

2011 RxBlue PDP PA Criteria

ACTEMRA.....	9
ACTEMRA®.....	9
ALPHA-1 PROTEINASE INHIBITORS.....	10
ARALAST®.....	10
PROLASTIN®.....	10
ZEMAIRA®.....	10
AMEVIVE.....	11
AMEVIVE®.....	11
ANABOLIC STEROIDS.....	13
ANADROL-50®.....	13
OXANDRIN®.....	13
OXANDROLONE.....	13
ARANESP.....	15
ARANESP®.....	15
ARCALYST.....	17
ARCALYST®.....	17
AVONEX.....	18
AVONEX ADMINISTRATION PACK®.....	18
AVONEX®.....	18
B vs D - Part B versus Part D Coverage PA.....	19
ANZEMET®.....	19
ATGAM®.....	19
AVASTIN®.....	19

AZASAN®.....	19
AZATHIOPRINE	19
CARIMUNE NF NANOFILTERED®.....	19
CELLCEPT®.....	19
CESAMET®.....	19
CYCLOPHOSPHAMIDE	19
CYCLOSPORINE	19
CYCLOSPORINE MODIFIED.....	19
DRONABINOL	19
EMEND®	19
ENGERIX-B®.....	19
FLEBOGAMMA®	19
GAMASTAN S-D®.....	19
GAMMAGARD LIQUID®	19
GAMUNEX®	19
GENGRAF	19
GRANISETRON HCL	19
GRANISOL	19
IMURAN®	19
KYTRIL®.....	19
MARINOL®.....	19
METHOTREXATE	19
MITOXANTRONE HCL.....	19
MYCOPHENOLATE MOFETIL.....	19
MYFORTIC®.....	19

NEORAL®	19
OCTAGAM®	19
ONDANSETRON HCL.....	19
ONDANSETRON ODT	19
PHENERGAN®.....	19
PROGRAF®.....	19
PROMETHAZINE HCL	19
RAPAMUNE®.....	19
RECOMBIVAX HB®	19
RHEUMATREX®	19
SANCUSO®.....	20
SANDIMMUNE®.....	20
TACROLIMUS	20
THYMOGLOBULIN®.....	20
TREXALL®	20
ZOFRAN ODT®.....	20
ZOFRAN®	20
BANZEL	21
BANZEL®	21
BETASERON	22
BETASERON®.....	22
EXTAVIA®.....	22
BISPHOSPHONATES (IV).....	23
BONIVA®.....	23
BOTOX.....	24

BOTOX®.....	24
CEREZYME	26
CEREZYME®	26
CIMZIA.....	27
CIMZIA®.....	27
COPAXONE	28
COPAXONE®.....	28
ENBREL.....	29
ENBREL®.....	29
EPOETIN/PROCRIT	31
EPOGEN®.....	31
PROCRIT®	31
FABRAZYME	33
FABRAZYME®	33
FORTEO	34
FORTEO®.....	34
GLUCAGON-LIKE PEPTIDE-1 AGONISTS.....	35
BYETTA®	35
VICTOZA 3-PAK®	35
GROWTH HORMONES.....	36
GENOTROPIN®.....	36
HUMATROPE®	36
NORDITROPIN NORDIFLEX®.....	36
NORDITROPIN®	36
NUTROPIN AQ®	36

NUTROPIN®.....	36
OMNITROPE®.....	36
SAIZEN®.....	36
SEROSTIM®.....	36
TEV-TROPIN®.....	36
ZORBTIVE®.....	36
HUMIRA.....	39
HUMIRA®.....	39
INCRELEX.....	41
INCRELEX®.....	41
KINERET.....	42
KINERET®.....	42
LAMISIL.....	44
LAMISIL®.....	44
TERBINAFINE HCL.....	44
LETAIRIS/TRACLEER.....	46
LETAIRIS®.....	46
TRACLEER®.....	46
LEUPROLIDE (LONG ACTING).....	47
ELIGARD®.....	47
LUPRON DEPOT®.....	47
LUPRON DEPOT-PED®.....	47
LIDODERM.....	49
LIDODERM®.....	49
MYOBLOC.....	50

MYOBLOC®	50
NEULASTA	51
NEULASTA®	51
NEUPOGEN.....	52
NEUPOGEN®.....	52
NUVIGIL/PROVIGIL	53
NUVIGIL®.....	53
PROVIGIL®	53
ORAL TRANSMUCOSAL FENTANYL DRUGS	55
ACTIQ®	55
FENTANYL CITRATE	55
FENTORA®.....	55
ONSOLIS®	55
ORENCIA.....	56
ORENCIA®.....	56
PENLAC.....	57
CICLOPIROX.....	57
PENLAC®.....	57
PEGYLATED INTERFERONS	58
PEGASYS®.....	58
PEGINTRON REDIPEN®.....	58
PEGINTRON®	58
PHOSPHODIESTERASE-5 INHIBITORS FOR PAH	60
ADCIRCA®.....	60
REVATIO®	60

REBIF.....	61
REBIF®.....	61
REGRANEX.....	62
REGRANEX®.....	62
REMICADE.....	63
REMICADE®.....	63
RITUXAN.....	65
RITUXAN®.....	65
SAMSCA.....	66
SAMSCA®.....	66
SIMPONI.....	67
SIMPONI®.....	67
SOMAVERT.....	68
SOMAVERT®.....	68
SPORANOX.....	69
ITRACONAZOLE.....	69
SPORANOX®.....	69
STELARA.....	71
STELARA®.....	71
SYMLIN.....	73
SYMLIN®.....	73
SYMLINPEN 120®.....	73
SYMLINPEN 60®.....	73
SYNAGIS.....	74
SYNAGIS®.....	74

TAZORAC	75
TAZORAC®	75
TOPAMAX/ZONEGRAN	76
TOPAMAX®	76
TOPIRAMATE	76
ZONEGRAN®	76
ZONISAMIDE	76
TOPICAL RETINOID PRODUCTS	77
ATRALIN®	77
AVITA®	77
DIFFERIN®	77
EPIDUO®	77
RETIN-A MICRO®	77
RETIN-A®	77
TRETINOIN	77
TRETIN-X®	77
ZIANA®	77
VFEND	79
VFEND®	79
XOLAIR	80
XOLAIR®	80
ZYVOX	82
ZYVOX®	82
Index	83

ACTEMRA

Affected Drugs

ACTEMRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on tocilizumab. Systemic-onset juvenile idiopathic arthritis (JIA).

Exclusion Criteria

Tocilizumab should not be given in combination with tumor necrosis factor (TNF) antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), abatacept, anakinra, or rituximab. Other uses excluded from coverage include JIA types other than systemic onset, Crohn's disease, and Castleman's disease. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

Required Medical Information

N/A

Age Restrictions

For indication of systemic-onset JIA, may approve for children and adolescents 18 years of age or younger. For rheumatoid arthritis (RA), approve for adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Adults with RA, approve for patients who have tried one of the following TNF antagonists for at least 2 months, adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab, AND patient must be receiving methotrexate (MTX) or another nonbiologic disease-modifying antirheumatic drug (DMARD) (eg, hydroxychloroquine, leflunomide, sulfasalazine) in combination with tocilizumab. Patients are not required to use MTX concurrently with tocilizumab if there are contraindications to MTX or the patient has a history of intolerance to MTX or to use other nonbiologic DMARDs concurrently with tocilizumab if there are contraindications or a history of intolerance. Systemic-onset JIA, approve for patients who have tried a systemic corticosteroid, and either MTX or sulfasalazine or another DMARD such as etanercept.

