

2013 Tufts Health Plan
Medicare Preferred
Prior Authorization
Medical Necessity Guidelines

Effective July 1, 2013

Updated June 24, 2013

ACTEMRA

Drugs

Actemra

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Member must have a documented diagnosis of Rheumatoid Arthritis or a documented diagnosis of Systemic Juvenile Idiopathic Arthritis.

Age Restriction

For SJIA, the member must be over 2 years of age.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

AFINITOR

Drugs

Afinitor

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

For Advanced Renal Cell Carcinoma, documented diagnosis of advanced renal cell carcinoma and the member has a demonstrated disease progression or intolerance following an appropriate trial with sunitinib (Sutent) or sorafenib (Nexavar). For Subependymal Giant Cell Astrocytoma (SEGA), documented diagnosis of subependymal giant cell astrocytoma associated with tuberous sclerosis and Member is not a candidate for surgical resection. For advanced hormone receptor–positive, human epidermal growth receptor 2–negative breast cancer, the member must be a postmenopausal woman and Afinitor is being used in combination with exemestane after failure of treatment with letrozole or anastrozole. For advanced neuroendocrine tumors of pancreatic origin, a documented diagnosis of progressive neuroendocrine tumors of pancreatic origin in adult patients with unresectable, locally advanced, or metastatic disease.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

AMPYRA

Drugs

Ampyra

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Multiple Sclerosis and the member is receiving concurrent therapy with a disease modifying agent (e.g. Avonex, Betaseron, Copaxone, Extavia, Gilenya, Rebif, or Tysabri) if indicated, and the member is ambulatory with a baseline timed 25 foot walk between 8 and 45 seconds.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Initial authorization will be for a period of 12 weeks.

Other Criteria

Additional authorization may be provided if there is documented improvement in walking speed from pre-treatment baseline by at least 25%.

ARCALYST

Drugs

Arcalyst

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of a Cryopyrin-Associated Periodic Syndrome, Familial Cold Autoinflammatory Syndrome, or Muckle-Wells Syndrome.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

AUBAGIO

Drugs

Aubagio

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapse) or the member has a documented failure, contraindication, or intolerance to fingolimod (Gilenya).

Age Restriction

The member must be 18 years or age or older.

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Life of Plan

Other Criteria

None

BANZEL

Drugs

Banzel

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Lennox-Gastaut Syndrome and has had an insufficient response or intolerance to at least one of the following medications: felbamate, lamotrigine, Onfi, topiramate, and/or a valproic acid derivative.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Life of Plan

Other Criteria

None

BENLYSTA

Drugs

Benlysta

Covered Uses

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

Exclusion Criteria

Benlysta (belimumab) will not be approved as monotherapy, for members with severe active lupus nephritis or severe active central nervous system lupus, for members who are autoantibody negative or in combination with other biologics or intravenous cyclophosphamide.

Required Medical Information

The member must have a documented diagnosis of active, autoantibody positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus and is concurrently compliant with standard therapy for systemic lupus erythematosus (e.g., corticosteroids, antimalarials, or immunosuppressives, alone or in combination).

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Initial authorization for Benlysta will be 6 months.

Other Criteria

For subsequent coverage requests, please submit documentation that a clinical benefit has been established and maintained compared to baseline. Re-authorization will be limited to 12-month intervals.

BOSULIF

Drugs

Bosulif

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome–positive (Ph+) chronic myelogenous leukemia (CML) with a documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate).

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

CAPRELSA

Drugs

Caprelsa

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.

Age Restriction

None

Prescriber Restriction

The prescriber must be an endocrinologist or oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

CARBAGLU

Drugs

Carbaglu

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

CELEBREX

Drugs

Celebrex

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Tufts Medicare Preferred may authorize coverage of Celebrex for members meeting one or more of the following clinical criteria: Age 65 or greater, diagnosis of Rheumatoid Arthritis and 50 years of age or older, previous or active GI bleeding or hemorrhage, history of GERD or peptic ulcer disease (PUD), demonstrated lack of effectiveness in relief of symptoms or inability to tolerate a fair trial of at least two (2) prescription non-COX-2 inhibitor NSAIDs (e.g. diclofenac, fenoprofen, ibuprofen, naproxen, etc), bleeding diathesis or other medical condition(s) that would constitute a significant predisposition to bleeding, or if the member is currently taking any of the following medications: anticoagulants (e.g. warfarin, heparin, Lovenox, Fragmin, Innohep), methotrexate, azathioprine or other metabolites, oral corticosteroids (e.g. prednisone, dexamethasone, etc.), proton pump inhibitors (PPIs) (e.g. lansoprazole, omeprazole, pantoprazole), H2 antagonists (e.g. cimetidine , famotidine, ranitidine) or misoprostol.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

CIALIS

Drugs

Cialis

Covered Uses

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

Exclusion Criteria

Cialis is excluded from coverage for the treatment of Erectile Dysfunction.

Required Medical Information

The member must have a documented diagnosis of Benign Prostatic Hyperplasia (BPH) and has had a documented failure, adverse reaction, or contraindication to a 30-day trial of at least two (2) of the following medications: alfuzosin, Avodart, doxazosin, finasteride, tamsulosin or terazosin.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

CIMZIA

Drugs

Cimzia, Cimzia Powder for Reconst

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Crohn's Disease: The member must have a documented diagnosis of Crohn's disease and has demonstrated an inadequate response to an appropriate trial with two (2) or more of the following agents:

Corticosteroids, 5-Aminosalicylates, 6-mercaptopurine and/or azathioprine or methotrexate, or if the member demonstrates a failure or intolerance to Remicade (infliximab).

