemic therapy (such as MTX [methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Humira, Remicade, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil OR oral methoxsalen plus UVA light [PUVA]).

ERYTHROID STIMULANTS

Affected Drugs

PROCRIT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF) (or renal insufficiency), including patients on dialysis and not on dialysis, if hemoglobin (Hb) is less than or equal to 11.0 g/dL for therapy initiation. If the patient has previously been receiving darbepoetin or epoetin alfa, approve only if Hb is less than or equal to 12.0 g/dL. Deny darbepoetin if hemoglobin exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemic patients with HIV who are receiving zidovudine therapy if Hb is less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 munits/mL and deny epoetin alfa if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia in cancer due to chemotherapy approve for 3 months if the patient has Hb less than or equal to 10.0 g/dL or Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL and the physician anticipates a Hb decrease or the patient has comorbidities that require higher Hb levels. Also, deny epoetin alfa if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia due to myelodysplastic syndrome (MDS) but do not approve if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia in HIV-infected patients if Hb is less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 mUnits/mL but deny if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Treatment of aplastic anemia if prescribed by a hematologist and to deny if Hb exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation).

Exclusion Criteria

Anemia associated with cancer. Anemia associated with acute myeloid leukemia (AML), chronic myelogenous leukemia (CML) or other myeloid cancers. Anemia associated with radiotherapy in cancer. 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 (SLE). Treatment of anemia in rheumatoid arthritis (RA). Treatment of anemia in inflammatory bowel disease (IBD) (e. g. , ulcerative colitis, Crohn's disease). Treatment of anemia in diabetes

mellitus. Hemochromatosis. Anemia in patients due to acute blood loss. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Hb value of less than or equal to 11.0 g/dL required for initiation of therapy in chronic renal failure (CRF). Also, in CRF [Chronic Renal Failure] Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa or darbepoetin. CRF [Chronic Renal Failure] indication should be denied if Hb exceeds 12.0 g/dL for this condition and in any situation (continuation or initiation). Anemic patients with HIV receiving zidovudine and in those with anemia due to HIV the Hb has to be less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 mUnits/mL also to deny if Hb exceeds 12.0 g/dL. For anemia in cancer patients due to chemotherapy a Hb of less than or equal to 10.0 g/dL is required or if Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL the physician must anticipate a Hb decrease or the patient has comorbidities that require higher Hb levels. Deny darbepoetin in any situation that Hb is greater than 12.0 g/dL in cancer due to chemotherapy. For anemic patients who are undergoing surgery the Hb has to be equal to or less than 13.0 g/dL. For MDS [Myelodysplastic syndrome], deny darbepoetin if hemoglobin is greater than 12.0 g/dL. For the treatment of aplastic anemia deny if Hb exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Patients must be on an iron supplement if tolerated. A request will not be approved for a member with serum ferritin less than 100 ng/ml or transferrin saturation less than 20% unless member is concurrently prescribed an iron supplement.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 3 months, unless otherwise specified.

Other Criteria

CONTINUATION OF THERAPY Approvals are issued for three months. Given recent FDA warnings, labs are monitored and dosing is discussed and modified with the prescriber as appropriate. If the member's hemoglobin is between 11 - 12g/dl, the drug will be approved if the dose is reduced by 25%. Continuation of therapy will not be approved with a hemoglobin that is greater than 12g/dl. If the member's hemoglobin

exceeds 12 g/dl, the dose will be withheld until the hemoglobin drops below 11 g/dl: with a reduction in dose by 25% after the hemoglobin reaches 11 g/dl or lower. Withhold the dose of the ESA if the hemoglobin increase exceeds 12 g/dL or rises by 1g/dL in any 2 week period. If after 3 months there is no increase in the member's hemoglobin, a letter will be sent to the prescriber stating that the benefit of therapy must be substantiated and this is the last approval. If after 6 months there is no increase in hemoglobin, the prescriber will need to substantiate the benefit of continuation of therapy or no further approvals will be issues.