ALPHA-1 PROTEINASE INHIBITORS

Affected Drugs

ARALAST®
PROLASTIN®
ZEMAIRA®

Covered Uses

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

Exclusion Criteria

Use in the management of cystic fibrosis, COPD without alpha1-antitrypsin deficiency, alpha1-antitrypsin deficiency without lung disease (even if deficiency-induced hepatic disease is present), or bronchiectasis (without alpha1-antitrypsin deficiency). Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

For AAT deficiency with emphysema (or COPD), approve in patients with baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

For AAT deficiency with emphysema (or COPD), approve in patients with baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL.

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 (PsA). Lichen planus (LP).

Exclusion Criteria

Alefacept should not be given in combination with a tumor necrosis factor (TNF) alpha antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), anakinra, or ustekinumab. Use in the management of RA, graft versus host disease, alopecia areata, alopecia universalis, pyoderma gangrenosum, or atopic dermatitis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

Greater than 16 years of age.

Coverage Duration

PP/PsA/LP, 12 wk. Hd/ft Ps, 16 wk. Approve 2nd course (exc LP), if off Amevive 12 or 16 wk, respectively.

Other Criteria

Plaque psoriasis (PP) and hand/foot psoriasis. Patients with body surface area (BSA) of 5% or more or with PP of palms, soles, head and neck, nails, intertriginous areas or genitalia must try a systemic therapy for 2 months with one of the following—methotrexate (MTX), cyclosporine, acitretin, etanercept, infliximab, adalimumab, or ustekinumab, OR phototherapy for psoriasis for 2 months with ultraviolet B (UVB) OR oral methoxsalen plus UVA light (PUVA). Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Plaque psoriasis (PP) and hand/foot psoriasis. Patient has BSA of less than 5%, approve if they have had an inadequate response to a 2-month trial of either topical therapy OR localized phototherapy (with UVB or PUVA), AND had an inadequate response to a 2-month trial of systemic therapy (MTX, cyclosporine, acitretin, etanercept, infliximab, adalimumab, or ustekinumab) or has contraindications to all of these, AND has significant disability or impairment in physical or mental functioning

according to the treating physician. PP and hand/foot psoriasis, the above criteria do not have to be met for a second course of alefacept therapy. Psoriatic arthritis. Patient has tried adalimumab, etanercept, infliximab, or golimumab for at least 2 months AND the patient will be receiving alefacept in combination with MTX. LP, patient has tried two other systemic therapies (photochemotherapy, acitretin, oral corticosteroid, mycophenolate mofetil, azathioprine, cyclosporine, oral tacrolimus, or MTX).

ANABOLIC STEROIDS

Affected Drugs

ANADROL-50®

OXANDRIN®

OXANDROLONE

Covered Uses

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

Exclusion Criteria

Coverage of oxandrolone and oxymetholone is not recommended in the following circumstances: Management of anorexia, weight gain (other than detailed in the FDA-approved indications or other covered uses), weight loss, HIV-associated lipodystrophy, Cronkhite-Canada Syndrome, antithrombin III deficiency, heart failure in patients with idiopathic dilated cardiomyopathy, mitral regurgitation, or aortic regurgitation, alcoholic liver disease, athletic performance (ability) enhancement, and anemia secondary to chronic kidney disease. Coverage of oxymetholone is not recommended in the following circumstances: Relief of bone pain due to osteoporosis or conditions other than osteoporosis. Coverage is not recommended for circumstances not listed in the Covered Uses.

Required Medical Information

N/A

Age Restrictions

Aged 8 years and older for girls with Turner's Syndrome or Ullrich-Turner Syndrome.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

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

ARANESP

Affected Drugs

ARANESP®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Anemia due to myelodysplastic syndrome (MDS). Anemia associated with use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products).

Exclusion Criteria

Any 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. Treatment of anemia of chronic disease/anemia of chronic inflammation (eg, anemia in inflammatory bowel disease [ulcerative colitis, Crohn's disease], rheumatoid arthritis, systemic lupus erythematosus). 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. An additional 6 months of therapy after initial 6 months allowed if Hb is 12.0 g/dL or less. Anemia due to ribavirin in Hep C patients. Approve therapy if Hb is 10.0 g/dL or less. Deny if Hb exceeds 12.0 g/dL in any situation.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Chemo course +8 wk after last chemo dose. Riba use/CRF=12 mos. MDS=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. Plus patient already started on riloncept for Muckle Wells Syndrome (MWS) or Familial Cold Autoinflammatory Syndrome (FCAS).

Exclusion Criteria

Use in the management of neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA), systemic juvenile idiopathic arthritis (JIA), gout, or Familial Mediterranean fever (FMF). Riloncept should not be given in combination with tumor necrosis factor (TNF) blocking agents (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), anakinra, or canakinumab. 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

Initial approval of MWS/FCAS, 2 mos. Subsequent authorization for 12 mos if patient had a response.

Other Criteria

For initial approval for MWS/FCAS, authorize for 2 months. After patient has received at least 6 weeks of therapy with riloncept and has had a response to therapy as determined by prescribing physician, then an additional authorization is allowed. Patients already started on riloncept for MWS/FCAS may receive continued authorization if they have had a response and are continuing therapy to maintain response/remission.

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 multiple sclerosis (MS) or have experienced an attack and who are at risk of MS.

Exclusion Criteria

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

B VS D - PART B VERSUS PART D COVERAGE PA

Affected Drugs

ANZEMET®
ATGAM®
AVASTIN®
AZASAN®
AZATHIOPRINE
CARIMUNE NF NANOFILTERED®
CELLCEPT®
CESAMET®
CYCLOPHOSPHAMIDE
CYCLOSPORINE
CYCLOSPORINE MODIFIED
DRONABINOL
EMEND®
ENGERIX-B®
FLEBOGAMMA®
GAMASTAN S-D®
GAMMAGARD LIQUID®
GAMUNEX®
GENGRAF
GRANISETRON HCL
GRANISOL
IMURAN®
KYTRIL®
MARINOL®
METHOTREXATE
MITOXANTRONE HCL
MYCOPHENOLATE MOFETIL
MYFORTIC®
NEORAL®
OCTAGAM®
ONDANSETRON HCL
ONDANSETRON ODT
PHENERGAN®
PROGRAF®
PROMETHAZINE HCL
RAPAMUNE®
RECOMBIVAX HB®
RHEUMATREX®

SANCUSO®
SANDIMMUNE®
TACROLIMUS
THYMOGLOBULIN®
TREXALL®
ZOFRAN ODT®
ZOFRAN®

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.

BANZEL

Affected Drugs

BANZEL®

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

12 months.

Other Criteria

N/A

BETASERON

Affected Drugs

BETASERON®
EXTAVIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of multiple sclerosis (MS) or have experienced an attack and who are at risk of MS.