Rheumatoid Arthritis: The member must have a documented diagnosis of Rheumatoid Arthritis and has had an inadequate response at optimal doses or an inability to take methotrexate.

Age Restriction

Member must be 18 years of age or older

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

CINRYZE

Drugs

Cinryze

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Hereditary Angioedema.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

COMETRIQ

Drugs

Cometriq

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of progressive, metastatic medullary thyroid cancer.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

DIFICID

Drugs

Dificid

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Clostridium difficile infection with a treatment failure or inadequate response to metronidazole or vancomycin.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

EGRIFTA

Drugs

Egrifta

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of lipodystrophy associated with human immunodeficiency virus (HIV).

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

ENBREL

Drugs

Enbrel

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: Soriatane, methotrexate or cyclosporine. **Rheumatoid Arthritis and Polyarticular Juvenile Idiopathic Arthritis:** The member must have a documented diagnosis of either disease and an inadequate response after three (3) months at optimal doses or an inability to take methotrexate. **Psoriatic Arthritis:** The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three months. Enbrel is covered for the diagnosis of ankylosing spondylitis.

Age Restriction

Member is 2 years of age or older.

Prescriber Restriction

The prescribing physician must be a dermatologist or rheumatologist.

Coverage Duration

Life of Plan

Other Criteria

None

ERIVEDGE

Drugs

Erivedge

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of advanced or metastatic basal cell carcinoma and is not a candidate for surgery or radiation.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

FABRAZYME

Drugs

Fabrazyme

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have the definitive diagnosis of Fabry disease.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

FIRAZYR

Drugs

Firazyr

Covered Uses

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

Exclusion Criteria

Firazyr (icatibant) will not be approved for members with acquired angioedema. Firazyr will not be approved for members concurrently taking an angiotensin converting enzyme (ACE) inhibitor.

Required Medical Information

The member must have a documented diagnosis of type I or II hereditary angioedema. The diagnosis must be confirmed by laboratory testing (e.g., low C4 level, reduced C1 esterase inhibitor level or function) and the member has a history of at least one severe attack per month.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an allergist, hematologist or immunologist.

Coverage Duration

Life of Plan

Other Criteria

None

FORTEO

Drugs

Forteo

Covered Uses

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

Exclusion Criteria

Coverage of Forteo will not be approved when used in combination with alendronate, Boniva, Fosamax or Miacalcin.

Required Medical Information

Tufts Medicare Preferred may authorize coverage of Forteo when the requesting physician has documented that the member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan or the requesting physician has documented that the member has had one or more osteoporotic fractures. For either condition previously listed, the member must also have had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments: alendronate, calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel) or zoledronic acid (Reclast).

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Coverage of Forteo is limited to 24 months.

Other Criteria

None

GATTEX

Drugs

Gattex One-Vial

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Short Bowel Syndrome(SBS) and a history of dependence on parenteral nutrition (PN).

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

GAUCHER DISEASE TYPE 1 TREATMENTS

Drugs

Cerezyme, Elelyso, VPRIV

Covered Uses

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

Exclusion Criteria

Not covered for Type 2 or Type 3 Gaucher Disease.

Required Medical Information

The member must have a documented diagnosis of Type 1 Gaucher disease with at least a minimal level of disease severity.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

GILENYA

Drugs

Gilenya

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of either relapsing remitting multiple sclerosis or secondary progressive multiple sclerosis or the member has a documented failure, contraindication, or intolerance to teriflunomide (Aubagio).

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Life of Plan

Other Criteria

None

GROWTH HORMONE REPLACEMENT THERAPY

Drugs

Genotropin, Genotropin Miniquick, Humatrope, Norditropin FlexPro, Norditropin Nordiflex, Nutropin, Nutropin AQ, Nutropin AQ Nuspin, Omnitrope, Saizen, Saizen click.easy, Serostim, Tev-Tropin, Zorbtive

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Pediatric GHD, Initiation, Member must be evaluated and treated by a pediatric endocrinologist, have not attained epiphyseal closure as determined by X-ray, have failed to respond to at least TWO standard GH stimulation test, have documented gender-specific delayed bone age, have the height at initiation of therapy at greater than 2 standard deviations below normal mean for age and sex. Member must have one of the following, Chronic Renal Insufficiency prior to transplantation, Turner Syndrome, Prader-Willi Syndrome, Intrauterine Growth Retardation or Noonan Syndrome. Pediatric GHD, continuation, documentation of the following is required, medical history as it relates to growth, including any test results and growth chart, Continuing care plan and at least a doubling of the annualized pre-treatment growth rate after the first 6 months of therapy then an increase growth velocity of at least 3cm per year thereafter. Continuation of Therapy after Completion of Linear Growth, member will be re-evaluated after GH treatments have been stopped for at least 3 months to determine growth hormone status AND Member must have failed to respond to at least one standard GH stimulation test. Acquired GHD, Member must have failed to respond to at least one standard GH stimulation test. AIDS Wasting Syndrome, documented diagnosis of AIDS AND a weight loss of at least 10% from baseline weight OR a BMI of less than 20 AND documentation that the member has had an adequate nutritional evaluation and has failed to respond adequately to a high calorie diet. Short Bowel Syndrome, a documented diagnosis of Short Bowel Syndrome from a gastroenterologist AND A documented dependence on IPN for nutritional support

Age Restriction

N/A

Prescriber Restriction

None

Coverage Duration

Pediatric GHD, 6 months. Acquired GHD, 1 year. Short Bowel Syndrome, Zorbtive only, 28 days

