

**Prior Authorization Group:****Abilify****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Members must have a diagnosis of Bipolar Disorder, or members must have a diagnosis of Schizophrenia, or members must have a diagnosis of Major Depression with Psychosis, or members must have a diagnosis of treatment resistant Major Depressive Disorder and failure of both mono and combination antidepressant therapy which includes: An adequate trial and failure, duration of at least 4 weeks, or intolerance to monotherapy with 2 different Antidepressant therapies AND trial and failure, duration of at least 4 weeks, or intolerance to a single trial of combination Antidepressant therapy (such as a SSRI and bupropion or SNRI and bupropion) OR trial and failure, duration of at least 4 weeks, or intolerance to a single trial of an Antidepressant with augmentation therapy (such as Lithium).

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## **Prior Authorization Group:**

## **Acne Products**

### **Covered Uses:**

All FDA approved indications not otherwise excluded from Part D incl Acne, Acne vulgaris, Cystic acne, Comedones, Papul, Pustul, Precanc or canc lesions, Psoriasis, Keratosis follicularis (Darier's Dis, Darier-White dis), Folliculitis, Molluscum contagiosum, Facial warts, Milia, Malig neopl, Rosacea, Grover's dis, Verruca plana, or Favre-Racouchot Synd (Nodular Elastosis with Cysts and Comedones).

### **Exclusion Criteria:**

Diagnoses not covered: solar elastosis, sun damage, wrinkles, actinic damage, melasma, lentigines / freckles (hyperpigmented macules, liver spots), heliodermatitis, dermatoheliosis

### **Required Medical Information:**

Diagnosis required for initial coverage. Reauthorization will require response to therapy.

### **Age Restrictions:**

Prior authorization applies to members 35 years of age and older.

### **Prescriber Restrictions:**

No Prescriber Restrictions

### **Coverage Duration:**

365 days

### **Clinical Criteria Used in Determining Coverage:**

Will be covered for members 35 years of age and older with the following diagnoses: Acne, Acne vulgaris, Cystic acne, Comedones, Papules, Pustules, Precancerous or cancerous lesions, Psoriasis, Keratosis follicularis (Darier's Disease, Darier-White disease), Folliculitis, Molluscum contagiosum, Facial warts, Milia, Malignant neoplasm, Rosacea, Grover's disease, Verruca plana, or Favre-Racouchot Syndrome (Nodular Elastosis with Cysts and Comedones).

**Prior Authorization Group:****Actimmune****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Diagnosis of basal cell carcinoma of the skin, breast cancer, burn infection, Chronic Myeloid Leukemia, condyloma acuminatum, graft vs. host disease, idiopathic pulmonary fibrosis, kaposi's Sarcoma, malignant mesothelioma, mycobacteriosis, ovarian cancer, rheumatoid arthritis, scleroderma, chronic hepatitis B, Whipple's disease will not be covered.

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

An immunologist, hematologist, or infectious disease physician or in consultation with these physicians must be prescribing for a diagnosis of Chronic Granulomatous Disease. An orthopedic surgeon, hematologist, or endocrinologist or in consultation with these physicians must be prescribing for a diagnosis of Severe Malignant Osteopetrosis.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

For Chronic Granulomatous Disease, Actimmune must be prescribed by an immunologist, hematologist, infectious disease physician or in consultation with these physicians AND conventional antibiotics (SMZ-TMP, cephalexin) and/or antifungals (itraconazole) must be tried and failed. For Severe malignant osteopetrosis, Actimmune must be prescribed by an orthopedic surgeon, hematologist, or endocrinologist or in consultation with these physicians AND diagnosis confirmed by radiological evidence.

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**Prior Authorization Group:****Actiq****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Treatment of acute or postoperative pain.

**Required Medical Information:**

The member must be opioid tolerant.

**Age Restrictions:**

16 years of age or greater.

**Prescriber Restrictions:**

Oncologist or pain specialist must write Actiq prescriptions.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

The member must have breakthrough cancer pain with their long-acting opioid therapy AND The member must be opioid tolerant .

**Prior Authorization Group:****Adagen****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

18 years of age or less.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Pediatric member must have a confirmed diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency disease (SCID) who have failed or are not candidates for bone marrow transplantation

**Prior Authorization Group:****Afinitor****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days

**Clinical Criteria Used in Determining Coverage:**

Patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib.