Exclusion Criteria

Concurrent use of Avonex, Rebif, Copaxone or Tysabri. 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

BISPHOSPHONATES (IV)

Affected Drugs

BONIVA®

Covered Uses

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

Exclusion Criteria

Use in the management of multiple myeloma patients, patients with osteolytic lesions of multiple myeloma, treatment of osteopenia or the prevention of bone loss in cancer patients, Paget's disease of bone, osteogenesis imperfecta, or prevention or treatment of glucocorticoid-induced osteoporosis (GIO). 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

All osteoporosis uses (treatment or prevention), approve if patient has tried one oral bisphosphonate-containing product AND they had an inadequate response (determined by prescribing physician) or intolerability to oral bisphosphonate, OR patient cannot take an oral bisphosphonate-containing product due to inability to swallow, unable to remain in an upright position for designated period of time following oral bisphosphonate administration, patient has pre-existing GI medical condition in which IV therapy is preferred over oral therapy, or patient has a chronic, complex medication regimen in which oral bisphosphonate may compromise therapy (as determined by prescribing physician), OR patient is currently receiving ibandronate injection for a covered use.

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. Dysphagia. Frey's syndrome (gustatory sweating). Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome. Additional indications will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

Exclusion Criteria

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

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, 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. Headache (eg, migraine, chronic tension headache, whiplash, chronic daily headache) after a trial with at least 2 other pharmacologic therapies (eg, anticonvulsants, antidepressants, beta-blockers, calcium channel blockers, non-steroidal anti-inflammatory drugs). Palmar/plantar and facial hyperhidrosis after a trial with at least 1 topical agent (eg, aluminum chloride). Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate). 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). Tourette's syndrome if after a trial with at least 1 more commonly used pharmacologic therapy (eg, neuroleptics, clonidine, SSRIs, psychostimulants).

CEREZYME

Affected Drugs

CEREZYME®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Type 2 or 3 Gaucher disease.

Exclusion Criteria

Use in the management of Tay-Sachs disease. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

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 or the patient was referred to a center that specializes in the treatment of Gaucher disease.

Age Restrictions

N/A

Prescriber Restrictions

N/A

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

Concurrent use with tumor necrosis factor (TNF) alpha antagonists (eg, adalimumab, etanercept, golimumab, and infliximab), or anakinra, rituximab, abatacept, or natalizumab. Use for the management of plaque psoriasis. Coverage not recommended for anything not listed under Covered uses.

Required Medical Information

N/A

Age Restrictions

RA/CD, Adults.

Prescriber Restrictions

N/A

Coverage Duration

Adult RA, 12 months. Adult CD, 6 months.

Other Criteria

Adult RA, approve if the patient has tried one DMARD (brand or generic, oral or injectable) for at least 2 months (this includes patients who have tried other biologic DMARDs for at least 2 months), or the patient is concurrently receiving methotrexate (MTX). Adult CD, to induce remission. Approve if patient has tried corticosteroids or if corticosteroids are contraindicated or if patient is currently on corticosteroids. Adult CD, to maintain remission. Approve if patient has received 3 doses of certolizumab pegol to induce response/remission or has had 12 weeks of therapy with certolizumab pegol AND the patient has responded to therapy OR if the patient has not received certolizumab pegol for induction of remission then authorize if patient has tried azathioprine, 6-mercaptopurine, or MTX or if patient has tried infliximab or adalimumab.

COPAXONE

Affected Drugs

COPAXONE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of multiple sclerosis (MS) or have experienced an attack and who are at risk of MS.

Exclusion Criteria

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

ENBREL

Affected Drugs

ENBREL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept. Active juvenile spondyloarthritis. Undifferentiated spondyloarthritis (undifferentiated arthritis). Reactive arthritis (Reiter's disease). Still's disease. Uveitis (noninfectious). Scleritis or sterile corneal ulceration. Chronic inflammatory demyelinating polyneuropathy. Myasthenia gravis. Acute or chronic graft versus host disease. 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

Concurrent use with anakinra, abatacept, certolizumab pegol, ustekinumab, infliximab, rituximab, or golimumab. Intra-articular injection of etanercept. Use in the management of alopecia areata, alopecia totalis, alopecia universalis, asthma, Crohn's disease, dermatomyositis/polymyositis, inclusion body myositis, Graves ophthalmopathy, hepatitis C, alcoholic hepatitis, idiopathic pulmonary fibrosis, immune-mediated cochleovestibular disorders, immune thrombocytopenic purpura, myelodysplastic syndrome, prevention of peri-prosthetic osteolysis, primary sclerosing cholangitis, recurrent spontaneous pregnancy loss, ocular sarcoidosis, pulmonary sarcoidosis, sciatica, Sjogren's syndrome, Takayasu's arteritis, Wegener's granulomatosis, cancer anorexia/weight loss syndrome, new-onset diabetes mellitus type 1, keloids, and Alzheimer's disease. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

For patients with systemic sclerosis, the patient must have inflammatory joint involvement.

Age Restrictions

For JIA approve for children aged 2 years and older.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

RA, pt tried one DMARD for at least 2 months (includes other biologic DMARDs for at least 2 months), or the pt is concurrently receiving methotrexate (MTX). JIA or JRA, polyarticular course, patient has tried MTX or will be starting on etanercept concurrently with MTX. Approve without trying MTX if the pt has an absolute contraindication to MTX. Plaque psoriasis (PP). Pt has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. Pt has a minimum BSA of 5% or more, exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to a 2-month trial of either topical therapy OR localized phototherapy (with ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had an inadequate response to a 2-month trial of systemic therapy (with one of the following - MTX, cyclosporine (CSA), acitretin, adalimumab, alefacept, infliximab, or ustekinumab) or has contraindications to all of these, and has significant disability or impairment in physical or mental functioning according to the treating physician. Pt has tried a systemic therapy (MTX, CSA, acitretin, adalimumab, alefacept, infliximab, or ustekinumab) or phototherapy with UVB or PUVA for psoriasis for 2 months. Rarely, a pt may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Juvenile spondylarthropathy. Tried at least one other DMARD. Reactive arthritis. Tried an NSAID and at least one DMARD. Still's disease. Tried one DMARD or is currently receiving MTX for at least 2 months. Uveitis (non-infectious). Tried topical (ophthalmic) or systemic corticosteroids (SCs), MTX, or CSA. Scleritis/corneal ulcer. Tried one other therapy for these conditions. CIDP. Tried two of the following- IVIG, SC, plasmapheresis, azathioprine, CSA, cyclophosphamide, interferon alfa. Myasthenia gravis. Approve if receiving corticosteroids and have received at least one other immunosuppressive agent. GVHD. Approve if managed by a transplant center and has tried or currently is receiving with etanercept one conventional GVHD txment (high-dose SC, CSA, tacrolimus, etc.). Behcet's. Have not responded to at least one conventional therapy (eg, SCs, immunosuppressives, etc). Giant cell arteritis. Tried corticosteroids but are unable to withdraw systemic steroid therapy. HS. Tried one other therapy (eg, intralesional/oral corticosteroids, topical/systemic antibiotics, isotretinoin). PMR. Tried corticosteroids but unable to reduce dose or withdraw steroid therapy. PG. Tried one other systemic therapy (eg, intralesional corticosteroids or CSA, SCs or immunosuppressives, etc.) AMBD. Tried conventional therapy (SCs AND immunosuppressive agent) or has contraindications to conventional tx. Systemic sclerosis. Tried an NSAID AND at least one DMARD. TRAPS. Tried corticosteroids.