Other Criteria

None

HUMIRA

Drugs

Humira, Humira Crohn's Dis Start Pck

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

For Crohn's disease, the Member has a documented diagnosis of Crohns disease and has demonstrated an inadequate response to an appropriate trial with two or more of the following agents, corticosteroids, 5-aminosalicylates, 6-mercaptopurine and/or azathioprine or methotrexate or if the member demonstrates a failure or intolerance to Remicade (infliximab). For Ulcerative Colitis, the Member has a documented diagnosis of Ulcerative Colitis and has demonstrated an inadequate response to an appropriate trial with two or more of the following agents, corticosteroids, 5-aminosalicylates, 6-mercaptopurine and/or azathioprine or methotrexate or if the member demonstrates a failure or intolerance to Remicade (infliximab). For psoriasis, the member must have a definitive diagnosis of moderate-to-severe chronic plaque psoriasis and the member has failed to respond to, or have been unable to tolerate, Psoralens with UVA light and ONE of the following, Soriatane, Methotrexate or Cyclosporine. For rheumatoid arthritis and juvenile idiopathic arthritis, the Member must have an inadequate response after three months at optimal doses or an inability to take methotrexate. For psoriatic arthritis, the Member must have an inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months. For ankylosing spondylitis, the Member must have a diagnosis of ankylosing spondylitis.

Age Restriction

Member is 4 years of age or older

Prescriber Restriction

The prescribing physician must be a dermatologist, rheumatologist or gastroenterologist.

Coverage Duration

Life of Plan

Other Criteria

None

ICLUSIG

Drugs

Iclusig

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Acute lymphoblastic leukemia: The member must have a documented diagnosis of Philadelphia chromosome–positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy. Chronic myeloid leukemia: The member must have a documented diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy.

Age Restriction

The member must be 18 years or age or older.

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

ILARIS

Drugs

Ilaris (PF)

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of a Cryopyrin-Associated Periodic Syndrome, Familial Cold Autoinflammatory Syndrome, or Muckle-Wells Syndrome.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

INCIVEK

Drugs

Incivek

Covered Uses

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

Exclusion Criteria

Incivek coverage will not be approved for members who have previously failed treatment with Victrelis (boceprevir).

Required Medical Information

The member must have a documented diagnosis of Chronic Hepatitis C, genotype 1 infection. Incivek must be given in combination with a pegylated interferon and ribavirin.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

INCRELEX

Drugs

Increlex

Covered Uses

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

Exclusion Criteria

Coverage of Increlex will not be authorized for conditions resulting in secondary forms of IGFD that include, but are not limited to: GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.

Required Medical Information

The member must have a documented diagnosis of severe primary IGFD as defined by a height SD score less than or equal to -3.0, a basal IGF-1 SD score less than to equal to -3.0 , normal or elevated GH level OR GH gene deletion and has developed neutralizing antibodies to GH. Radiographs documenting open epiphyses are required for members who are Tanner stage III or greater.

Age Restriction

Members age 2 to 18 years

Prescriber Restriction

The prescribing physician must be an endocrinologist.

Coverage Duration

6 months initial. Subsequent authorization are annual

Other Criteria

None

INFUSED BISPHOSPHONATES

Drugs

Boniva, Reclast, zoledronic acid, zoledronic acid-mannitol-water, Zometa

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Boniva (ibandronate sodium) and Reclast (zoledronic acid) Injections: The member must have a documented diagnosis of osteoporosis and meet one (1) of the following criteria: 1. Documentation of an inadequate response or inability to tolerate one or more oral bisphosphonates (e.g., alendronate, Actonel, Boniva tablets). 2. Documented inability to swallow. 3. Documented inability to remain in an upright position for one hour post oral bisphosphonate administration. Tufts Medicare Preferred does not require prior authorization for coverage of Reclast Injection for the treatment of Paget's disease of the bone. Tufts Medicare Preferred does not require prior authorization for coverage of Zometa (zoledronic acid) Injection for members for the following diagnoses: Hypercalcemia of malignancy, Multiple myeloma, or documented bone metastases from solid tumors.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Initial Authorization: 24 months

Other Criteria

For coverage requests beyond 24 months, documentation must be submitted that the member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan or that the member has had one or more osteoporotic fractures. Boniva IV is not covered for members who are identified by CMS as having End Stage Renal Disease (ESRD) and are undergoing dialysis.

INJECTABLE DRUGS FOR ACROMEGALY

Drugs

Somavert

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of acromegaly and has had a failure of, or is unable to tolerate, a treatment regimen that includes octreotide, and the member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an endocrinologist.

Coverage Duration

Life of Plan

Other Criteria

None

INLYTA

Drugs

Inlyta

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of advanced renal cell carcinoma and has failed a trial of at least one first-line systemic therapy (e.g. Afinitor, Avastin, Nexavar, Sutent, Torisel, Votrient).