**Prior Authorization Group:****Aldurazyme****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

Must 5 years of age or older.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Must have a confirmed diagnosis of Mucopolysaccharidosis, Type I (Hurler and Hurler-Scheie forms) and Scheie form with moderate to severe symptoms.

**Prior Authorization Group:****Amevive****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis and CD4 count.

**Age Restrictions:**

Member is age 18 or older.

**Prescriber Restrictions:**

Dermatologist

**Coverage Duration:**

Initial authorization for 12 weeks. Maximum treatment length is 24 weeks.

**Clinical Criteria Used in Determining Coverage:**

Member must have a diagnosis of chronic (greater than or equal to 1 year) moderate to severe plaque psoriasis, who is a candidate for systemic therapy, member must have a minimum body surface area involvement of greater than or equal to 10%, (members with plaque psoriasis of the palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement), member must have tried methotrexate and TNF blocking agent for at least 3 months with an inadequate response as reported by the prescribing provider, or, member has experienced significant side effects / toxicity of methotrexate and/or TNF blocking agents, approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy and/or TNF blocking agents, member must have a normal CD4 lymphocyte count (250 cells/ $\mu$ L or greater), member cannot have Human Immunodeficiency Virus (HIV), and currently not using a TNF-blocking agent or other biologic agent, such as Kineret, Enbrel, or Humira. For reauthorization, member must have had at least 12 weeks off of therapy after the initial 12 weeks on therapy and chart documentation from the provider must indicate that the member's disease has improved based upon the provider's assessment while on therapy.

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**Prior Authorization Group:****Amphetamines****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D including ADHD, adjunct to antidepressant therapy, adjunct to pain therapy, adjunct to Alzheimer's treatment (methylphenidate), fatigue associated with chronic disease such as HIV, MS or Cancer, post traumatic brain injury or narcolepsy.

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

Prior authorization applies to members age 19 and above.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Amphetamines will be covered for ADHD, adjunct to antidepressant therapy, adjunct to pain therapy, adjunct to Alzheimer's treatment (methylphenidate), fatigue associated with chronic disease such as HIV, MS or Cancer, post traumatic brain injury or narcolepsy.

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**Prior Authorization Group:****Androgens****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis and morning serum testosterone level less than 300ng/Dl.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Androgenic agents will be covered for Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy, or, Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation.

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**Prior Authorization Group:****Aranesp****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D include anemia of CRF and on renal dialys w Hg ls thn /equal to 11 gDl, ane CRF, not requ dialy w Hg ls thn/eq to 11gDl or ane (Hg ls thn/eq to 11 gDl) in mem with non-myeloid malig w ane due to eff of concom adm chemo,ane assoc use of ribavirin if Hg ls thn 12 gdl or 2gdl dec base Hg or ane asso w myelody synd when Hg s thn 12gdl

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Hemoglobin level, iron studies, and diagnosis for initial authorization. Continued authorization requires an increase in Hgb of 1gm/dl and a Hgb less than or equal to 12gm/dl.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

6 weeks initially then every 6 months.

**Clinical Criteria Used in Determining Coverage:**

Mem must have ONE of follow diag: anemia of CRF and on renal dialysis with hemoglobin (Hgb) less than or equ to 11 g/Dl or anem of CRF, not requ dialysis with Hgb less than or equ to 11g/Dl or anem (Hgb less than or equal to 11 g/Dl) in mem with non-myeloid malignancies where ane is due to effect of concomitantly adm chem or anem assoc with use of ribavirin if Hgb less than 12.0 g/dl or a 2g/dl decr from baseline Hgb or anem assoc with myelodysplastic syn when Hgb less than 12.0 g/dl and iron stat must be eval by prov for all mem before and during treat. Supp iron therapy is requ for all mem whose ferritin below 100 mcg/L (less than 300 mcg/L in mem withCKD) or transferrin sat is below 20 and memb must not have uncontrolled hypertension and mem must not have known hypersensitivity active sub or any excipients of the product and pres dose must be within the rec dosing guide.

**Prior Authorization Group:****Arcalyst****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Negative Tuberculin PPD for initial authorization. For continued authorization, chart documentation must be submitted from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

12 years of age or older.

**Prescriber Restrictions:**

Confirming diagnosis by a rheumatologist, dermatologist, immunologist, or genetic specialist.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a diagnosis of Muckle-Wells syndrome (MWS) or familial cold autoinflammatory syndrome (FCAS) and not currently using a Tumor Necrosis Factor (TNF) blocking agent or other biologic agent such as Kineret.

