

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|---|---|--------------------------|--|-------------------|----------------|
| Afinitor | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> • Documented diagnosis of advanced renal cell carcinoma AND • The member has demonstrated disease progression or intolerance following an appropriate trial with sunitinib (Sutent) or sorafenib (Nexavar) | | The prescribing physician must be an Oncologist | Life of Plan | |
| Aldurazyme | All FDA-approved indications not otherwise excluded from Part D | Not covered for members mildly affected with the Scheie form of MPS 1 | <ul style="list-style-type: none"> • The member must have the definitive diagnosis of the Hurler or Hurler-Scheie form of MPS I OR • The member has the Scheie form of MPS I with moderate to severe symptoms which include, but are not limited to: <ul style="list-style-type: none"> ○ Above normal growth and head size ○ Chronic rhinitis ○ Corneal clouding ○ Developmental delay ○ Facial dysmorphisms ○ Joint stiffness ○ Recurrent ear infections ○ Skeletal deformities ○ Umbilical or inguinal hernia ○ Valvular heart disease | | The prescribing physician must specialize in metabolic disorders or genetics | Life of Plan | |
| Amevive | Plaque psoriasis | | <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Soriatane ○ Methotrexate ○ Cyclosporine | 16 years of age or older | The prescribing physician must be a Dermatologist | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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|---------------------------------------|---|--------------------|---|-----------------|--|---|----------------|
| Amitiza | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The Member has failed conservative treatment of an appropriate trial with one or more cathartics or fiber supplements | | | 12-week course initially. Subsequent coverage may be authorized for up to one year. | |
| Apokyn | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The member has a documented occurrence of hypomobility episodes associated with end-of-dose wearing-off of Sinemet | | The prescribing physician must be a Neurologist | Life of Plan | |
| Arcalyst | All FDA-approved indications not otherwise excluded from Part D | | <p>The Member has a documented diagnosis of one of the following:</p> <ul style="list-style-type: none"> Cryopyrin-Associated Periodic Syndrome Familial Cold Autoinflammatory Syndrome Muckle-Wells Syndrome | | The prescriber has expertise in the treatment of the conditions listed in Required Medical Information | Life of Plan | |
| Banzel | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The member has a documented diagnosis of Lennox-Gastaut Syndrome <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> The member has had an insufficient response or intolerance to at least one of the following medications: <ul style="list-style-type: none"> Valproic acid derivative (e.g. Depakene, Depakote) Topamax (topiramate) Lamictal (lamotrigine) Felbatol (felbamate) | | The prescribing physician must be a Neurologist | Life of Plan | |

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| Botulinum Toxin A and B | All FDA-approved indications not otherwise excluded from Part D | Cosmetic Procedures | <ul style="list-style-type: none"> Documented response to injections following two sequential treatments or sets of injections in a 4 to 6 month period, using maximum dose for the size of the muscle | | | Initial authorization will expire in 2 months from original authorization date for any diagnosis | |
| Brovana and Perforomist | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The member has a physical limitation that prevents the use of a non-nebulized long-acting bronchodilator with or without the use of a spacer <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> The member has failed to respond to treatment with one or more of the agents listed under Other Criteria | | | Life of Plan | Advair Diskus, Advair HFA, Foradil, Serevent Diskus, Spiriva Handihaler, Symbicort |
| Celebrex | All FDA-approved indications not otherwise excluded from Part D | | <p>The member is/has one or more of the following:</p> <ul style="list-style-type: none"> Age 65 or greater Age 50 or greater with Rheumatoid Arthritis Previous or active GI bleeding or hemorrhage GERD/PUD Demonstrated lack of effectiveness or intolerance to a fair trial of at least 2 prescription non-COX₂ inhibitor NSAIDs Medical condition(s) that would constitute a predisposition to bleeding Member is currently taking one or more of the following: <ul style="list-style-type: none"> Anticoagulants Methotrexate Imuran Oral corticosteroids PPIs/H₂ antagonists Arthrotec History or diagnosis of FAP | | | Life of Plan | |

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| Ceredase or Cerezyme | All FDA-approved indications not otherwise excluded from Part D | Not covered for Type 2 or Type 3 Gaucher Disease | <ul style="list-style-type: none"> Diagnosis of Type 1 Gaucher disease with at least a minimal level of disease severity | | | Life of Plan | |