EPOETIN/PROCRIT

Affected Drugs

EPOGEN®
PROCRIT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13.0 g/dL or less) at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Anemia due to myelodysplastic syndrome (MDS). Anemia associated with use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products).

Exclusion Criteria

Any 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. 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 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

N/A

Coverage Duration

Chemo course +8 wk after last chemo dose. MDS=6mo. Addtl 6 mo, Hb 12 or less. Transfus=3wk. 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 those using medicine that resulted in bone loss (eg, steroids [prednisone]). For use in hypoparathyroidism (primary or secondary).

Exclusion Criteria

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

Required Medical Information

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

Age Restrictions

N/A

Prescriber Restrictions

N/A

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 regardless of risk status of the treatment of osteoporosis.

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Affected Drugs

BYETTA®
VICTOZA 3-PAK®

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

Patient has inadequate glycemic control demonstrated on two-drug therapy (eg, metformin, sulfonylurea, thiazolidinedione).

GROWTH HORMONES

Affected Drugs

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

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Growth hormone (GH) deficiency. Non-GH deficient short stature (idiopathic short stature). Turner's syndrome. SHOX (short stature homeobox-containing gene) deficiency. Chronic renal insufficiency. Prader-Willi syndrome. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Noonan syndrome. Short bowel syndrome. HIV infection with wasting or cachexia (Serostim only). HIV-associated failure to thrive (Serostim only).

Exclusion Criteria

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

Required Medical Information

Child/adolesc w/GH DF (initial tx), eval by a pediatric endocrinologist (PE), documented GH stim test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) w/GH response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile for gender/age AND pretx Ht growth rate (GR) child less than 3 yrs of less than 7 cm/yr and child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age GR less than the 10th percentile for age/gender based on at least 6 mos of data. Child w/brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or GR criteria. Child w/hypophysectomy, approve. Child/adolesc w/GH DF, cont tx, GR increased by 2.5 cm/yr or more in most recent yr (MRY) per MD AND epiphyses open (older than 12 yrs), both crit exclude adolesc w/hypopituitarism. Review pts GR annually (does not apply to hypopituitarism). Adoles/young adults who completed linear growth (GR less than 2 cm/yr), review for txment of adult GH DF. Greater than 18 yrs, auth not allowed if mid-parental ht attained. Non-GH DF short stature (ISS) child w/open epiphyses. 6 mo trial. Baseline Ht less than 3rd percentile (greater than 2 SD below mean for gender/age) AND pretx GR child less than 3 yrs of less than 7 cm/yr and child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age GR less than the 10th percentile for age/gender based on at least 6 mos of data AND PE certifies child's basic activities of daily living limited by short stature and has condition for which GH is effective (or may be effective during tx trial) AND PE certifies vis bone-age x-ray, predicted adult Ht less than 3rd percentile. Authorization after initial tx (auth for 12 mos) based on adequate clinical response (annualized GR doubles). Cont tx (after 12 to 18 mos), GR increased by 2.5 cm/yr or more in MRY per MD AND epiphyses open (older than 12 yrs). Greater than 18 yrs, auth not allowed if mid-parental ht attained.

Age Restrictions

Turner' syndrome, children. SHOX/CRI, children/adolescents. SGA, 2 to 8 yrs. Noonan, 17 yrs or younger. HIV failure to thrive, less than 17 yrs. SBS/HIV cachexia, adults.

Prescriber Restrictions

N/A

Coverage Duration

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

Other Criteria

Adult GH def (start) AND adult onset (GH alone or multiple hormone deficiencies/hypopituitarism from pituitary dz, hypothalamic dz, surgery, cranial radiation tx, tumor txment, traumatic brain injury, or subarachnoid hemorrhage) or childhood-onset AND negative response to 1 GH stimulation test (insulin tolerance [peak less than 5 mcg/L], or glucagon [peak less than 3 mcg/L]) [GHRH plus arginine may be used if available], transition adoles off somatropin 1 mo before retesting, OR 3 or more pituitary hormone deficiencies (TSH, ACTH, LH/FSH, or AVP) AND serum IGF-1 84 microg/L or less using the Esoterix ECB RIA or age/gender adjusted serum IGF-1 SDS below the 2.5 percentile. Turners, initial tx, female, and has short stature. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. SHOX, start, open epiphyses. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. CRI, start, approve. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. Prader-Willi, initial tx, approve. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. SGA/IUGR, initial tx, born SGA, AND no sufficient catch-up growth before age 4 yr, AND age 2 to 8 yrs, if older than 8 yrs, approve 1 yr trial if prepubertal, AND baseline ht less than 3rd percentile for gender/age. Cont tx, GR increased by 2.5 cm/yr or more in most recent, if aged 2 to 8 yrs, or by 3 or more cm/yr if older than 8 yrs and prepubertal. Noonan syndrome, initial tx, baseline ht less than 3rd percentile. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. HIV infection w/wasting or cachexia, HIV-positive AND have 1 of the following, documented unintentional wt loss of greater than or equal to 10% from baseline OR wt less than 90% of the lower limit of ideal body wt OR BMI less than or equal to 20 kg/m² AND able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body weight AND on antiretroviral tx greater than or equal to 30 days prior to beginning GH tx and will continue antiretroviral tx throughout GH txment. Repeat 12 or 24-wk courses of GH may be authorized after initial 12 or 24-wk GH course for HIV infection w/wasting or cachexia provided that they are off GH for at least 1 mo and meet all of previous HIV criteria. HIV-assoc failure to thrive. Able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body wt AND on antiretroviral tx for greater than or equal to 30 days prior to beginning GH tx and will continue antiretroviral tx. SBS pts eval on case-by-case basis for more than one 4-wk course per yr.

HUMIRA

Affected Drugs

HUMIRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab for non-Crohn's disease uses. Crohn's disease (CD) patients already on adalimumab. Undifferentiated spondylarthritis (undifferentiated arthritis). Crohn's disease (induction/remission) in adolescents (15 up to 18 yrs). Uveitis (noninfectious). Behcet's disease. Sarcoidosis. Pyoderma gangrenosum. Hidradenitis suppurativa.

Exclusion Criteria

Concurrent use with anakinra, abatacept, rituximab, ustekinumab, certolizumab pegol, etanercept, infliximab, or golimumab. Children aged less than 15 yrs with Crohn's disease. Use in the management of osteoarthritis, ulcerative colitis, recurrent spontaneous pregnancy loss, in vitro fertiliation (IVF). Intra-articular injection of adalimumab. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

RA, adults. Crohn's disease adults and adolescents aged 15 to up to 18 yrs.