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

INTRAVENOUS IMMUNE GLOBULIN

Drugs

Carimune NF Nanofiltered, Gammagard Liquid, Gammaplex, Gamunex-C, Privigen

Covered Uses

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

Exclusion Criteria

Coverage not approved for progressive MS

Required Medical Information

Documented diagnosis one of the following, primary humoral immunodeficiency (Congenital agammaglobulinemia, Common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked agammaglobulinemia, or Severe combined immunodeficiency). Recurrent severe infection and documented severe deficiency or absence of IgG subclass. Clinically significant functional deficiency of humoral immunity as evidenced by documented failure to produce antibodies to specific antigens and a history of recurrent infections. Immune thrombocytopenic purpura (ITP) (Acute and Chronic refractory ITP). Chronic lymphocytic leukemia with associated hypogammaglobulinemia. Symptomatic human immunodeficiency virus (HIV) in patients less than 13 years of age, who are immunologically abnormal. Bone marrow transplantation. Solid organ transplantation. Kawasaki disease (mucocutaneous lymph node syndrome). Acute and chronic inflammatory Demyelinating polyradiculoneuropathy, Guillain-Barre syndrome, myasthenia gravis, Immune thrombocytopenic purpura in pregnancy, multifocal motor neuropathy (MMN) and dermatomyositis. Autoimmune mucocutaneous blistering diseases (Pemphigus vulgaris, Pemphigus foliaceus, Bullous pemphigoid, Mucous membrane pemphigoid (a.k.a., cicatricial pemphigoid), or Epidermolysis bullosa Acquisita). Scleromyxedema is covered for patients whose treatment with more traditional measures has failed. Humoral or vascular allograft rejection. Hemolytic uremic syndrome, Hemolytic anemia. Polymyositis and Dermatomyositis. Sensitized renal transplant recipients. Sepsis, Kidney disease, CMV infection, von Willebrand disorder, Uveitis, Toxic shock syndrome, RSV infection, HIV-associated thrombocytopenia, West Nile virus infection (including meningitis and encephalitis) and treatment of post-transfusion Purpura, chronic inflammatory demyelinating polyneuropathy, Hepatitis A, Measles (Rubeola), Rubella, Varicella in immunosuppressed patients when varicella zoster immunoglobulin is not available.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

6 months upon initial approval

Other Criteria

None

ITRACONAZOLE

Drugs

itraconazole

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of onychomycosis of the fingernails or toenails, or tinea capitis, and the requesting physician has documented that the member has had a treatment failure of, or is unable to tolerate, an adequate trial of terbinafine tablets or Lamisil oral granules, or the requesting physician has documented that the member has a case of one of the following fungal infections: Blastomycosis, Histoplasmosis, Cryptococcus neoformans, Aspergillosis or Tinea (pedis, corporis) resistant to aggressive topical therapy.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

This criteria applies to brand name Onmel

JAKAFI

Drugs

Jakafi

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of intermediate or high-risk myelofibrosis.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Tufts Medicare Preferred will initially authorize Jakafi (ruxolitinib) for a period of 6 months.

Other Criteria

Subsequent authorization requires documentation of spleen size reduction or symptomatic improvement.

JUXTAPID

Drugs

Juxtapid

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a laboratory-confirmed documented diagnosis of homozygous familial hypercholesterolemia (HoFH) based on one of the following tests: a) LDLR DNA Sequence Analysis or LDLR Deletion/Duplication Analysis for large gene rearrangement testing - only if the Sequence Analysis is negative or APOB and PCSK9 testing if both of the above tests are negative but a strong clinical picture exists and the member is concurrently taking lipid-lowering medications.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

KADCYLA

Drugs

Kadcyla

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of human epidermal growth factor receptor 2 (HER2)-positive, metastatic breast cancer and has previously received trastuzumab (Herceptin) and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

KALYDECO

Drugs

Kalydeco

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Kalydeco is covered for members with a documented diagnosis of cystic fibrosis with a confirmed G551D mutation in the CFTR gene.

Age Restriction

The member must be 6 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

KINERET

Drugs

Kineret

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Rheumatoid Arthritis and has documented inadequate response at optimal doses or an inability to take methotrexate.

Age Restriction

Member is 18 years of age or older

Prescriber Restriction

The prescribing physician must be a rheumatologist.

Coverage Duration

Life of Plan

Other Criteria

None

KORLYM

Drugs

Korlym

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an endocrinologist.

Coverage Duration

Life of Plan

Other Criteria

None

KUVAN

Drugs

Kuvan

Covered Uses

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

Exclusion Criteria

Tufts Health Plan will not cover Kuvan unless used in conjunction with a phenylalanine-restricted diet.

Required Medical Information

The member must have a documented diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH₄-) responsive phenylketonuria (PKU).

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a specialist in metabolic diseases.

Coverage Duration

Up to 8 weeks after initial approval.

Other Criteria

None

KYNAMRO

Drugs

Kynamro

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a laboratory-confirmed documented diagnosis of homozygous familial hypercholesterolemia (HoFH) based on one of the following tests: a) LDLR DNA Sequence Analysis or LDLR Deletion/Duplication Analysis for large gene rearrangement testing - only if the Sequence Analysis is negative or APOB and PCSK9 testing if both of the above tests are negative but a strong clinical picture exists and the member is concurrently taking lipid-lowering medications.

Age Restriction

The member must be 12 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

LIDODERM

Drugs

Lidoderm

Covered Uses

All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D.

Exclusion Criteria

None

Required Medical Information

Postherpetic Neuralgia or Diabetic Neuropathy: The member must have had a failure, adverse reaction, or contraindication to gabapentin. Coverage will be authorized for members new to Tufts Medicare Preferred if their pain is currently-well controlled on Lidoderm.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

MEDICATIONS FOR CHRONIC HEPATITIS B AND C INFECTION

Drugs

Infergen, Pegasys, Pegasys Convenience Pack, Pegasys ProClick, PegIntron, PegIntron Redipen

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Histologic and virologic evidence of chronic infection including HCV genotype and viral load and documented use of a ribavirin product in conjunction with the pegylated interferon. For Genotype 1, must have abnormal serum ALT (at least twice normal) or a liver biopsy showing portal or bridging fibrosis and at least moderate inflammation and necrosis. Authorization for genotypes 2 and 3 does not require elevated transaminase levels or abnormal liver biopsy. Coverage of Infergen therapy for up to 48 weeks if the member demonstrates a tolerance to previous pegylated interferon therapy with Pegasys and has an inadequate response or has relapsed following its discontinuation or intolerance to Pegasys. Pegasys therapy may be authorized for Members diagnosed with HBeAg positive and HBeAg negative hepatitis B when there is histologic and virologic evidence of chronic infection. Member must be HBeAg positive for more than six months and has evidence of active virus replication (greater than 20,000 IU/ml) or the member is HBeAg-negative and has evidence of active virus replication (greater than 2,000 IU/ml) and has active liver disease with a serum ALT greater than twice the upper limit of normal or chronic hepatitis on liver biopsy.