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 [Bone mass density] (defined as (ie, BMD [Bone mass density] 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

NORDITROPIN NORDIFLEX®

NORDITROPIN®

SAIZEN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus mcg/L, if GH [growth hormone] peak is between 10 and 20 mcg/L with this test, then the clinical context should be considered or a second provocative test should be done. For retesting the transition adolescent with childhood onset GH [growth hormone] deficiency, the peak GH [growth hormone] response for the insulin tolerance test, arginine alone, or glucagon must be less than 5 mcg/L and for GHRH [growth hormone releasing hormone] plus arginine must be less than or equal to 20 mcg/L. Arginine alone may be used in a transition adolescent who is not obese. A GH [growth hormone] stimulation test is not required in adults with childhood-onset GH [growth hormone] deficiency who have known mutations, embryopathic lesions, or irreversible structural lesions/damage. OR both of the following if there is no GH [growth hormone] stimulation testing, patient has 2 or more of the following pituitary hormone deficiencies TSH deficiency, ACTH deficiency, gonadotropin deficiency (LH and/or FSH deficiency are counted as 1 deficiency), and AVP deficiency (central diabetes insipidus) AND Serum IGF-I less than 84 mcg/L (11 nmol/L) using the Esoterix Endocrinology competitive binding RIA. Other causes of low serum IGF-I must be excluded (eg, malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy) before using IGF-I as a marker of GH [growth hormone] deficiency. Serum IGF-I alone is not specific enough for diagnosis. Turner's syndrome. Demonstrated by chromosome analysis. Child with SHOX (short stature homeobox-containing gene) deficiency. Demonstrated by chromosome analysis and epiphyses are not closed. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Child must have been born SGA [Short child born small for gestational age], defined as birth weight and/or birth length that is greater than 2 SD below the mean for gestational age and gender and did not have sufficient catch-up growth before age 2 AND child is greater than or equal to 2 years and less than or equal to 8 years OR If child is greater than 8 years and prepubertal, coverage is recommended for 1 year on a trial basis AND If growth increases by greater than or equal to 3 cm/year in addition to their baseline growth with therapy, then authorize for continued therapy OR If the child is greater than 8 ys and is clearly pubertal, then no exception AND baseline height is less than third percentile (greater than 2 SD below the mean for gender and age). Child with Noonan syndrome. Baseline height must be less than third percentile (greater than 2 SD below

the mean for gender and age for children without Noonan syndrome). Short bowel syndrome. Adult is receiving specialized nutritional support (defined as a high carbohydrate, low-fat diet adjusted for individual requirements and preferences) AND therapy is limited to one 4-week course per year. Patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis for more than 4 weeks treatment or more than one 4-week/ year.

Exclusion Criteria

Constitutional delay of growth and puberty. Familial short stature (normal short stature). 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

Children with acquired GH [growth hormone] deficiency. Documented GH [growth hormone] stimulation testing with 1 test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon) showing deficiency defined by a diminished serum GH [growth hormone] response to stimulation testing of less than 10 ng/mL AND baseline height less than the third percentile for gender and age AND pretreatment height velocity in child less than 3 years of less than 7 cm/year and in child greater than or equal to 3 years of less than 4 cm/year OR child of any age growth velocity less than the tenth percentile for age and gender based on at least 6 months of data. Child who has undergone brain radiation does not have to meet criteria for baseline height. . Congenital hypopituitarism does not have to meet criteria for height or growth velocity. Child who has had a hypophysectomy does not have to meet any criteria. Non-GH

[growth hormone] deficient short stature (idiopathic short stature) in child with open epiphyses. 6 month trial. Baseline height less than third percentile (ie, greater than 2 SD below the mean for gender and age AND pretreatment height velocity in child less than 3 years of less than 7 cm/year and in child greater than or equal to 3 years of less than 4 cm/year OR child of any age growth velocity less than the tenth percentile for age and gender based on at least 6 months of data AND pediatric endocrinologist must certify that the child's ability to participate in basic activities of daily living is limited by their short stature and the child has a condition for which GH [growth hormone] is effective (or will possibly be effective during the initial trial of therapy) AND pediatric endocrinologist must certify that based on bone-age x-ray, the predicted adult height is less than the third percentile. The 6-month trial of GH [growth hormone] is to establish that the child's condition responds to GH [growth hormone] therapy. Authorization for continued therapy is based on an adequate clinical response defined as an annualized growth rate that doubles in comparison to the previous year.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Short bowel 4 weeks. NonGH stature 6 months. Adult HIV wasting 24 weeks. HIV failure to thrive 12 weeks.