Prescriber Restrictions

N/A

Coverage Duration

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

Other Criteria

RA, pt has tried one DMARD (brand or generic, oral or injectable) for at least 2 months (this includes patients who have tried other biologic DMARDs for at least 2 months), or the pt is concurrently receiving methotrexate (MTX). JIA/JRA polyarticular course. Tried MTX or will be starting on adalimumab concurrently with MTX. Approve without trying MTX if pt has absolute contraindication to MTX. Plaque psoriasis (PP). Pt has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. Pt has a minimum BSA of 5% or more, exceptions

allowed for patients with less than 5% BSA if they have had an inadequate response to a 2-month trial of either topical therapy OR localized phototherapy (with ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had an inadequate response to a 2-month trial of systemic therapy (with one of the following - MTX, cyclosporine (CSA), acritretin, etanercept, alefacept, infliximab, or ustekinumab) or has contraindications to all of these, and has significant disability or impairment in physical or mental functioning according to the treating physician. Pt has tried a systemic therapy (MTX, CSA, acritretin, etanercept, alefacept, infliximab, or ustekinumab) for 2 months or phototherapy with UVB or PUVA for psoriasis for 2 months. Rarely, a pt may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. CD to induce remission. Tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids (adolescents with CD must also have tried infliximab). CD to maintain remission. Pt 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 pt tried azathioprine, 6-mercaptopurine, or MTX or has tried infliximab (or certolizumab pegol for adults). Uveitis (non-infectious). Tried periocular/intraocular corticosteroids, immunosuppressants, or etanercept or infliximab. Behcet's. Pt has not responded to at least one conventional tx (eg, systemic corticosteroids, immunosuppressants, interferon alfa, or infliximab). Sarcoidosis. Tried corticosteroid and immunosuppressive agent, or infliximab, or chloroquine, or thalidomide. PG. Tried one other systemic therapy (eg, systemic corticosteroids, immunosuppressives, cyclophosphamide, chlorambucil, infliximab, or intralesional corticosteroids or CSA). HS. Tried one other therapy (eg, intralesional/oral corticosteroids, antibiotics, isotretinoin).

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. Use in patients with closed epiphyses. 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 at baseline AND Age adjusted Basal IGF-1 standard deviation score is less than or equal to -3.0 at baseline AND Growth hormone concentration is normal or increased at baseline.

Age Restrictions

Children.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

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

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 (MWS). 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

Use in the management of symptomatic osteoarthritis, lupus arthritis, or type 2 diabetes mellitus. Anakinra should not be given in combination with TNF blocking agents (etanercept, adalimumab, infliximab, certolizumab pegol, and golimumab), or abatacept, or rituximab. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

RA and Still's disease, adults.

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 adalimumab, etanercept, or infliximab for at least 2 months. JIA, JRA (regardless of onset), approve if patient has tried etanercept, adalimumab, or abatacept. Systemic onset of JIA, approve if patient has tried a systemic corticosteroid. Ankylosing spondylitis, approve if the patient has tried etanercept, infliximab, golimumab, or adalimumab. Adult with Still's disease, approve if patient has tried one DMARD or is currently receiving MTX. MWS, approve if

patient has tried two other drugs (rilonacept, canakinumab, colchicine, corticosteroids, chlorambucil, antihistamines, dapson, azathioprine, mycophenolate mofetil) for MWS. FCAS, approve if patient has tried two other drugs (eg, colchicine, corticosteroids, antihistamines, azathioprine, mycophenolate mofetil, rilonacept, or canakinumab) for FCAS. Schnitzler's syndrome, approve if patient has tried one other prescription medication used in Schnitzler's syndrome (eg, NSAIDs, antihistamines, colchicine, corticosteroids, immunosuppressive drugs). Acute gout, patient has tried 2 standard therapies for acute gout (eg, NSAIDs, colchicine, corticosteroid) or patient cannot tolerate or has contraindications to standard therapies. FMF, approve in patients who have tried colchicine. TRAPS, approve in patients who have tried corticosteroids.

LAMISIL

Affected Drugs

LAMISIL®
TERBINAFINE HCL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. The following additional approval criteria is for tablets only: Tinea corporis after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, pedis, and imbricate after a trial of a topical antifungal agent. Plantar- or moccasin-type dry tinea pedis. Black piedra. Tinea capitis. Tinea barbae. 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. Eumycetoma/mycetoma.

Exclusion Criteria

Use in the management of tinea versicolor (pityriasis versicolor), systemic fungal infections, or oral, esophageal or vaginal candidiasis. Use of topical ciclopirox 8% solution with terbinafine is not permitted. Use of Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) 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 topical ciclopirox 8% solution with terbinafine is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

N/A

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 oral azole antifungal. Other superficial fungal skin infections after a trial of a topical antifungal agent or an oral antifungal agent.

LETAIRIS/TRACLEER

Affected Drugs

LETAIRIS®
TRACLEER®

Covered Uses

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

Exclusion Criteria

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

Required Medical Information

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

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Digital ulcers, approve Tracleer if the patient has tried two other therapies for this condition such as calcium channel blockers (eg, amlodipine, felodipine, isradipine, nifedipine), alpha-adrenergic blockers (eg, prazosin), nitroglycerin, phosphodiesterase-5 inhibitors (eg, sildenafil, vardenafil), or angiotensin-converting enzyme inhibitors (ACE inhibitors), or the patient has tried one vasodilator product (eg, intravenous epoprostenol, intravenous alprostadil).

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. Osteoarthritis (OA).

Exclusion Criteria

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]). OA, approve after trying at least two other pharmacologic therapies (e.g., acetaminophen, COX-2 inhibitors, NSAIDs, salicylates, tramadol, opioids, intraarticular glucocorticoids, topical capsaicin, topical methylsalicylate, or intraarticular hyaluronan). Carpal tunnel syndrome. Approve after a trying one other pharmacological therapy used to treat carpal tunnel syndrome (e.g., steroids [oral or injectable], NSAIDs).

MYOBLOC

Affected Drugs

MYOBLOC®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus spasticity (eg, due to cerebral palsy, stroke, brain injury, etc). Hemifacial spasm. Blepharospasm. Myofascial pain. Bladder dysfunction. Salivary hypersecretion (sialorrhea). Speech/voice disorder (spasmodic dysphonias). Anal fissures. Headache (post whiplash headaches, migraine, tension-type headache). Primary hyperhidrosis (palmar or axillary). Additional indications will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

Exclusion Criteria

Use in the management of cosmetic uses (e.g., facial and/or glabellar rhytides [wrinkles, lines], crow's feet, brow lifts, platysmal bands), Carpal Tunnel Syndrome (CTS), gait freezing in Parkinson's disease, or headaches other than post-whiplash, migraine, tension-type headache (TTH).

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Blepharospasm after a trial with botulinum toxin type A. Bladder dysfunction after a trial with at least 1 other pharmacologic therapy and prescribed by or after consultation with a urologist. Headache (post whiplash headaches, migraine, tension-type headache) if after a trial with at least 2 other pharmacologic therapies and prescribed by or after consultation with a neurologist or headache specialist. Primary hyperhidrosis (palmar or axillary) after a trial with at least 1 topical agent and botulinum toxin type 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 myelosuppressive chemotherapy. Radiation injury.