Age Restriction

For Infergen, the member must be at least 18 years of age. For Pegasys, the member must be at least 5 years of age. For Peg-Intron, the member must be at least 3 years of age.

Prescriber Restriction

None

Coverage Duration

Geno1, 16 wks, Geno2 and 3, 24 wks. 48 wks for Infergen, co-infection w HIV or HBV. Pegasys 48 wks

Other Criteria

Tufts Health Plan will not cover pegylated interferon therapy for a member who have failed or relapsed after prior pegylated interferon therapy or for members with uncontrolled major depression due to increased risk of suicide during interferon treatment or other interferon preparations unless a member has a contraindication to Pegasys or has failed a trial of Pegasys

MEDICATIONS FOR THE TREATMENT OF PULMONARY HYPERTENSION

Drugs

Adcirca, Letairis, Remodulin, Revatio, sildenafil, Tracleer, Tyvaso, Ventavis

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a definitive diagnosis of pulmonary artery hypertension (WHO Group 1) as confirmed by right heart catheterization. World Health Organization (WHO) Classification of Pulmonary Hypertension Group I: Idiopathic PAH (primary pulmonary hypertension), Heritable PAH, drug- and toxin-induced PAH, PAH associated with other diseases and conditions (APAH), such as: Connective tissue diseases, HIV infection, portal hypertension, congenital heart disease, Schistosomiasis, or chronic hemolytic anemia.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a cardiologist or pulmonologist.

Coverage Duration

Life of Plan

Other Criteria

None

MOZOBIL

Drugs

Mozobil

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

The member must have a documented diagnosis of non-Hodgkin's lymphoma or multiple myeloma and Mozobil is being used in combination with one of the following colony stimulating factors: Neupogen (filgrastim) or Leukine (sargramostim), and standard stem cell mobilization procedures utilizing one of the above medications alone have been unsuccessful.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

NEXAVAR

Drugs

Nexavar

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of advanced Renal Cell Carcinoma or biopsy-proven, unresectable hepatocellular carcinoma.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a nephrologist, oncologist, or urologist.

Coverage Duration

Life of Plan

Other Criteria

None

NUEDEXTA

Drugs

Nuedexta

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

The member must have a documented diagnosis of pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), or bilateral stroke.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

ORENCIA

Drugs

Orencia

Covered Uses

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

Exclusion Criteria

Coverage of Orencia will not be approved if administered concomitantly with another tumor necrosis factor antagonist or Kineret (anakinra).

Required Medical Information

Rheumatoid Arthritis: The member has a documented diagnosis of Rheumatoid Arthritis has a documented inadequate response or inability to tolerate at least one tumor necrosis factor antagonist, including Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab) or Simponi (golimumab). Juvenile Idiopathic Arthritis: The member has a documented inadequate response or inability to tolerate Enbrel (etanercept) or Humira (adalimumab).

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

ORFADIN

Drugs

Orfadin

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of genetic tyrosinemia Type-1 (hereditary tyrosinemia Type-1)

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

PART B/D DRUGS

Drugs

acetylcysteine, albuterol sulfate, Aloxi, Aminosyn 8.5 %-Electrolytes, Aminosyn II 10 %, Aminosyn II 15%, Aminosyn II 7 %, Aminosyn II 8.5 %, Aminosyn II 8.5 %-Electrolytes, Aminosyn M 3.5 %, Aminosyn-HBC 7%, Aminosyn-PF 10 %, Aminosyn-PF 7 % (Sulfite-Free), Anzemet, Azasan, azathioprine, azathioprine sodium, Brovana, budesonide, calcitonin (salmon), CellCept, Cesamet, Clinimix 5%/D15W Sulfite Free, Clinimix 5%/D25W Sulfite Free, Clinimix 2.75%/D5W Sulfite Free, Clinimix 4.25%/D10W Sulf Free, Clinimix 4.25%/D20W Sulf Free, Clinimix 4.25%/D25W Sulf Free, Clinimix 4.25%/D5W Sulfite Free, Clinimix 5%/D20W Sulfite Free, Clinimix E 2.75%/D10W Sulf Free, Clinimix E 2.75%/D5W Sulf Free, Clinimix E 4.25%/D25W Sulf Free, Clinimix E 4.25%/D5W Sulf Free, Clinimix E 5%/D15W Sulfite Free, Clinimix E 5%/D20W Sulfite Free, Clinimix E 5%/D25W Sulfite Free, Clinisol SF 15 %, cromolyn, CUBICIN, cyclophosphamide, cyclosporine, cyclosporine modified, dronabinol, Emend, Engerix-B (PF), Freamine III 3 %-Electrolytes, Freamine III 8.5 %, Gengraf, granisetron, granisetron (PF), Granisol, Hectorol, heparin (porcine), heparin (porcine) in D5W, heparin (porcine) in NaCl (PF), heparin(porcine) in 0.45% NaCl, Hepatamine 8%, Hepatasol 8 %, Intralipid, ipratropium bromide, ipratropium-albuterol, levalbuterol HCl, levocarnitine, levocarnitine (with sugar), methotrexate sodium, mycophenolate mofetil, Myfortic, Nebupent, Nephramine 5.4 %, Nulojix, ondansetron, ondansetron HCl, ondansetron HCl (PF), Pentam, Perforomist, Premasol 10 %, Premasol 6 %, Procalamine 3%, Prograf, Prosol 20%, Pulmicort, Pulmozyme, Rapamune, Recombivax HB (PF), Sancuso, Simulect, tacrolimus, Tobi, TPN Electrolytes, Travasol 10 %, Trexall, TrophAmine 10 %, Trophamine 6%, vancomycin, Xopenex, Zortress