Other Criteria

Therapy should be discontinued if there is no significant increase in growth rate during the first year. Adult GH [growth hormone] 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 [growth hormone] stimulation test as follows, 1 of the following stimulation tests must be used (insulin tolerance, glucagon, GH [growth hormone] releasing hormone (GHRH) plus arginine, or GHRH [growth hormone releasing hormone] plus GH [growth hormone] releasing peptide (GHRP-6). Arginine alone may be used in non-obese adolescents with childhood onset. Cutoff values for GH [growth hormone] peak for each test are For the insulin tolerance or glucagon peak less than 3 mcg/L, For GHRH [growth hormone releasing hormone] 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 weeks of therapy or more than one 4-week course per year. 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 [growth hormone] therapy and will continue antiretroviral therapy throughout the course of GH [growth hormone] treatment AND Therapy with GH [growth hormone] is limited to 24 weeks. Repeat 12 or 24-week courses of GH [growth hormone] may be authorized in patients who have received a previous 12 or 24-week course of GH [growth hormone] for HIV infection with wasting or cachexia provided that they have been off GH [growth hormone] for at least 1 month and meet all of the previous criteria. HIV-associated failure to thrive. Child less than 17 years 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 [growth hormone] therapy and will continue antiretroviral ther.

HUMIRA

Affected Drugs

HUMIRA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D plus patients already started on adalimumab. Uveitis (noninfectious) in children. Approve if patient has tried topical (ophthalmic) or systemic corticosteroids, MTX [methotrexate], Enbrel, Remicade, Cellcept or cyclosporine. Uveitis or other systemic manifestations of Behcet's disease in adults. Approve if patient has tried topical (ophthalmic) or systemic corticosteroids, MTX [methotrexate], Enbrel, Remicade, Cellcept or cyclosporine. Sarcoidosis. Approve if patient has tried corticosteroids and immunosuppressive agents (MTX, azathioprine, cyclosporine, chlorambucil) or thalidomide or chloroquine. Pyoderma gangrenosum. Approve if patient has tried 1 other systemic therapy (eg, intralesional injections of corticosteroids or cyclosporine [for localized pyoderma gangrenosum], systemic corticosteroids or immunosuppressants such as azathioprine/6-mercaptopurine, cyclosporine, cyclophosphamide, chlorambucil, Remicade).

Exclusion Criteria

Sciatica. Humira should not be given in combination with Kineret or Orencia. Children with Crohn's disease. Osteoarthritis. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Plaque psoriasis. Patient has minimum BSA [Body surface area] involvement with plaque psoriasis of greater than or equal to 5%. Exceptions to the requirement for greater than or equal to 5% BSA [Body surface area] involvement in the following instances (i or ii):i. Patients with plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia are not required to have a minimum BSA [Body surface area] involvement OR ii. The patient who meets all 3 of the following conditions is not required to have a minimum BSA [Body surface area] involvement:Patient has had an inadequate response to either topical therapy OR localized phototherapy and Patient has had an inadequate response to systemic therapy (See other Criteria for list) and Patient has significant disability or impairment in physical or mental functioning according to the treating physician.

Age Restrictions

Crohn's disease adults only. Uveitis in children. 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 12 weeks/induce remission or 12 months for maint of remission. 12 months all other indications.