| Enbrel | Ankylosing spondylitis, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis | | <p>Ankylosing Spondylitis</p> <ul style="list-style-type: none"> The member has a diagnosis of Ankylosing Spondylitis from a rheumatologist. <p>Psoriasis</p> <ul style="list-style-type: none"> The member must have a definitive diagnosis of moderate-to-severe chronic plaque psoriasis <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> The member has failed to respond to, or has been unable to tolerate Psoralens with UVA light and ONE of the following: <ul style="list-style-type: none"> Soriatane Methotrexate Cyclosporine <p>Psoriatic Arthritis</p> <ul style="list-style-type: none"> The member must have had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three months <p>Rheumatoid Arthritis or Juvenile Idiopathic Arthritis</p> <ul style="list-style-type: none"> The member must have had an inadequate response after three months at optimal doses or an inability to take methotrexate. | Member is 4 years of age or older | The prescribing physician must be a Dermatologist or Rheumatologist | Life of Plan | |
| Fabrazyme | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The member must have a definitive diagnosis of Fabry disease | | The prescriber must be a Cardiologist, Nephrologist, or specialize in metabolic disorders or genetics | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| Forteo | All FDA-approved indications not otherwise excluded from Part D | Coverage of Forteo will not be approved when used in combination with Actonel, Boniva, Fosamax or Miacalcin | <ul style="list-style-type: none"> • Documented diagnosis of osteoporosis and is at high risk for fracture <li style="text-align: center;">OR • Documented history of one or more osteoporotic fractures <li style="text-align: center;">OR • Documented diagnosis of hypogonadism and is at high risk for fracture (Males) <li style="text-align: center;">EITHER 1, 2 OR 3 <li style="text-align: center;">AND • Member had an inadequate response to or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments (Actonel, Boniva, Fosamax, Miacalcin) | | | Coverage of Forteo is limited to 24 months | |
| Gleevec | All FDA-approved indications not otherwise excluded from Part D | | <p>Documented diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Chronic Myeloid or Myelogenous Leukemia • Relapsed or refractory Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia • Myelodysplastic/ myeloproliferative diseases associated with platelet derived growth factor receptor gene rearrangements • Aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown • Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (CEL) • Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans • Gastrointestinal stromal tumor (GIST) <li style="text-align: center;">ANY of the above OR • Documented diagnosis of other cancer provided effective treatment with Gleevec is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature | | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| <p align="center">Growth Hormone Replacement Therapy</p> | <p align="center">All FDA-approved indications not otherwise excluded from Part D</p> | <p align="center">Tufts Health Plan does not provide coverage for off-label uses that are not listed in approved compendia</p> | <p>Pediatric GHD (Initiation) Tufts Health Plan may authorize coverage for members if all of the following criteria are met:</p> <ul style="list-style-type: none"> • Member must has been evaluated and treated by a pediatric endocrinologist • Member <u>must have not</u> attained epiphyseal closure as determined by X-ray • Member must have failed to respond to at least TWO standard GH stimulation test • Member must have documented gender-specific delayed bone age • Member’s height at initiation of therapy must 2 or more standard deviations below normal mean for age and sex. <p align="center">ALL of the above OR</p> <ul style="list-style-type: none"> • Member must have one of the following diseases: <ul style="list-style-type: none"> ○ Chronic Renal Insufficiency prior to transplantation ○ Turner Syndrome ○ Prader-Willi Syndrome ○ Intrauterine Growth Retardation ○ Noonan Syndrome <p>Pediatric GHD (Continuation Prior to Completion of Linear Growth)</p> <ul style="list-style-type: none"> • Documentation of the following is required: <ul style="list-style-type: none"> ○ Medical history as it relates to growth, including any test results and growth chart ○ Continuing care plan ○ 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 | | | <p align="center">Pediatric GHD 6 months</p> <p align="center">Acquired GHD 1 year</p> <p align="center">Short Bowel Syndrome (Zorbtive only) 28 days</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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|---|---|--|---|-----------------|------------------------|---|----------------|
| <p align="center">Growth Hormone Replacement Therapy (continued)</p> | <p align="center">All FDA-approved indications not otherwise excluded from Part D</p> | <p align="center">Tufts Health Plan does not provide coverage for off-label uses that are not listed in approved compendia</p> | <p>Pediatric GHD (Continuation of Therapy after Completion of Linear Growth)</p> <ul style="list-style-type: none"> • Member will be re-evaluated after GH treatments have been stopped for at least 3 months to determine growth hormone status <p align="center">AND</p> <ul style="list-style-type: none"> • Member must have failed to respond to at least one standard GH stimulation test. <p>Acquired GHD</p> <ul style="list-style-type: none"> • Member must have failed to respond to at least one standard GH stimulation test. • Acquired GHD can be due to, but not limited to the following: <ul style="list-style-type: none"> ○ CNS tumors ○ Cranial irradiation ○ Panhypopituitarism ○ Pituitary insufficiencies/surgery/tumor ○ Radiation treatments <p>AIDS Wasting Syndrome</p> <ul style="list-style-type: none"> • Member must have a 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 <p>Short Bowel Syndrome (Zorbtive only)</p> <ul style="list-style-type: none"> • Member must have a documented diagnosis of Short Bowel Syndrome from a gastroenterologist <p align="center">AND</p> <ul style="list-style-type: none"> • A documented dependence on IPN for nutritional support | | | <p align="center">Pediatric GHD 6 months</p> <p align="center">Acquired GHD 1 year</p> <p align="center">Short Bowel Syndrome (Zorbtive only) 28 days</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| <p align="center">Humira</p> | <p align="center">Ankylosing spondylitis, Crohn's disease, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis</p> | | <p>Ankylosing Spondylitis</p> <ul style="list-style-type: none"> The member has a diagnosis of ankylosing spondylitis from a Rheumatologist <p>Crohn's disease</p> <ul style="list-style-type: none"> The Member has a documented diagnosis of Crohn's disease <p align="center">AND</p> <ul style="list-style-type: none"> The Member has demonstrated an inadequate response to an appropriate trial with two or more of the following agents: <ul style="list-style-type: none"> Corticosteroids 5-Aminosalicylates 6-mercaptopurine and/or azathioprine methotrexate <p align="center">OR</p> <ul style="list-style-type: none"> The member demonstrates a failure of or intolerance to Remicade (infliximab). <p>Psoriasis</p> <ul style="list-style-type: none"> The member must have a definitive diagnosis of moderate-to-severe chronic plaque psoriasis <p align="center">AND</p> <ul style="list-style-type: none"> The member has failed to respond to, or have been unable to tolerate Psoralens with UVA light and ONE of the following: <ul style="list-style-type: none"> Soriatane, methotrexate or cyclosporine <p>Psoriatic Arthritis</p> <ul style="list-style-type: none"> The member must have an inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months <p>Rheumatoid Arthritis or Juvenile Idiopathic Arthritis</p> <ul style="list-style-type: none"> The member must have had an inadequate response after three months at optimal doses or an inability to take methotrexate. | <p align="center">Member is 4 years of age or older</p> | <p align="center">The prescribing physician must be a Dermatologist, Rheumatologist or Gastroenterologist</p> | <p align="center">Life of Plan</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| Increlex | All FDA-approved indications not otherwise excluded from Part D | Not covered for conditions resulting in secondary forms of IGFD that include, but are not limited to, GH deficiency, malnutrition, hypothyroidism, chronic steroid therapy | <p>Member has a documented diagnosis of either of the following:</p> <ul style="list-style-type: none"> • Severe primary insulin-like growth factor-1 (IGF-1) deficiency (primary IGFD) as defined by: <ul style="list-style-type: none"> ○ 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 <p style="text-align: center;">OR</p> ○ GH gene deletion and has developed neutralizing antibodies to GH. <ul style="list-style-type: none"> • Radiographs documenting open epiphyses are required for members who are Tanner stage III or greater | Members age 2 to 18 years | The prescribing physician must be a Pediatric Endocrinologist | 6 months initial. Subsequent authorization are annual | |
| Intravenous Immune Globulin | All FDA-approved indications not otherwise excluded from Part D | Coverage not approved for progressive MS | <p>Member has a documented diagnosis one of the following:</p> <p>Immunologic Conditions</p> <ul style="list-style-type: none"> • Primary Humoral Immunodeficiency <ul style="list-style-type: none"> ○ X-linked agammaglobulinemia ○ Congenital agammaglobulinemia ○ Wiskott-Aldrich Syndrome ○ Severe combined immunodeficiency • Common variable immunodeficiency • Hypogammaglobulinemia • Immune Neutropenia • Agranulocytosis • HIV/AIDS <p>Neurological Conditions</p> <ul style="list-style-type: none"> • Guillain-Barre Syndrome • Chronic Inflammatory Demyelinating Polyneuropathy • Hereditary and idiopathic peripheral neuropathy • Inflammatory Myopathies | | | <p>Pediatric GHD 6 months</p> <p>Acquired GHD 1 year</p> <p>Short Bowel Syndrome (Zorbtive only) 28 days</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| <p align="center">Intravenous Immune Globulin (continued)</p> | <p align="center">All FDA-approved indications not otherwise excluded from Part D</p> | <p align="center">Coverage not approved for progressive MS</p> | <ul style="list-style-type: none"> • Myasthenia Gravis • Relapsing/Remitting MS Oncology and Hematology • Chronic or Idiopathic Thrombocytopenia Purpura • CLL with hypogammaglobulinemia • Immunoproliferative neoplasms • Plasma cell leukemia • Fetal or neonatal alloimmune thrombocytopenia Transplant • Bone Marrow • Solid organ transplant Dermatology • Dermatomyositis • Autoimmune mucocutaneous blistering diseases • Epidermolysis Bullosa Acquisita Kawasaki Disease | | | <p align="center">Pediatric GHD 6 months</p> <p align="center">Acquired GHD 1 year</p> <p align="center">Short Bowel Syndrome (Zorbtive only) 28 days</p> | |