Covered Uses

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

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration

Other Criteria

PERJETA

Drugs

Perjeta

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of metastatic breast cancer and Perjeta is being used in combination with trastuzumab (Herceptin) and docetaxel for the treatment of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer and the member has not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

POMALYST

Drugs

Pomalyst

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of multiple myeloma and has received at least 2 prior therapies including lenalidomide (Revlimid) and (Velcade) bortezomib, and has demonstrated disease progression on or within 60 days of completion of the last therapy.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

POTIGA

Drugs

Potiga

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to at least one other medication indicated for adjunct partial seizures (e.g. Felbatol (felbamate), Gabitril (tiagabine), Lamictal (lamotrigine), Lyrica (pregabalin), Keppra / Keppra XR (levetiracetam), Neurontin (gabapentin), Topamax (topiramate), Trileptal (oxcarbazepine) and/or Zonegran (zonisamide)).

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Life of Plan

Other Criteria

None

PRADAXA

Drugs

Pradaxa

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of non-valvular atrial fibrillation.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

PROLIA AND XGEVA

Drugs

Prolia, Xgeva

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Tufts Health Plan may authorize coverage of Prolia (denosumab) for the treatment of osteoporosis in men and postmenopausal women when the following criteria are met: The member is at high risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture and a T score less than or equal to -2.0 as evidenced via bone density scan or the member has had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments [alendronate (Fosamax), calcitonin (Miacalcin), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)]. Tufts Health Plan may authorize coverage of Xgeva (denosumab) for prevention of skeletal-related events in patients with bone metastases from solid tumors only. Tufts Health Plan may authorize coverage of Prolia for men at high risk of fracture who are receiving androgen deprivation therapy for nonmetastatic prostate cancer.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

PROMACTA

Drugs

Promacta

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Tufts Health Plan may authorize coverage of Promacta for members with a documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) and have had an insufficient response or intolerance to corticosteroids and/or immunoglobulins, OR the member has not responded to splenectomy. Coverage may also be authorized for the treatment of thrombocytopenia in patients with chronic hepatitis C.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

REMICADE

Drugs

Remicade

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Crohn's Disease or Ulcerative Colitis / Pediatric Ulcerative Colitis: The member has a documented diagnosis of Crohn's disease or Ulcerative Colitis and has demonstrated an inadequate response to an appropriate trial with one (1) or more of the following agents: Corticosteroids, 5-Aminosalicylates, 6-mercaptopurine and/or azathioprine or methotrexate. Plaque Psoriasis: The member must have a documented diagnosis of severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate, treatment with one (1) of the following medications: Soriatane, methotrexate or cyclosporine. Rheumatoid Arthritis: The member must have a documented diagnosis of rheumatoid arthritis and a documented inadequate response or inability to tolerate methotrexate. Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and a documented inadequate response or inability to tolerate methotrexate. Remicade is covered for the diagnosis of ankylosing spondylitis.

Age Restriction

The member must be 18 years of age or older. For pediatric Crohn's Disease and Ulcerative Colitis, the member must be 6 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

RESTASIS

Drugs

Restasis

Covered Uses

All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D.

Exclusion Criteria

None

Required Medical Information

The member must have a definitive diagnosis of Keratoconjunctivitis Sicca (KCS), Sjogrens Syndrome, or is being treated for Ocular Graft vs. Host Disease or Corneal Transplant Rejection.

Age Restriction

The member must be 16 years of age or older.

Prescriber Restriction

The prescribing physician must be an ophthalmologist or optometrist.

Coverage Duration

Life of Plan

Other Criteria

None

RETINOIDS FOR THE TOPICAL TREATMENT OF ACNE VULGARIS AND PSORIASIS

Drugs

adapalene, Atralin, Avita, Differin, Retin-A, Retin-A Micro, Tazorac, tretinoin, TRETIN-X, TRETIN-X (gel)

Covered Uses

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

Exclusion Criteria

Tufts Medicare Preferred will not authorize coverage of topical acne products for cosmetic purposes,

Required Medical Information

Tufts Medicare Preferred may authorize coverage of the topical acne products for members 26 years of age or older, when either one of the following criteria is met: The member has a physician documented diagnosis of acne, comedones (white heads), or actinic keratosis. For Tazorac, the member must have a physician documented diagnosis of plaque psoriasis or documented diagnosis of skin cancer provided effective treatment with Tazorac is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

REVLIMID

Drugs

REVLIMID

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Myelodysplastic Syndrome: The member must have a documented diagnosis of transfusion-dependent anemia due to myelodysplastic syndrome associated with the 5q-deletion cytogenetic abnormality.