Other Criteria

Adults with RA [Rheumatoid Arthritis]. Approve if the patient has tried 1 DMARD [Disease-modifying antirheumatic drug] for at least 2 months or is concurrently receiving MTX [methotrexate]. Some patients with unfavorable prognostic factors (eg, early age of disease onset, high titer of rheumatoid factor, increased ESR, swelling of greater than 20 joints, extraarticular manifestations of RA [Rheumatoid Arthritis]) or with joint erosions may be started early on biologic agents, patients will be evaluated by a pharmacist and/or physician on a case-by-case basis. Crohn's Disease, active (to induce remission). Approve 12 weeks in adults if patient has tried corticosteroids or if corticosteroids are contraindicated or if the patient is currently on corticosteroids to avoid increasing the dose of the corticosteroid). After 12 weeks patients are evaluated for response and further authorization for maintenance of remission. If patients do not respond by week 12 additional therapy does not result in significantly more responses. Crohn's Disease (to maintain remission). If the patient (adult) has received 2 doses of adalimumab to induce remission or has had 12 weeks of therapy with adalimumab and has had a response to therapy, then authorization is recommended for 12 months. Further authorization is not recommended if there is no response by week 12. OR If the patient (adult) has not received Humira for induction of remission, then authorize Humira for maintenance (i. e. , for 12 months) if the patient has tried azathioprine, 6-mercaptopurine, or MTX [methotrexate] or if Humira will be used concurrently with one of these drugs OR if the patient has tried Remicade and Humira will be used concurrently with azathioprine, 6-mercaptopurine or MTX [methotrexate]. Patients with fistulizing Crohn's disease must meet the above criteria for Crohn's disease, active (to induce or maintain remission), since Humira is not FDA approved for fistulizing Crohn's disease. Plaque psoriasis in patients without psoriatic arthritis. Approve if Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND Patient has tried a systemic therapy (eg, MTX [methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Enbrel, Amevive, Remicade, Raptiva, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis. JIA [Juvenile Idiopathic Arthritis] or JRA [Juvenile Rheumatoid Arthritis], polyarticular

course. Approve if the patient has tried MTX [methotrexate] or will be starting on Humira concurrently with MTX [methotrexate]. Approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate] (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Patients with aggressive disease, as determined by the prescribing physician, may be started early on a biologic agent (such as Humira), patients will be evaluated by a pharmacist and/or physician on a case-by-case basis.

INCRELEX

Affected Drugs

INCRELEX®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Patients with primary IGFD [Increlex growth forum database] 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 [Increlex growth forum database] 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

INVEGA

Affected Drugs

INVEGA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. For a stabilized patient that is new to the plan or patients with compliance and/or failure issues of other drugs within the class.

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 requested by prescriber for a period of less than 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 rheumatoid arthritis polyarticular course. Patient has tried Enbrel. Systemic onset JIA [Juvenile Idiopathic Arthritis]. Patient has tried a systemic corticosteroid. Ankylosing spondylitis. Patient has tried Enbrel, Remicade, or Humira. Adult with Still's disease. Patient has tried 1 DMARD [Disease-modifying antirheumatic drug] or is currently on MTX [methotrexate]. Muckle-Wells syndrome. Patient has tried 2 other drugs (eg, colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, Cellcept, Remicade) for MWS. Neonatal Onset Multisystem Inflammatory disease or Chronic infantile neurological cutaneous and articular (CINCA) syndrome. Schnitzler's syndrome. Patient has tried 1 other prescription medication. Acute gout. Patient has tried standard therapies (NSAID, colchicine, corticosteroid). Familial Mediterranean fever. Patient has tried colchicine.

Exclusion Criteria

Osteoarthritis, symptomatic. Lupus arthritis. Anakinra should not be given in combination with TNF [Tumor necrosis factor] blocking agents (Enbrel, Humira, Remicade) 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

Authorization will be for 12 months unless requested by prescriber for a period less than 12 months.

Other Criteria

Adults with RA [Rheumatoid Arthritis]. Approve if the patient has tried 1 DMARD [Disease-modifying antirheumatic drug] for at least 2 months or is concurrently receiving

MTX [methotrexate] AND anakinra is formulary. If anakinra is nonformulary, then Enbrel, Humira, or Remicade must be tried first, this is in addition to having tried a DMARD [Disease-modifying antirheumatic drug] such as auranofin, aurothioglucose, azathioprine, cyclosporine, d-penicillamine, gold sodium thiomalate, hydroxychloroquine, leflunomide, MTX [methotrexate] or sulfasalazine. Some patients with unfavorable prognostic factors (eg, early age of disease onset, high titer of rheumatoid factor, increased ESR, swelling of greater than 20 joints, extraarticular manifestations of RA [Rheumatoid Arthritis]) or with joint erosions may be started early on biologic agents patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