| <p align="center">Iressa and Tarceva</p> | <p align="center">All FDA-approved indications not otherwise excluded from Part D</p> | <p align="center">Tufts Health Plan will not authorize the use of Iressa or Tarceva when used in combination with other chemotherapies except when Tarceva is used in combination with gemcitabine</p> | <p>Tufts Health Plan may authorize coverage of and Tarceva (erlotinib) or Iressa (gefitinib) for Members when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of locally advanced or metastatic non-small cell lung cancer <p align="center">AND</p> <ul style="list-style-type: none"> • Documented treatment failure of or is unable to tolerate platinum based and docetaxel chemotherapies or for whom the use of these chemotherapies is contraindicated <p align="center">Either 1 and 2 OR</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of other cancer provided effective treatment with Iressa and Tarceva is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L AND documented diagnosis from an oncologist of locally advanced, unresectable, or metastatic pancreatic cancer (Tarceva Only) | | <p align="center">The prescribing physician must be an Oncologist</p> | <p align="center">Life of Plan</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| Kineret | Rheumatoid Arthritis | | Rheumatoid Arthritis or Juvenile Idiopathic Arthritis <ul style="list-style-type: none"> The member must have had an inadequate response after three months at optimal doses or an inability to take methotrexate. | Member is 18 years of age or older | The prescribing physician must be a Dermatologist | Life of Plan | |
| Kuvan | All FDA-approved indications not otherwise excluded from Part D | Tufts Health Plan will not cover Kuvan unless used in conjunction with a phenylalanine-restricted diet | <ul style="list-style-type: none"> The member has a baseline phenylalanine level ≥ 600 $\mu\text{mol/L}$ <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> Tetrahydrobiopterin (BH4) deficiency has been ruled-out | | The prescribing physician must be a specialist in metabolic diseases | Up to 8 weeks after initial approval | |
| Lamisil | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> Documented diagnosis of onychomycosis of the fingernails or toenails. Lamisil granules are covered for a diagnosis of tinea capitis | | | 6 weeks for fingernail onychomycosis, 12 weeks for toenail onychomycosis. Annual limit of 12 weeks | |
| Lidoderm | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The member must have a documented diagnosis of pain associated with post-herpetic neuralgia (PHN) | | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| Medications for Chronic Hepatitis C Infection | All FDA-approved indications not otherwise excluded from Part D | Tufts Health Plan will not cover pegylated interferon therapy for members 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 | <p>Initial Therapy</p> <ul style="list-style-type: none"> • Histologic and virologic evidence of chronic infection including HCV genotype and viral load <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Documented use of a ribavirin product in conjunction with the pegylated interferon <p>Continuation of Therapy</p> <ul style="list-style-type: none"> • 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 | Member must be at least 18 years of age. For Peg-Intron, member must be 3 years of age or older. | | Genotype 1: 16 weeks Genotypes 2 & 3: 24 weeks Infergen or co-infection with HIV or HBV: 48 weeks | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| <p style="text-align: center;">Medications for the Treatment of Pulmonary Hypertension</p> | <p style="text-align: center;">All FDA-approved indications not otherwise excluded from Part D</p> | <p>Tufts Health Plan will not authorize coverage of Flolan, Remodulin, Tracleer, Ventavis, or sildenafil for PH secondary to the following conditions:</p> <ul style="list-style-type: none"> • Diseases of the left atrium and ventricle such as congestive heart failure (CHF) or cardiomyopathy • Diseases of the mitral and aortic valves • Chronic lung diseases such as COPD, restrictive pulmonary disease or interstitial pulmonary disease • Obstructive sleep apnea or other sleep disorders involving breathing or alveolar hyperventilation disorders | <p>Tufts Health Plan may authorize coverage of Flolan, Letairis, Remodulin, Tracleer, Ventavis, or sildenafil for members when the following criterion is met:</p> <ul style="list-style-type: none"> • Definitive diagnosis of pulmonary arterial hypertension as diagnosed by a pulmonologist or cardiologist and confirmed by right heart catheterization | | <p style="text-align: center;">The prescribing physician must be a Cardiologist or Pulmonologist</p> | <p style="text-align: center;">Life of Plan</p> | |
| <p style="text-align: center;">Nexavar</p> | <p style="text-align: center;">All FDA-approved indications not otherwise excluded from Part D</p> | | <p>Tufts Health Plan may authorize coverage of Nexavar when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of advanced Renal Cell Carcinoma <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Documented failure to or inability to tolerate treatment involving high-dose interleukin 2 or interferon therapy <p style="text-align: center;">Either 1 and 2 OR</p> <ul style="list-style-type: none"> • Documented diagnosis of other cancer provided effective treatment with Nexavar is recognized for | | <p style="text-align: center;">The prescribing physician must be an Oncologist, Nephrologist or Urologist</p> | <p style="text-align: center;">Life of Plan</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| Nexavar (continued) | All FDA-approved indications not otherwise excluded from Part D | | treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L | | The prescribing physician must be an Oncologist, Nephrologist or Urologist | Life of Plan | |