Exclusion Criteria

Use after undergoing peripheral blood progenitor cell (PBPC) transplantation. Use in the management of myelodysplastic syndrome. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Radiation injury, approve if the estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged less than 60 years, or at least 2 Grays in children (aged 12 years or less) or in adults aged 60 years or older, or in those who have major trauma injuries or burns.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Radiation injury, approve if the estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged less than 60 years, or at least 2 Grays in children (aged 12 years or less) or in adults aged 60 years or older, or in those who have major trauma injuries or burns.

NEUPOGEN

Affected Drugs

NEUPOGEN®

Covered Uses

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

Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Radiation injury, approve if the estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged less than 60 years, or at least 2 Grays in children (aged 12 years or less) or in adults aged 60 years or older, or in those who have major trauma injuries or burns.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Radiation injury, approve if the estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged less than 60 years, or at least 2 Grays in children (aged 12 years or less) or in adults aged 60 years or older, or in those who have major trauma injuries or burns.

NUVIGIL/PROVIGIL

Affected Drugs

NUVIGIL®
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. EDS in Parkinson's. Idiopathic hypersomnia. Fatigue associated with HIV infection. Myasthenia gravis. Fatigue or sleepiness associated with chronic use of narcotic analgesics. Cancer-related fatigue.

Exclusion Criteria

Use in the management of alcoholic organic brain syndrome, chronic fatigue syndrome, EDS associated with primary insomnia, adjunctive therapy in the treatment of schizophrenia, seasonal affective disorder, post-stroke sleep-wake disorders or sleep disorders, bipolar disorder (including bipolar depression), fatigue and EDS in chronic traumatic brain injury, fatigue in post-polio patients, and spasticity due to cerebral palsy. 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

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

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. 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). Fatigue associated

with HIV infection/Fatigue or sleepiness due to chronic use of narcotic analgesics, if the patient has tried one CNS stimulant (eg, methylphenidate, dextroamphetamine), unless use of CNS stimulant is not clinically appropriate (eg, contraindication, comorbid condition, history of substance abuse).

ORAL TRANSMUCOSAL FENTANYL DRUGS

Affected Drugs

ACTIQ®
FENTANYL CITRATE
FENTORA®
ONSOLIS®

Covered Uses

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

Exclusion Criteria

Breakthrough Chronic (Non-Cancer) Pain. 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).

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? 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 or if the patient has tried at least one of the following biologic DMARDs, adalimumab (Humira), etanercept (Enbrel), or infliximab (Remicade), for at least 2 months or was intolerant to one of these TNF antagonists, approve without trying MTX if the patient has an absolute contraindication to MTX.

PENLAC

Affected Drugs

CICLOPIROX
PENLAC®

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 mobility, 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 topical ciclopirox 8% solution with terbinafine, itraconazole, or fluconazole (for onychomycosis use) is not permitted.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for up to 48 weeks.

Other Criteria

N/A

PEGYLATED INTERFERONS

Affected Drugs

PEGASYS®
PEGINTRON REDIPEN®
PEGINTRON®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. 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. Coinfection 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). Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Hepatitis C. depending on genotype, response in HCV RNA, liver fibrosis, HIV status, and HIV RNA. See Other Criteria and Covered Uses for details.

Age Restrictions

For acute hepatitis, coinfection w/hepatitis B and C, retreatment in pts previously txd for Hep C with interferon alfa or pegylated interferon alfa, recurrent Hep C after liver transplant, or chronic Hep C on waiting list for liver tranplant, approve for adults. For hepatitis C in children (txment, re-txment), approve if aged 2 to 17 yrs.

Prescriber Restrictions

N/A

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

Adult not previously txd for chronic hepatitis C (HC) w/ interferon alfa (IA)/peginterferon alfa (PA) and not HIV co-infected, HC genotype 2/3 authorize 24 wks initial tx, or HC genotype 3 w/ a high level of HCV RNA (per MD) or advanced fibrosis authorize 48 wks (total), or HC genotypes 1/4 authorize 12 wks initial tx (document

baseline HCV RNA) and reassess viral titer at 12 wks, if decreased by 2log₁₀ or more and virus is undetectable, authorize 36 wks (total 48 wks), or if not decreased by 2log₁₀, authorize 12 wks and reassess at 24 wks, or genotype 1 w/ viral titer decrease of 2log₁₀ but virus still detectable, authorize 12 wks and reassess at 24 wks. At 24 wk, if advanced fibrosis (via liver bx) and undetectable virus, authorize 24 wks (48 wks total), or if advanced fibrosis and detectable HCV RNA MD and pt to decide whether to cont w/ another 24 wks OR If no advanced fibrosis and do not have greater than or equal to 2 log₁₀ decrease or virus undetectable, no further authorization, or if genotype 1 w/ 2log₁₀ decrease AND detectable virus at wk 12 but no detectable virus at wk 24, then authorize for 48 wks (72 wks total, retreatment). HC viral genotype 5/6 use genotype 1/4 criteria above. Coinfected with HIV/HC (genotype 1,2,3,4) and not previously txd for HC, authorize for up to 48 wks (total). Children 2 to 17 yrs w/ HC (genotypes 1,2,3,4) who have not been previously txd for HC w/IA/PA AND not HIV co-infected, authorize 24 wks initial tx. At 24 wk, if viral titer is undetectable after 24 wks or if viral titer decreased by 2log₁₀ after 12 wks of tx, authorize 24 wks (48 wks total), or if viral titer is still detectable after 24 wks of tx, then no further authorization. Coinfected w/ HC and Hep B, authorize 48 wks. Acute hep C (ie, infection within 6 mos of exposure), authorize 6 to 12 mos of tx if at least 2 to 4 mos after acute onset. Retreatment of pts who have been previously txd for HC w/ IA or PA, authorize 48 wks. Retreatment of pts who failed to attain a sustained virologic response (SVR) [undetectable HCV RNA at the end of txment and 24 wks after txment completion] w/ PA and ribavirin is not recommended unless specific factors that contributed to the nonresponse are identified and corrected before retxment. Recurrent hep C after liver transplant, authorize 48 wks if PA prescribed by hepatologist or liver transplant MD affiliated w/ a liver transplant program. HC on waiting list for liver transplantation, authorize initial 12 wks if administered in liver clinic affiliated with liver transplant program. At 12 wks, genotype 2/3 and viral titer decreased by 2log₁₀ or more and virus undetectable authorize 24 wks total from the time pt has achieved an optimal dose of PA and ribavirin, for genotype 1 and viral titer decreased by 2log₁₀ or more and virus undetectable authorize 48 wks total from the time pt has achieved an optimal dose of PA and ribavirin, or genotype 1/2/3 and viral titer not decreased by 2log₁₀, then no further authorization.

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Affected Drugs

ADCIRCA®
REVATIO®

Covered Uses

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

Exclusion Criteria

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

Required Medical Information

For initial approval for use in PAH, approve if patient has had a right-heart catheterization to confirm diagnosis of PAH. For patients currently receiving sildenafil or tadalafil, approve if patient has a diagnosis of PAH.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

N/A

REBIF

Affected Drugs

REBIF®

Covered Uses

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

Exclusion Criteria

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

REGRANEX

Affected Drugs

REGRANEX®

Covered Uses

All FDA approved indications not otherwise excluded from Part D.