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 and doses as follows: Prostate cancer (Lupron Depot 30 mg [4-month], 22.5 mg [3-month] and 7.5 mg OR Eligard 7.5 mg, 22.5 mg, 30 mg and 45 mg), Endometriosis (Lupron Depot 3.75 mg and 11.25 mg [3-month]), Uterine leiomyomata (Lupron Depot 3.75 mg and 11.25 mg [3-month]), Treatment of central precocious puberty (Lupron Depot Ped 7.5 mg, 11.25 mg, and 15 mg). Ovarian cancer (Lupron Depot 3.75 mg and 7.5 mg). Breast cancer (Lupron Depot). Preserve ovarian function in women undergoing chemotherapy (Lupron Depot). Induce amenorrhea during bone marrow transplant (Lupron Depot 7.5 mg). Premenstrual syndrome (Lupron Depot 3.75 mg and 7.5 mg) in patients who have tried two other therapies (e.g., SSRIs [Selective Serotonin Reuptake Inhibitors], oral contraceptives). Menstrual migraine (Lupron Depot 3.75 mg) after 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). Catamenial pneumothorax (Lupron 3.75 mg and 7.5 mg). Paraphilias (Lupron Depot 3.75 mg and 7.5 mg). Dysfunctional uterine bleeding. Lymphangiomyomatosis (Lupron Depot 3.75 mg and 11.25 mg).

Exclusion Criteria

PCOS [Polycystic ovarian syndrome]. Hirsutism. BPH [Benign Prostatic Hypertrophy]. 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 months.

Other Criteria

N/A

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 [Acute Myeloid Lymphoma] receiving chemotherapy, cancer patients receiving BMT [Bone Marrow Transplant], 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 [Bone Marrow Transplant] 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

NOXAFIL

Affected Drugs

NOXAFIL®

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 3 months unless requested by prescriber for a period less than 3 months.

Other Criteria

N/A

ORENCIA

Affected Drugs

ORENCIA®

Covered Uses

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

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 requested by prescriber for a period less than 12 months.

Other Criteria

N/A

PEGYLATED INTERFERONS

Affected Drugs

PEGASYS®

Covered Uses

All FDA approved indications not otherwise excluded from Part D plus (note all are in patients with Hepatitis C). Patient coinfecting with Hepatitis C and hep B. Acute Hepatitis C. It is at least 2 to 4 months after acute onset. Retreatment of Hepatitis C. Genotype 1 Hepatitis C extending therapy to 72 weeks. Not coinfecting with HIV and not previously treated with interferon/peginterferon if HCV RNA has decreased by greater than or equal to 2 log 10 but still detectable at week 12 AND virus undetectable at week 24 then allow total 72 weeks. Recurrent Hepatitis C after liver transplant and grade II fibrosis or greater. Chronic Hepatitis C on waiting list for liver transplant. Administered in a liver clinic affiliated with a liver transplant program. Any indication besides Hepatitis C.

Exclusion Criteria

Children less than 18 years old. Maintenance treatment of Hepatitis C extending treatment to 72 weeks or longer (one exception for 72 weeks for genotype 1 Hepatitis 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. Response assessed after 12 weeks. 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 or equal to 18 years of age.

Prescriber Restrictions

For all patients with hepatitis C, must be prescribed by an infectious disease physician, gastroenterologist, hepatologist, or a transplant physician or in consultation

with these physicians. Recurrent Hepatitis C after liver transplant and grade II fibrosis or.

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

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

reassess after 24 weeks. 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 weeks If HCV RNA is decreased by greater than or equal to 2 log₁₀ or virus undetectable authorize 24 more weeks OR If HCV RNA has not decreased by greater than or equal to 2 log₁₀ or virus undetectable no authorization.

PROVIGIL

Affected Drugs

NUVIGIL®
PROVIGIL®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Alcoholic organic brain syndrome. Enhancement of performance in situations of induced sleep deprivation. Fibromyalgia. ALS [Amyotrophic Lateral Sclerosis]. Primary insomnia with symptom of EDS [Excessive daytime sleepiness]. Adjunctive therapy in the treatment of schizophrenia. Seasonal affective disorder. Post-stroke sleep-wake disorders or sleep disorders. ADHD [Attention Deficit Hyperactive Disorder] and ADD [Attention Deficit Disorder] for patients aged greater than 16 years who have not tried two alternative medications from two different classes as follows: methylphenidate products, amphetamines, atomoxetine, bupropion, or tricyclic antidepressants. Bipolar disorder, including bipolar depression. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

For the FDA-approved indication of obstructive sleep apnea/hypoapnea syndrome patients must have tried CPAP [Continuous positive airway pressure]. 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

Children less than or equal to 16 years of age.