| Orencia | All FDA-approved indications not otherwise excluded from Part D | Not approved if administered concomitantly with another tumor necrosis factor antagonist (e.g. Enbrel, Humira or Remicade) or Kineret (anakinra) | <p>Tufts Health Plan may authorize coverage of Orencia when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of Rheumatoid Arthritis or Juvenile Idiopathic Arthritis <li style="text-align: center;">AND • Documented inadequate response or inability to tolerate at least one tumor necrosis factor antagonist (Enbrel, Humira or Remicade) | | The prescribing physician must be a Rheumatologist | Life of Plan | |
| Orfadin | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> • Member must have a documented diagnosis of genetic tyrosinemia Type 1 (hereditary tyrosinemia Type 1) | | | Life of Plan | |
| Penlac | All FDA-approved indications not otherwise excluded from Part D | Penlac will not be covered for onychomycosis with lunula involvement or paronychia | <p>Tufts Health Plan may authorize coverage of Penlac when the following criteria are met:</p> <ul style="list-style-type: none"> • Physician documented case of onychomycosis with one of the following conditions: <ul style="list-style-type: none"> ○ Immunodeficiency ○ Diabetes mellitus ○ Vascular compromise ○ Venous ulcers ○ Venostatis dermatitis ○ Poor arterial circulation ○ Vascular insufficiency | | | Coverage is limited to 48 weeks of therapy | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

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| Penlac (continued) | All FDA-approved indications not otherwise excluded from Part D | Penlac will not be covered for onychomycosis with lunula involvement or paronychia | <ul style="list-style-type: none"> ○ Peripheral vascular disease or claudication ○ Vasculitis <li style="text-align: center;">AND ○ Physician-documented contraindication to using Lamisil, such as: <ul style="list-style-type: none"> • Abnormal liver function tests • History of hepatitis or other liver disease • Allergy to oral antifungal agents • Currently on a drug with significant hepatotoxic potential • Drug-drug interactions | | | Coverage is limited to 48 weeks of therapy | |
| Promacta | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage of Promacta for members when all of the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) <li style="text-align: center;">AND • The member has had an insufficient response or intolerance to corticosteroids and/or immunoglobulins OR the member has not responded to splenectomy | | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--------------------|---|--|---|------------------------------------|----------------|
| <p align="center">Remicade</p> | <p align="center">Ankylosing Spondylitis, Crohn's disease, Juvenile Idiopathic Arthritis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Ulcerative Colitis</p> | | <p>Ankylosing Spondylitis</p> <ul style="list-style-type: none"> The member has a diagnosis of ankylosing spondylitis from a rheumatologist. <p>Crohn's disease or Ulcerative Colitis</p> <ul style="list-style-type: none"> The Member has a documented diagnosis of Crohn's disease or Ulcerative Colitis <p align="center">AND</p> <ul style="list-style-type: none"> The Member has demonstrated an inadequate response to an appropriate trial with two or more of the following agents: <ul style="list-style-type: none"> Corticosteroids 5-Aminosalicylates 6-mercaptopurine and/or azathioprine Methotrexate <p>Psoriasis</p> <ul style="list-style-type: none"> The member must have a definitive diagnosis of moderate-to-severe chronic plaque psoriasis <p align="center">AND</p> <ul style="list-style-type: none"> The member has failed to respond to, or have been unable to tolerate Psoralens with UVA light and ONE of the following: <ul style="list-style-type: none"> Soriatane Methotrexate Cyclosporine | <p align="center">Adults 18 years or older except for pediatric Crohn's disease (member must be age 6 to 17 years)</p> | <p align="center">The prescribing physician must be a Dermatologist, Rheumatologist or Gastroenterologist</p> | <p align="center">Life of Plan</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---|---|---|---|--|---|-------------------|----------------|
| Remicade (continued) | Ankylosing Spondylitis, Crohn's disease, Juvenile Idiopathic Arthritis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Ulcerative Colitis | | Psoriatic Arthritis <ul style="list-style-type: none"> The member must have an inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months Rheumatoid Arthritis or Juvenile Idiopathic Arthritis <ul style="list-style-type: none"> The member must have had an inadequate response after three months at optimal doses or an inability to take methotrexate | Adults 18 years or older except for pediatric Crohn's disease (member must be age 6 to 17 years) | The prescribing physician must be a Dermatologist, Rheumatologist or Gastroenterologist | Life of Plan | |