Multiple Myeloma: The member must have a documented diagnosis of Multiple Myeloma and Revlimid is being used in combination with dexamethasone and the member has received and failed to respond to at least one prior therapy.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a hematologist or oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

RITUXAN

Drugs

Rituxan

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Tufts Medicare Preferred may authorize coverage of Rituxan in combination with methotrexate for members with a diagnosis of active rheumatoid arthritis and have a documented inadequate response to an appropriate trial with at least one tumor necrosis factor (TNF) antagonist therapy, including Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab) or Simponi (golimumab). Tufts Medicare Preferred may authorize coverage of Rituxan for members with a documented diagnosis of Wegener's granulomatosis or microscopic polyangiitis, and the member is concurrently taking glucocorticoids (e.g., prednisone). Rituxan does not require prior authorization for members with a diagnosis of Non-Hodgkins Lymphoma or Chronic Lymphocytic Leukemia.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Authorization for Wegener's granulomatosis or microscopic polyangiitis will be limited to 6 months.

Other Criteria

Additional authorization for Wegener's granulomatosis or microscopic polyangiitis may be given if documentation of an objective measurable effect is provided indicating clinical improvement of condition. Subsequent authorizations may be given in 6-month intervals.

SIGNIFOR

Drugs

Signifor

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The Member has a documented diagnosis of Cushing's disease AND Pituitary surgery is not an option or has not been curative for the Member

Age Restriction

The member must be 18 years of age or older

Prescriber Restriction

The prescribing physician is an endocrinologist

Coverage Duration

Life of Plan

Other Criteria

None

SIMPONI

Drugs

Simponi

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Rheumatoid Arthritis: The member must have a documented diagnosis of Rheumatoid Arthritis and has had an inadequate response or inability to tolerate methotrexate at optimal doses. Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to tolerate methotrexate or sulfasalazine at maximal doses. Simponi is covered for members with a documented diagnosis of ankylosing spondylitis.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be a dermatologist or rheumatologist.

Coverage Duration

Life of Plan

Other Criteria

None

SPRYCEL

Drugs

Sprycel

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Chronic Myeloid (or Myelogenous) Leukemia (CML): The member must have a documented diagnosis of accelerated, or myeloid or lymphoid blast phase Ph+ CML and documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate). Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL): The member must have a documented diagnosis of Ph+ALL and documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate). Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CP-CML): The member must have a documented diagnosis of Ph+ CP-CML.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

STELARA

Drugs

Stelara

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a definitive diagnosis of moderate-to-severe chronic plaque psoriasis.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

STIVARGA

Drugs

Stivarga

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of metastatic colorectal cancer and has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an antivascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an antiepidermal growth factor receptor (EGFR) therapy. For advanced gastrointestinal stromal tumors (GIST), the member must have a documented diagnosis of GIST and documented prior failure, contraindication or intolerance to therapy with both imatinib mesylate (Gleevec) and sunitinib malate (Sutent).

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

SUBOXONE

Drugs

Suboxone

Covered Uses

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

Exclusion Criteria

Suboxone will not be covered to treat pain.

Required Medical Information

The member must have a documented diagnosis of opioid dependence.

Age Restriction

None

Prescriber Restriction

The requesting physician must be certified to prescribe buprenorphine for opioid dependence and has been granted a special DEA waiver and prefix code (X DEA number), in accordance with DATA 2000.

Coverage Duration

Life of Plan

Other Criteria

None

SUTENT

Drugs

Sutent

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Advanced Renal Cell Carcinoma: The member must have a documented diagnosis of advanced renal cell carcinoma. Gastrointestinal Stromal Tumor (GIST): The member must have a documented diagnosis of gastrointestinal stromal tumor and has a demonstrated disease progression or intolerance following an appropriate trial with Gleevec (imatinib mesylate). Progressive Neuroendocrine Tumors: The member must have a documented diagnosis of progressive neuroendocrine tumor located in the pancreas and the tumor cannot be removed by surgery or has spread to other parts of the body.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

SYLATRON

Drugs

Sylatron

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of melanoma with microscopic or gross nodal involvement and the melanoma has been completely excised with adequate surgical margins and complete lymphadenectomy must have occurred within 84 days.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a dermatologist or an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

TASIGNA

Drugs

Tasigna

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Newly Diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML-CP): The member must have a documented diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Resistant or Intolerant Ph+ CML-CP and CML-AP: The member must have a documented diagnosis of Philadelphia chromosome positive chronic myelogenous leukemia in chronic phase or in accelerated phase and documented resistance or intolerance to prior therapy, including Gleevec (imatinib mesylate).

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

TECFIDERA

Drugs

Tecfidera

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The Member must have a definitive diagnosis of a relapsing form of multiple sclerosis AND The Member has a documented failure, contraindication, or intolerance to at least ONE of the following multiple sclerosis immunomodulator agents: •teflunomide (Aubagio®) •fingolimod (Gilenya™)

Age Restriction

None

Prescriber Restriction

The prescribing physician is a neurologist

Coverage Duration

Life of Plan

Other Criteria

None

TYKERB

Drugs

Tykerb

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

For HER2 overexpressing advanced or metastatic breast cancer, the member must have all of the following: 1. A documented diagnosis of HER2 overexpressing advanced or metastatic breast cancer. 2. The member has failed prior therapy with an appropriate trial of an anthracycline and a taxane chemotherapeutic agent. 3. The member has failed prior therapy with an appropriate trial of Herceptin (trastuzumab). 4. The member is concurrently treated with Xeloda (capecitabine). Hormone receptor positive metastatic breast cancer in post-menopausal women: The member must have a documented diagnosis of hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor and is concurrently being treated with an aromatase inhibitor (e.g. anastrozole, exemestane, or letrozole).