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 unless requested by prescriber for a period of less than 12 months.

Other Criteria

For the FDA-approved indication of obstructive sleep apnea/hypoapnea syndrome patients must have tried CPAP [Continuous positive airway pressure]. 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. Fatigue associated with MS [Multiple Sclerosis]. Excessive daytime sleepiness (EDS) due to myotonic dystrophy. Adjuvant/augmentation for treatment of depression in adults if the patient has tried one other CNS stimulant. EDS [Excessive daytime sleepiness] in Parkinson's. Idiopathic hypersomnia if the diagnosis is confirmed by a sleep specialist physician or an institution that specializes in sleep disorders (e. g. , sleep center).

RANEXA

Affected Drugs

RANEXA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

RA [Rheumatoid Arthritis]nexa will require review for patients diagnosed with significant hepatic impairment or currently on a medication which is considered a strong CYP3A inhibitor or inducer.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months unless requested by prescriber for a period of less than 12 months.

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, diabetic neuropathic ulcers) that is classified as NPUAP Stage III or IV. Any clean and granulating ulcer/wound classified as NPUAP Stage II (eg, 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.

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

N/A

Age Restrictions

N/A

Prescriber Restrictions

Must be prescribed by a wound care specialist or under consult of a wound care nurse.

Coverage Duration

Authorization will be for 1 month, 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.

RELISTOR

Affected Drugs

RELISTOR®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Relistor will not be covered for patients with non opioid-induced constipation. Relistor will not be covered for patients with known or suspected mechanical gastrointestinal obstruction.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 4 months, unless requested for less than 4 months by prescriber.

Other Criteria

N/A

REMICADE

Affected Drugs

REMICADE®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage of infliximab is not recommended in the following circumstances: Ulcerative Colitis, Primary Sjögren's syndrome, Sciatica, Fistulas in patients without Crohn's disease. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

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

Patient has already been started on infliximab. Ankylosing spondylitis. Psoriatic arthritis. Plaque psoriasis in patients without psoriatic arthritis. Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND Infliximab is prescribed by a dermatologist AND Patient has minimum BSA [Body surface area] involvement with plaque psoriasis of 10%, (patients with plaque psoriasis of the palms, soles, head and neck, or genitalia are not required to have a minimum BSA [Body surface area] involvement). Wegener's granulomatosis. Adults with RA [Rheumatoid Arthritis]: If the patient has tried one DMARD [Disease-modifying antirheumatic drug] (brand or generic, oral or injectable) for at least 2 months OR is concurrently receiving MTX [methotrexate], then authorization may be given. Crohn's Disease active (to induce remission) Approve 3 doses of infliximab (weeks 0, 2, and 6) if the patient has tried corticosteroids OR if corticosteroids are contraindicated OR if the patient is currently on corticosteroids. About 8 weeks after the first 3 doses (about week 14) of infliximab patients are evaluated for response and further authorization for maintenance of

remission. Crohn's Disease (to maintain remission). If the patient has received 3 doses of infliximab to induce remission and has had a response to therapy, then authorization is recommended. Further authorization is not recommended if there is no response by week 14. Fistulizing Crohn's Disease. For enterocutaneous (perianal or abdominal) or rectovaginal fistulas approve 3 doses of infliximab (weeks 0, 2 and 6). About 8 weeks after the first 3 doses (about week 14) of infliximab patients are evaluated for response and further authorization for maintenance. Perianal fistulas may be simple or complex. If the patient has received 3 doses of infliximab and has had a response to therapy, then authorization is recommended. Further authorization is not recommended if there is no response by week 14. Indeterminate colitis (defined as colitis that cannot be classified with certainty as either ulcerative colitis or Crohn's disease), Enterovesical fistulas (bowel to bowel, bowel to bladder, bowel to urethra) in patients with Crohn's disease and Remicade is considered after the failure of at least 1 first line therapy (ie, corticosteroids, immunosuppressives [azathioprine, MTX [methotrexate], cyclosporine, tacrolimus, chlorambucil, cyclophosphamide], interferon alfa-2a [Roferon« A]), DMARDs [Disease-modifying antirheumatic drugs] (brand or generic) or other first line standards of care).