| Restasis | All FDA-approved indications not otherwise excluded from Part D | | <ul style="list-style-type: none"> The member must have a definitive diagnosis of Keratoconjunctivitis Sicca or Sjogrens Syndrome | 16 years of age or older | | Life of Plan | |
| Retinoids for the Topical Treatment of Acne Vulgaris and Psoriasis | All FDA-approved indications not otherwise excluded from Part D | Tufts Health Plan will only authorize coverage of topical acne products for the criteria listed in the Required Medical Information | Tufts Health Plan may authorize coverage when either of the following criteria is met: <ul style="list-style-type: none"> Physician-documented diagnosis of acne or comedones (white heads) For Tazorac <ul style="list-style-type: none"> Physician-documented diagnosis of plaque psoriasis <p align="center">OR</p> <ul style="list-style-type: none"> Documented diagnosis of skin cancer provided Tazorac is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L | | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--------------------|--|-----------------|--|-------------------|----------------|
| Revlimid | All FDA-approved indications not otherwise excluded from Part D | | <p>Myelodysplastic Syndrome</p> <ul style="list-style-type: none"> Documented diagnosis of transfusion dependent anemia due to myelodysplastic syndrome associated with the 5q-deletion cytogenetic abnormality <p>Multiple Myeloma</p> <ul style="list-style-type: none"> Must be used in combination with dexamethasone <p align="center">AND</p> <ul style="list-style-type: none"> Member has received and failed to respond to at least one prior therapy <p align="center">Either 1 and 2 OR</p> <ul style="list-style-type: none"> Coverage for other cancer diagnoses may be authorized provided effective treatment with Revlimid is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L | | The prescribing physician must be a Hematologist or Oncologist | Life of Plan | |
| Rituxan | All FDA-approved indications not otherwise excluded from Part D | | <p>Rheumatoid Arthritis</p> <ul style="list-style-type: none"> The member must have diagnosis of active rheumatoid arthritis <p align="center">AND</p> <ul style="list-style-type: none"> The member has had a documented inadequate response to an appropriate trial with at least one tumor necrosis factor (TNF) antagonist therapy, including Enbrel (etanercept), Humira (adalimumab), or Remicade (infliximab) <p>Non-Hodgkin's Lymphoma</p> <ul style="list-style-type: none"> Rituxan does not require authorization | | The prescribing physician must be a Rheumatologist or Oncologist | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
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| Somavert | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage when all of following criteria are met:</p> <ul style="list-style-type: none"> • Physician-documented diagnosis of acromegaly <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member has had a failure of, or is unable to tolerate, a treatment regimen that included octreotide <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member is not a candidate for surgery and/or radiation or has had an inadequate response to surgery and/or radiation. | | The prescribing physician must be an Endocrinologist | Life of Plan | |
| Sporanox | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage when all of following criteria are met:</p> <ul style="list-style-type: none"> • The member has met the coverage criteria for Lamisil <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The requesting physician has documented that the member has had a treatment failure of, or is unable to tolerate, an adequate trial of Lamisil <p style="text-align: center;">Either 1 and 2 OR</p> <ul style="list-style-type: none"> • The requesting physician has documented that the member has one of the following fungal infections: <ul style="list-style-type: none"> ○ Aspergillosis ○ Blastomycosis ○ Cryptococcus neoformans ○ Histoplasmosis ○ Tinea (pedis, corporis) resistant to aggressive topical therapy | | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--------------------|---|-----------------|---|-------------------|----------------|
| Sprycel | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage of Sprycel (dasatinib) for members when the following criteria are met:</p> <ul style="list-style-type: none"> • Documented diagnosis of Chronic Myeloid or Myelogenous Leukemia OR Philadelphia chromosome-positive acute lymphoblastic leukemia AND • Documented resistance or intolerance to prior therapy, including Gleevec Either 1 and 2 OR • Documented diagnosis of other cancer provided effective treatment with Sprycel is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L | | | Life of Plan | |
| Sutent | All FDA-approved indications not otherwise excluded from Part D | | <p>Advanced Renal Cell Carcinoma</p> <ul style="list-style-type: none"> • The member must have a documented diagnosis of Advanced renal Cell Carcinoma <p>Gastrointestinal Stromal Tumor</p> <ul style="list-style-type: none"> • The member must have a documented diagnosis of gastrointestinal stromal tumor <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member has a demonstrated disease progression or intolerance following an appropriate trial with Gleevec | | The prescribing physician must be an Oncologist | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--|--|-----------------|------------------------|---|--|