Exclusion Criteria

Prevention of ulcers/wounds. Treatment of Stage I or II ulcers/wounds. Clean and granulating ulcer/wound (e.g., pressure ulcers, venous stasis ulcers) that is classified as Stage III or IV. Clean and granulating ulcer/wound classified as Stage II (e.g., Stage II diabetic neuropathic ulcers and pressure ulcers). 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.

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.

REMICADE

Affected Drugs

REMICADE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus patients already started on infliximab for non-Crohn's disease uses. Crohn's disease (CD) patients already on infliximab. Undifferentiated spondyloarthropathy/spondyloarthritis (undifferentiated arthritis). Juvenile rheumatoid arthritis (JRA) or juvenile idiopathic arthritis (JIA), polyarticular course. Behcet's disease. Still's disease. Uveitis. Sarcoidosis. 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. Cogan's syndrome. Crohn's disease after ileocolonic resection, to reduce the chance of recurrence. Pouchitis.

Exclusion Criteria

Use in the management of primary Sjorgren's syndrome, sciatica, fistulas in pts without Crohn's disease, myelodysplastic syndrome, COPD, asthma, atopic dermatitis, renal cell carcinoma, Wegener's granulomatosis, systemic vasculitis, giant cell arteritis, Takayasu's arteritis, primary sclerosing cholangitis, inflammatory myopathies (polymyositis, dermatomyositis, inclusion body myositis), or diffuse cutaneous systemic sclerosis (scleroderma). Concurrent use with anakinra, abatacept, rituximab, ustekinumab, certolizumab pegol, etanercept, adalimumab, or golimumab. Intra-articular injection of infliximab. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Pouchitis, pt has active disease.

Age Restrictions

N/A

Prescriber Restrictions

N/A

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 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). Patient with chronic plaque psoriasis has tried a systemic therapy. Patient with Psoriatic arthritis (PsA) has tried 1 oral DMARD or Enbrel or Humira. Ulcerative colitis. Patient has tried 1 other oral or IV therapy for UC.

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.

Exclusion Criteria

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), or anakinra, or abatacept. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

RA, adults.

Prescriber Restrictions

N/A

Coverage Duration

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

Other Criteria

Adult with RA (initial course), approve if patient has tried at least 1 of the following biologic DMARDs, etanercept, certolizumab pegol, golimumab, infliximab, or adalimumab, for at least 2 months. Adult with RA (repeat course), approve if 6 or more months after the first dose of the previous rituximab regimen the patient has responded (eg, less joint pain, morning stiffness, or fatigue, or improved mobility, or decreased soft tissue swelling in joints or tendon sheaths) as determined by the prescribing physician.

SAMSCA

Affected Drugs

SAMSCA®

Covered Uses

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

Exclusion Criteria

Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

Required Medical Information

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

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

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

SIMPONI

Affected Drugs

SIMPONI®

Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus patients already started on golimumab. Ankylosing spondylitis.

Exclusion Criteria

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (e.g., adalimumab, certolizumab pegol, etanercept, infliximab), or anakinra, or rituximab, or with abatacept. Management of plaque psoriasis without psoriatic arthritis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

RA, adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

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

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.

Coverage Duration

12 months.

Other Criteria

N/A

SPORANOX

Affected Drugs

ITRACONAZOLE
SPORANOX®

Covered Uses

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

Exclusion Criteria

Management of candidiasis hypersensitivity syndrome. Itraconazole should not be administered for the treatment of onychomycosis in patients with CHF. Use of topical ciclopirox 8% solution with itraconazole is not permitted. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) 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 topical ciclopirox 8% solution with itraconazole is not permitted. Itraconazole should not be given for the treatment of onychomycosis in patients with CHF. Itraconazole is permitted for the treatment of patients with Candida onychomycosis if they have a culture positive for Candida.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

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

STELARA

Affected Drugs

STELARA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on ustekimumab.

Exclusion Criteria

Ustekinumab should not be given in combination with a tumor necrosis factor (TNF) antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), with anakinra, or with alefacept. Use in children or adolescents aged 18 years or less. Use in the management of psoriatic arthritis without plaque psoriasis. Use in the management of Crohn's disease, or multiple sclerosis. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

Adults.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months.

Other Criteria

Plaque psoriasis in adults. 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 a 3-month trial of either topical therapy OR localized phototherapy (with ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had an inadequate response to a 3-month trial of systemic therapy (with one of the following - MTX, cyclosporine, or acitretin (Soriatane)) or has contraindications to all of these, and has tried a TNF antagonist (adalimumab, etanercept, infliximab), and has significant disability or impairment in physical or mental functioning according to the treating physician. Pt has tried a

systemic therapy or phototherapy for 3 months with one of the following - MTX, cyclosporine, or acitretin (Soriatane), or phototherapy with UVB or 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. Pt has tried adalimumab, etanercept, or infliximab for plaque psoriasis.

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.

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

SYNAGIS

Affected Drugs

SYNAGIS®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D, including palivizumab use for prevention of RSV disease for the duration of one RSV season as recommended in the 2009 American Academy of Pediatrics policy statement on the use of palivizumab for prevention of RSV infections.

Exclusion Criteria

Use of palivizumab for the treatment of RSV disease. Coverage not recommended for anything not listed under Covered Uses.

Required Medical Information

N/A

Age Restrictions

Child w/ CLD/BPD or CHD must be 24 mos of age or less. Born prematurely, approve if: a. 12 mos of age or younger and born at 28 wks 6 days gestation (GT) or earlier, b. 6 mos of age or younger and born at 29 wks 0 day GT to 31 wks 6 days GT, c. child with risk factor(s) is 3 mos of age or younger and born at 32 wks 0 day GT to 34 wks 6 days GT. Child w/ congenital abnormalities of airways or a neuromuscular disease, must be 12 mos of age or younger and born at equal to or less than 34 wks 6 days GT.

Prescriber Restrictions

N/A

Coverage Duration

5 doses with an additional dose if needed.

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

TOPAMAX®
TOPIRAMATE
ZONEGRAN®
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 RETINOID PRODUCTS

Affected Drugs

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

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. For topical tretinoin products (examples include Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X, and generic topical tretinoin), additional covered uses include: 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). For topical adapalene products (examples include Differin gel, Differin cream), additional covered uses include: Acne rosacea. Actinic keratosis/treatment of precancerous skin lesions. 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, Darier's disease, molluscum contagiosum). Coverage of the combination of clindamycin plus tretinoin (Ziana) and the combination of adapalene plus benzoyl peroxide (Epiduo) is recommended for acne vulgaris ONLY.

Exclusion Criteria

Use in the treatment of 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). Use for the treatment of psoriasis. Coverage of Ziana and Epiduo 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, unless otherwise noted.

Other Criteria

For topical tretinoin products (examples include Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X, and generic topical tretinoin), approval for the treatment of other non-cosmetic conditions (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis) can be made if the patient has tried at least 1 other therapy. For topical adapalene products (examples include Differin gel, Differin cream), approval for the treatment of other non-cosmetic conditions (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis, Darier's disease, molluscum contagiosum) can be made if the patient has tried at least 1 other therapy. Coverage of the combination clindamycin plus tretinoin product (Ziana) and the combination adapalene plus benzoyl peroxide product (Epiduo) is recommended for acne vulgaris ONLY and all other indications are not recommended.