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

Coverage not recommended for anything not listed under Covered Uses. Revatio will not be approved for erectile dysfunction.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

12 months.

Other Criteria

N/A

SCHIZOP

Affected Drugs

FANAPT®
SAPHRIS®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses. Fanapt or Saphris will not be approved for the treatment of patients with dementia related psychosis.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Prescribed by a psychiatrist or in consultation with a psychiatrist.

Coverage Duration

Up to 12 months unless requested by prescriber for a period less than 12 months.

Other Criteria

N/A

SIMPONI

Affected Drugs

SIMPONI®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Plaque Psoriasis, Crohns, or Ulcerative Colitis until approved by the FDA. Coverage not recommended for anything not listed under Covered Uses. Use with MTX [methotrexate] required for treatment of Rheumatoid Arthritis.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Up to 12 months unless requested by prescriber for a period less than 12 months.

Other Criteria

N/A

SOLARAZE

Affected Drugs

SOLARAZE®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Currently the only approved Indication is the Topical Treatment of Actinic Keratoses.

Exclusion Criteria

Coverage not allowed for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

12 months, unless requested by prescriber for a period of less than 12 months.

Other Criteria

N/A

SOMAVERT

Affected Drugs

SOMAVERT®

Covered Uses

All FDA approved indications not otherwise excluded from Part D including Acromegaly and treatment of excess 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

Prescribed by an endocrinologist or in consultation with an endocrinologist.

Coverage Duration

12 months.

Other Criteria

N/A

STELARA

Affected Drugs

ISTODAX®
STELARA®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

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

Up to 12 months unless requested by prescriber for a period less than 12 months.

Other Criteria

N/A

STRATTERA

Affected Drugs

STRATTERA®

Covered Uses

ADHD [Attention Deficit Hyperactive Disorder] or ADD [Attention Deficit Disorder]. Patient has tried a formulary methylphenidate product (brand or generic), either immediate-release or sustained-release (eg, Ritalin, Ritalin SR, Metadate CD [Chron's Disease], Metadate ER, Methylin ER, Concerta): or Focalin: or an amphetamine [Adderall/Adderall XR, Dexedrine, Desoxyn], or pemoline (rarely used because of hepatotoxicity). ADHD [Attention Deficit Hyperactive Disorder] or ADD [Attention Deficit Disorder]. Considered for a patient that has a history of stimulant drug abuse or other substance abuse: \ Product labeling for the stimulants warns against their use in patients with a history of recent stimulant drug abuse or dependence. However, patients with a history of using or abusing other substances such as cigarettes, alcohol, opiates, benzodiazepines, or sedatives may use stimulants to treat ADHD [Attention Deficit Hyperactive Disorder]. A history of abuse of stimulants may not be an absolute contraindication, but these patients must be monitored more carefully than others.

Exclusion Criteria

Exception not recommended for: Patient/parent/primary caregiver has concern of drug abuse or dependence with stimulant medications. Depression without ADHD [Attention Deficit Hyperactive Disorder] or ADD [Attention Deficit Disorder]. Limited information is available on Strattera's use for treatment of major depressive disorder. Some patients with ADHD [Attention Deficit Hyperactive Disorder] may also have a diagnosis of depression and exceptions can be made as outlined in use criteria. Nocturnal enuresis.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

12 months.

Other Criteria

N/A

SYMLIN

Affected Drugs

SYMLIN®

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. Pramlintide is FDA-approved in patients with type 1 or 2 diabetes mellitus using insulin therapy. In type 2 diabetics, it is FDA-approved as combination therapy with metformin and/or sulfonylureas (in addition to insulin).

Exclusion Criteria

Weight loss treatment. Coverage not recommended for anything not listed under Covered Uses. Clinical review will be required in patients with known gastroparesis or with hypoglycemia unawareness, patients who: have poor compliance with current insulin regimen, have poor compliance with self-blood glucose monitoring, have an HbA1c greater than 9%, and those who require the use of drugs that stimulate GI motility.