| <p align="center">Synagis</p> | <p align="center">All FDA-approved indications not otherwise excluded from Part D</p> | <p>Synagis may not be covered in the following situations:</p> <ul style="list-style-type: none"> • Use in the absence of chronic lung disease or pre-maturity as defined in the Required Medical Information section • Experimental uses not approved by the FDA • Use in months outside of the specified regional RSV season • Infants with mild cardiomyopathy who are not receiving medical therapy • Children with hemodynamically insignificant heart disease, such as: <ul style="list-style-type: none"> ○ Secundum atrial septal defect ○ Pulmonic stenosis ○ Patent ductus arteriosus ○ Small ventricular septal defect ○ Uncomplicated aortic stenosis ○ Mild aortic coarctation ○ S/P corrective surgery, unless continued treatment of congestive heart failure is required. | <p>Chronic Lung Disease</p> <ul style="list-style-type: none"> • Infants and children less than 24 months of age with a diagnosis of chronic lung disease (CLD, formerly Bronchopulmonary Dysplasia) requiring medical management within the 6 months prior to the anticipated RSV season. <ul style="list-style-type: none"> ○ Examples of medical management include, but are not limited to, oxygen therapy, diuretics or inhaled corticosteroids <p>Prematurity</p> <ul style="list-style-type: none"> • Infants born at 32 weeks gestation or less who do not have a diagnosis of chronic lung disease or do not meet the above criteria, but are either: <ul style="list-style-type: none"> ○ Born at 29 - 32 weeks of gestation and are age 6 months or less at onset of the RSV season ○ Born at 28 weeks of gestation or less and are age 12 months or less at onset of the RSV season. <p>Immunodeficiency</p> <ul style="list-style-type: none"> • Children under 24 months of age at the onset of RSV season with an immunodeficiency caused by, but not limited to, HIV or cancer chemotherapy that may make them more susceptible to severe lower respiratory tract disease | | | <p align="center">Injections are administered monthly for a maximum of 5 doses during the RSV season.</p> | <p align="center">The first dose must be administered after October 15 and the last dose before March 15</p> |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--|--|-----------------|---|---|--|
| Synagis (continued) | All FDA-approved indications not otherwise excluded from Part D | | <p>Congenital Heart Disease</p> <ul style="list-style-type: none"> • Infants and children under age 24 months at the start of the RSV season with hemodynamically significant congenital heart disease, which includes congestive heart failure, moderate to severe pulmonary artery hypertension or cyanotic heart disease. <p>Risk Factors</p> <ul style="list-style-type: none"> • For infants born at 32 to 35 weeks gestation and age less than 6 months at the beginning of the RSV season with two (2) or more of the following underlying conditions: <ul style="list-style-type: none"> ○ Severe neuromuscular disease ○ School-aged siblings ○ Congenital abnormalities of the airways ○ Daycare ○ Exposure to environmental air pollutants, including tobacco smoke | | | Injections are administered monthly for a maximum of 5 doses during the RSV season. | The first dose must be administered after October 15 and the last dose before March 15 |
| Tasigna | All FDA-approved indications not otherwise excluded from Part D | Tufts Health Plan will not authorize the use of Tasigna for conditions other than those listed without appropriate documentation | <p>Tufts Health Plan may authorize coverage of Tasigna for Members when the following criteria are met</p> <ul style="list-style-type: none"> • Documented diagnosis of Philadelphia chromosome positive chronic myelogenous leukemia in chronic phase or in accelerated phase <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Documented resistance or intolerance to prior therapy, including Gleevec | | The prescribing physician must be an Oncologist | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--|--|-----------------|------------------------|-------------------|----------------|
| Tasigna (continued) | All FDA-approved indications not otherwise excluded from Part D | Tufts Health Plan will not authorize the use of Tasigna for conditions other than those listed without appropriate documentation | <p style="text-align: center;">1 and 2 OR</p> <p>Documented diagnosis of other cancer provided effective treatment with Tasigna is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L</p> | | | | |
| Tykerb | All FDA-approved indications not otherwise excluded from Part D | <p>Tykerb may not be covered in the following instances:</p> <ul style="list-style-type: none"> • For advanced or metastatic breast cancer tumors that do not overexpress the HER2 protein • For monotherapy treatment of HER2 overexpressing advanced or metastatic breast cancer | <p>Tufts Health Plan may authorize coverage of Tykerb (lapatinib) for members when all the following criteria are met:</p> <ul style="list-style-type: none"> • Documented diagnosis of HER2 overexpressing advanced or metastatic breast cancer • The member has failed prior therapy with an appropriate trial of an anthracycline and a taxane chemotherapeutic agent • The member has failed prior therapy with an appropriate trial of Herceptin • The member is concurrently treated with Xeloda <p style="text-align: center;">All of the above OR</p> <ul style="list-style-type: none"> • Documented diagnosis of other cancer provided effective treatment with Tykerb is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L. | | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--|--|-----------------|---|--------------------------------|----------------|