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

TYSABRI

Drugs

TYSABRI

Covered Uses

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

Exclusion Criteria

Tufts Health Plan will not approve Tysabri when used in conjunction with other medications for the treatment of progressive multiple sclerosis (Betaseron, Avonex, Rebif or Copaxone) or when used in conjunction with other medications (corticosteroids, 5-aminosalicylates, 6-mercaptopurine and/or azathioprine, methotrexate or Humira)

Required Medical Information

Multiple Sclerosis: The member must have a documented diagnosis of relapsing multiple sclerosis and has a documented inadequate response or inability to tolerate an appropriate trial with at least one of the following agents: Avonex, Betaseron, Copaxone, Extavia, Gilenya, or Rebif. For Crohn's Disease, the member must have all of the following: 1. A documented diagnosis of Crohn's Disease. 2. Demonstrated an inadequate response to an appropriate trial with two (2) or more of the following agents: Corticosteroids (e.g., prednisone, prednisolone, methylprednisolone), 5-Aminosalicylates (e.g., sulfasalazine, Azulfidine, Asacol, Pentasa, Rowasa, Dipentum, Colazal), 6-mercaptopurine (6-MP, Purinethol) and/or azathioprine, and/or methotrexate. 3. The Member has demonstrated an inadequate response to an appropriate trial with at least one of the following TNF-inhibitors: Cimzia, Humira or Remicade.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a gastroenterologist or neurologist.

Coverage Duration

Coverage will be initially authorized for 6 months. Re-authorization will be in 6-month increments.

Other Criteria

None

VICTRELIS

Drugs

Victrelis

Covered Uses

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

Exclusion Criteria

Victrelis coverage will not be approved for members who have previously failed treatment with Incivek (telaprevir).

Required Medical Information

The member must have a documented diagnosis of Chronic Hepatitis C, genotype 1 infection. Victrelis must be given in combination with a pegylated interferon and ribavirin.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

VIMPAT

Drugs

Vimpat

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to at least one other medication indicated for adjunct partial seizures, such as: felbamate, Gabitril (tiagabine), Lamictal XR, lamotrigine, Lyrica (pregabalin), levetiracetam, gabapentin, topiramate, oxcarbazepine and/or zonisamide.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Life of Plan

Other Criteria

None

VOTRIENT

Drugs

Votrient

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of advanced Renal Cell Carcinoma or Advanced Soft Tissue Sarcoma.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

XALKORI

Drugs

Xalkori

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by a Food and Drug Administration (FDA)-approved test.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

XELJANZ

Drugs

Xeljanz

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

The member must have a documented diagnosis of Rheumatoid Arthritis and has a documented inadequate response at optimal doses or an inability to take methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be a rheumatologist.

Coverage Duration

Life of Plan

Other Criteria

None

XENAZINE

Drugs

Xenazine

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of at least moderate chorea associated with Huntington's Disease and has demonstrated an inadequate response to OR is unable to tolerate an adequate trial with at least one of the following medications or classes of medication: Benzodiazepines, amantadine and/or Antipsychotics.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be a neurologist.

Coverage Duration

Life of Plan

Other Criteria

None

XIFAXAN 550 MG

Drugs

Xifaxan

Covered Uses

All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D.

Exclusion Criteria

Coverage will not be authorized for treatment of diarrhea caused by pathogens other than E. coli, diarrhea complicated by fever or bloody stools, Irritable Bowel Syndrome, or prevention of traveler's diarrhea.

Required Medical Information

Hepatic Encephalopathy: The member must have a documented diagnosis of hepatic encephalopathy and has had an inadequate response or has a contraindication to lactulose (Constulose, Duphalac, Enulose, Generlac). Inflammatory Bowel Disease: The member must have a documented diagnosis of Inflammatory Bowel Disease (IBD) and has failed to respond to or has a contraindication to standard antibiotic treatment (e.g., ciprofloxacin, metronidazole).

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

Xifaxan 200 mg tablets do not require authorization.

XOLAIR

Drugs

Xolair

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

Tufts Medicare Preferred may authorize coverage of Xolair when all of the following criteria are met: 1. The member has had a failure of a treatment regimen that included inhaled corticosteroids, oral corticosteroids, leukotriene modifiers and inhaled long-acting bronchodilators, or is unable to tolerate these medications. 2. The member shows a definitive sensitivity on allergy testing to one or more perennial allergens. 3. The member has a pre-treatment serum IgE level equal to or greater than 30 IU/mL and less than or equal to 700 IU/mL.

Age Restriction

The member must 12 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

XTANDI

Drugs

Xtandi

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of metastatic castration-resistant prostate cancer and has previously received docetaxel.

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

ZAVESCA

Drugs

ZAVESCA

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of Type 1 Gaucher Disease and cannot be treated with enzyme replacement therapy (e.g. Cerezyme).

Age Restriction

The member must be 18 years of age or older.

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

ZELBORAF

Drugs

Zelboraf

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of unresectable or metastatic melanoma that is BRAF V600E mutation-positive as detected by an FDA-approved test.

Age Restriction

None

Prescriber Restriction

The prescribing physician must be an oncologist.

Coverage Duration

Life of Plan

Other Criteria

None

ZOLINZA

Drugs

Zolinza

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of advanced cutaneous T-cell lymphoma (Stage IIB and higher) and progressive, persistent or recurrent disease and documented current or prior treatment or treatment failure with at least one (1) systemic chemotherapeutic agents for cutaneous T-cell lymphoma.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

ZYTIGA

Drugs

Zytiga

Covered Uses

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

Exclusion Criteria

None

Required Medical Information

The member must have a documented diagnosis of metastatic castration-resistant prostate cancer (CRPC) and Zytiga is being used in combination with prednisone.

Age Restriction

None

Prescriber Restriction

None

Coverage Duration

Life of Plan

Other Criteria

None

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