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.

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).

TOPICAL TRETINOIN PRODUCTS

Affected Drugs

TRETINOIN

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus 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). For treatment of other non-cosmetic conditions not listed above (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis) exceptions can be made if the patient has tried at least 1 other therapy. Coverage of the combination of clindamycin plus tretinoin (ZianaÖ) 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

Prior authorization and prescription benefit coverage is not recommended for Renova.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Prior authorization and prescription benefit coverage is not recommended for Renova.

VFEND

Affected Drugs

VFEND®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

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. Clinical review will be required for patients currently taking CYP3A4 substrates which include: Sirolimus, Rifampin, Carbamazepine, long-acting barbiturates, high-dose ritonavir, Rifabutin, Ergot alkaloids, St. John's Wort.

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 up to 28 days, unless otherwise specified.

Other Criteria

N/A

VOLTARENGEL

Affected Drugs

VOLTAREN®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage not allowed for anything not listed under Covered Uses.

Required Medical Information

Documentation of normal transaminases at 2 month after treatment initiation and at yearly renewals required.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Up to 12 months unless requested by prescriber for a period less than 12 months.

Other Criteria

Approval requires the prescriber to document the patients or caregivers ability to properly administer the gel based on the manufactures dosing instructions. This restriction is based on the FDA announcement of the potential for increase in liver dysfunction from use of diclofenac products including the gel formulation.

XOLAIR

Affected Drugs

XOLAIR®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients with seasonal or perennial allergic rhinitis with at least moderate-to-severe symptoms.

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 [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). For EG/EE/eosinophilic colitis, biopsy with at least 15 eosinophils/HPF.

Age Restrictions

Moderate to severe persistent asthma, patient is at least 6 years old. SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis], patient is at least 12 years old.

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 an allergist, immunologist, or pulmonologist. EG, EE, and eosinophilic colitis if prescribed by, or in co.

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Patients 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 patient has a positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as the radioallergosorbent test [RAST]) for one 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) AND patient's asthma symptoms have not been adequately controlled (demo by hospitalization for asthma or requirement for systemic corticosteroids to control exacerbations or increasing need [usually more than 4 times/day] for SABAs for symptoms) by inhaled corticosteroids and LABA (if the patient has a contraindication or intolerance to use of LABAs, then one of the following agents are noted alternatives according to the GINA guidelines: SR theophylline or leukotriene modifier [eg, montelukast] and the patient must have been on concomitant therapy with an inh corticosteroid and a LABA [or listed alt or collective use of LABA followed by a listed alt(s)] for at least 3 months) AND patient is at least 6 years old. patients with SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] must meet the following criteria prescribed by an allergist, immunologist, or pulmonologist AND baseline IgE level at least 30 IU/mL AND patient has SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] as demo by positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or pos. in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for 1 or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) AND patient has tried therapy with at least 1 drug from 2 of the following groups of drugs at the same time fexofenadine, loratadine, desloratadine, or cetirizine or their combination with pseudoephedrine, a nasal corticosteroid (eg, beclomethasone, fluticasone), montelukast or patient must have tried therapy with at least 1 drug from all 3 of the above groups individually or in any combination during 1 allergy season (ie, 6 months) AND patient has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy (exceptions can be made for patients when there is no immunotherapy available for the allergen identified as causing clinically significant allergy or there are contraindications to immunotherapy) AND if the patient has allergies to animals (eg, cats, dogs), these animals have been removed from the pt's immediate environment (eg, work, home) AND the patient is at least 12 years old. Patients with EG, EE, or eosinophilic colitis must meet all of the following criteria prescribed by or in consultation with an allergist, immunologist, or gastroenterologist AND patient has tried therapy with a systemic or orally admin topical corticosteroid AND the dx has been confirmed based on biopsy showing at least 15 eosinophils per high-power field.

ZYVOX

Affected Drugs

ZYVOX®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

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

Required Medical Information

VRE [Vancomycin resistant enterococcus], cultures must be done. Methicillin-resistant Staphylococcus, cultures must be done.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be up to 28 days, unless otherwise specified.

Other Criteria

N/A

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