| <p align="center">Tysabri</p> | <p align="center">All FDA-approved indications not otherwise excluded from Part D</p> | <p align="center">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)</p> | <p>Multiple Sclerosis</p> <ul style="list-style-type: none"> • The Member must have a definitive diagnosis of relapsing multiple sclerosis <p align="center">AND</p> <ul style="list-style-type: none"> • The member has a documented inadequate response or inability to tolerate an appropriate trial with Avonex, Betaseron, Copaxone or Rebif <p>For Crohn’s Disease</p> <ul style="list-style-type: none"> • The member must have a definitive diagnosis of Crohn’s Disease <p align="center">AND</p> <ul style="list-style-type: none"> • The member has demonstrated an inadequate response to an appropriate trial with two or more of the following: <ul style="list-style-type: none"> ○ Corticosteroids ○ 5-Aminosalicylates ○ 6-mercaptopurine and/or azathioprine ○ Methotrexate <p align="center">AND</p> <ul style="list-style-type: none"> • The member has demonstrated an inadequate response to an appropriate trial with Humira or Remicade | | <p align="center">The prescribing physician must be a Gastroenterologist or Neurologist</p> | <p align="center">6 months</p> | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--------------------|---|-----------------|---|-------------------|----------------|
| Vimpat | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage of Vimpat for Members when the following criteria are met:</p> <ul style="list-style-type: none"> • Documented diagnosis of partial-onset seizures by a neurologist <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member has had an insufficient response or intolerance to at least one other medication indicated for adjunct partial seizures, such as: <ul style="list-style-type: none"> ○ Felbatol (felbamate) ○ Gabitril (tiagabine) ○ Lamictal (lamotrigine) ○ Lyrica (pregabalin) ○ Keppra /Keppra XR (levetiracetam) ○ Neurontin (gabapentin) ○ Topamax (topiramate) ○ Trileptal (oxcarbazepine) ○ Zonegran (zonisamide) | | | Life of Plan | |
| Xenazine | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage for members when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of moderate chorea associated with Huntington’s Disease <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member has demonstrated an inadequate response to or is unable to tolerate an adequate trial with amantadine, antipsychotics or benzodiazepines | | The prescribing physician must be a Neurologist | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
|---------------------------------------|---|--------------------|---|---|--|-------------------|----------------|
| Xolair | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage for members when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented failure of at least 3 months of treatment that included high-dose inhaled corticosteroids or oral corticosteroids, leukotriene modifiers or inhaled long-acting bronchodilators <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member shows a definitive sensitivity on allergy testing to one or more perennial allergens <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • 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 | Member must be 12 years of age or older | The prescribing physician must be an asthma specialist (Allergist, Immunologist, or Pulmonologist) | Life of Plan | |
| Zavesca | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage for members when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of Type 1 Gaucher Disease <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • The member cannot be treated with enzyme replacement therapy (Ceredase or Cerezyme) | Member must be 18 years of age or older | | Life of Plan | |

2010 Tufts Medicare Preferred HMO and PDP Prior Authorization Guidelines

| Prior Authorization Group Description | Covered Uses | Exclusion Criteria | Required Medical Information | Age Restriction | Prescriber Restriction | Coverage Duration | Other Criteria |
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| Zolinza | All FDA-approved indications not otherwise excluded from Part D | | <p>Tufts Health Plan may authorize coverage of Zolinza (vorinostat) for members when the following criteria are met:</p> <ul style="list-style-type: none"> • The member has a documented diagnosis of advanced cutaneous T-cell lymphoma (Stage IIB and higher) and progressive, persistent or recurrent disease <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Documented contraindication or treatment failure of radiotherapy, total skin electron beam therapy, PUVA, or extracorporeal photophoresis <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Documented current or prior treatment or treatment failure with at least two systemic chemotherapeutic agents for cutaneous T-cell lymphoma <p style="text-align: center;">1, 2 & 3 OR</p> <ul style="list-style-type: none"> • Documented diagnosis of other cancer provided effective treatment with Zolinza is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of section 47L | | | Life of Plan | |