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

Use in the management of onychomycosis, treatment or prevention of vaginal or vulvovaginal candidiasis, tinea cruris, tinea manuum, tinea pedis, tinea faciei, tinea capitis, tinea barbae, tinea corporis, tinea versicolor (pityriasis versicolor), or other superficial fungal infections. Coverage is not recommended for circumstances not listed in the Covered Uses.

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

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

XOLAIR

Affected Drugs

XOLAIR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Seasonal or perennial allergic rhinitis. Eosinophilic gastroenteritis (EG), eosinophilic esophagitis (EE), or eosinophilic colitis (EC).

Exclusion Criteria

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/EC, diagnosis confirmed by biopsy with at least 15 eosinophils/HPF.

Age Restrictions

Patients aged 12 years and older. Asthma patients aged 6 to 12 years, if already started and stabilized on omalizumab.

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

Other Criteria

Moderate to severe persistent asthma must meet all criteria baseline IgE of at least 30 IU/mL AND pt has a positive skin test or in vitro testing for 1 or more seasonal or perennial aeroallergens AND patient's asthma symptoms have not been adequately controlled by concomitant use of at least 3 months of inhaled corticosteroid and a long-

acting beta-agonist (LABA), if LABA contraindicated or pt has intolerance then alternatives include sustained-release theophylline or a leukotriene modifier (eg, montelukast), or LABA alternative AND inadequate control demonstrated by hospitalization for asthma, requirement for systemic corticosteroids to control asthma exacerbation(s), or increasing need (eg, more than 4 times a day) for short-acting inhaled beta2 agonists for symptoms (excluding preventative use for exercise-induced asthma). SAR/PAR must meet the following criteria - 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 pt has tried concurrent therapy with at least one drug from 2 of the following classes, a non-sedating or low-sedating antihistamine/nasal antihistamine, a nasal corticosteroid, or montelukast or pt has tried at least one drug from all 3 of these classes during one allergy season AND pt has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy, AND for pts with allergies to animals, these animals must be removed from the patient's immediate environment (eg, work, home). EG/EE/EC, patient has tried therapy with a systemic or orally administered topical corticosteroid.

ZYVOX

Affected Drugs

ZYVOX®

Covered Uses

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

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. For patients already started on linezolid, approve oral linezolid for patients already started in hospital, or other inpatient facility, or as an outpatient on intravenous linezolid (which is now being switched to oral linezolid for continuation of therapy). For patients already started on linezolid, approve oral linezolid for patients already started in hospital or other inpatient facility on oral linezolid (to allow continuation of therapy).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Authorization will be for one fill up to one month.

Other Criteria

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

INDEX

ACTEMRA®, 9
ACTIQ®, 55
ADCIRCA®, 60
AMEVIVE®, 11
ANADROL-50®, 13
ANZEMET®, 19
ARALAST®, 10
ARANESP®, 15
ARCALYST®, 17
ATGAM®, 19
ATRALIN®, 77
AVASTIN®, 19
AVITA®, 77
AVONEX ADMINISTRATION PACK®,
18
AVONEX®, 18
AZASAN®, 19
AZATHIOPRINE, 19
BANZEL®, 21
BETASERON®, 22
BONIVA®, 23
BOTOX®, 24
BYETTA®, 35
CARIMUNE NF NANOFILTERED®, 19
CELLCEPT®, 19
CEREZYME®, 26
CESAMET®, 19
CICLOPIROX, 57
CIMZIA®, 27
COPAXONE®, 28
CYCLOPHOSPHAMIDE, 19
CYCLOSPORINE, 19
CYCLOSPORINE MODIFIED, 19
DIFFERIN®, 77
DRONABINOL, 19
ELIGARD®, 47
EMEND®, 19
ENBREL®, 29
ENGERIX-B®, 19
EPIDUO®, 77
EPOGEN®, 31
EXTAVIA®, 22
FABRAZYME®, 33
FENTANYL CITRATE, 55
FENTORA®, 55
FLEBOGAMMA®, 19
FORTEO®, 34
GAMASTAN S-D®, 19
GAMMAGARD LIQUID®, 19
GAMUNEX®, 19
GENGRAF, 19
GENOTROPIN®, 36
GRANISETRON HCL, 19
GRANISOL, 19
HUMATROPE®, 36
HUMIRA®, 39
IMURAN®, 19
INCRELEX®, 41
ITRACONAZOLE, 69
KINERET®, 42
KYTRIL®, 19
LAMISIL®, 44
LETAIRIS®, 46
LIDODERM®, 49
LUPRON DEPOT®, 47
LUPRON DEPOT-PED®, 47
MARINOL®, 19
METHOTREXATE, 19
MITOXANTRONE HCL, 19
MYCOPHENOLATE MOFETIL, 19
MYFORTIC®, 19
MYOBLOC®, 50
NEORAL®, 19
NEULASTA®, 51
NEUPOGEN®, 52
NORDITROPIN NORDIFLEX®, 36
NORDITROPIN®, 36
NUTROPIN AQ®, 36

NUTROPIN®, 36
NUVIGIL®, 53
OCTAGAM®, 19
OMNITROPE®, 36
ONDANSETRON HCL, 19
ONDANSETRON ODT, 19
ONSOLIS®, 55
ORENCIA®, 56
OXANDRIN®, 13
OXANDROLONE, 13
PEGASYS®, 58
PEGINTRON REDIPEN®, 58
PEGINTRON®, 58
PENLAC®, 57
PHENERGAN®, 19
PROCRI®T, 31
PROGRAF®, 19
PROLASTIN®, 10
PROMETHAZINE HCL, 19
PROVIGIL®, 53
RAPAMUNE®, 19
REBIF®, 61
RECOMBIVAX HB®, 19
REGRANEX®, 62
REMICADE®, 63
RETIN-A MICRO®, 77
RETIN-A®, 77
REVATIO®, 60
RHEUMATREX®, 19
RITUXAN®, 65
SAIZEN®, 36
SAMSCA®, 66
SANCUSO®, 20

SANDIMMUNE®, 20
SEROSTIM®, 36
SIMPONI®, 67
SOMAVERT®, 68
SPORANOX®, 69
STELARA®, 71
SYMLIN®, 73
SYMLINPEN 120®, 73
SYMLINPEN 60®, 73
SYNAGIS®, 74
TACROLIMUS, 20
TAZORAC®, 75
TERBINAFINE HCL, 44
TEV-TROPIN®, 36
THYMOGLOBULIN®, 20
TOPAMAX®, 76
TOPIRAMATE, 76
TRACLEER®, 46
TRETINOIN, 77
TRETIN-X®, 77
TREXALL®, 20
VFEND®, 79
VICTOZA 3-PAK®, 35
XOLAIR®, 80
ZEMAIRA®, 10
ZIANA®, 77
ZOFRAN ODT®, 20
ZOFRAN®, 20
ZONEGRAN®, 76
ZONISAMIDE, 76
ZORBTIVE®, 36
ZYVOX®, 82