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**Prior Authorization Group:****Banzel****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Neurologist

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a diagnosis of Lennox-Gastaut syndrome. Authorizations may be extended at one-year intervals based upon chart documentation from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy.

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**Prior Authorization Group:****Botox****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D incl tor dyst,blepharo,orfac dysk, spas tort,org wrir's crmp,frs of tors dyst,herd spas parap,MS,Neuro opt,Schlder's ds,demy ds of CNS, spas hmi aff dom/nondm,InfCP, fc nv do, esotrop,exotrop,heterphor, para/mech strab, strab,do of bin eye move,do of eye move,lary sps,ds of larynx, achal, cdiosp,anl spas, anl fis, tortico, mus spasm.

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis for initial authorization. For reauthorization, chart documentation from the prescriber indicating that the member's condition has improved as a result of therapy must be submitted.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

90 days initially then 365 days per reauthorization criteria.

**Clinical Criteria Used in Determining Coverage:**

Botox will be covered for the following diagnoses: Idiopathic torsion dystonia, Symptomatic torsion dystonia, Blepharospasm, Orofacial dyskinesia, Spasmodic torticollis, Organic writer's cramp, Fragments of torsion dystonia, other, Hereditary spastic paraplegia, Multiple sclerosis, Neuromyelitis optica, Schilder's disease, Other demyelinating disease of central nervous system, Demyelinating disease of central nervous system, unspecified, Spastic hemiplegia, affecting dominant side, Spastic hemiplegia, affecting nondominant side, Infantile cerebral palsy, Other specified infantile cerebral palsy, Infantile cerebral palsy, unspecified, Other facial nerve disorders, Esotropia, Exotropia, Intermittent Heterotropia, Other and unspecified heterotropia, Heterophoria, Paralytic strabismus, Mechanical strabismus, Other specified strabismus, Other disorder of binocular eye movements, Unspecified disorder of eye movements, Laryngeal spasm, Other diseases of larynx, not elsewhere defined, Achalasia and cardiospasm, Anal spasm, Anal fissure, Torticollis, unspecified, or Spasm of muscle.

**Prior Authorization Group:****Buphenyl****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a diagnosis of urea cycle disorder AND this drug will be used as an adjunct to dietary therapy.

**Prior Authorization Group:****Bystolic****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Claims history of trial and failure of 2 beta-blockers. Chart doc can also be submitted indicating that the member has failed or had an intolerance to 2 different beta-blockers

## UPMC for Life: Prior Authorization Criteria 2010

**Prior Authorization Group:****Celebrex****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Celebrex will be covered for members whose age is 65 or greater, have a history of GI bleed or documented ulcer (peptic, duodenal or gastric), or have chronic steroid use, or use anticoagulant (coumadin/warfarin, or have coagulopathy or have tried and failed two prescription strength non steroidal anti-inflammatory agents.

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**Prior Authorization Group:****Ceredase / Cerezyme****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Tay-Sachs Disease

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Prescribed by, or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders or the patient was referred to a center that specializes in the treatment of Gaucher disease.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Not Applicable

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**Prior Authorization Group:****Cimzia****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Negative Tuberculin PPD for initial authorization. For continued authorization, chart documentation must be submitted from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

18 years of age or older.

**Prescriber Restrictions:**

Confirming diagnosis by a gastroenterologist or rheumatologist.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

For a diagnosis of moderate to severe Crohn's disease members must have tried conventional therapy including aminosalicylates (i.e., sulfasalazine, mesalamine), corticosteroids or immunomodulators (i.e., azathioprine, 6-mercaptopurine) and member must currently not be using a TNF-blocking agent, such as Humira, Enbrel, or Remicade or other biologic agent, such as Kineret.

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<b>Prior Authorization Group:</b>	<b>Elaprase</b>
<b>Covered Uses:</b>	All FDA approved indications not otherwise excluded from Part D
<b>Exclusion Criteria:</b>	No Exclusion Criteria
<b>Required Medical Information:</b>	Diagnosis
<b>Age Restrictions:</b>	5 years of age and older
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	365 days
<b>Clinical Criteria Used in Determining Coverage:</b>	Not Applicable

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**Prior Authorization Group:****Enbrel****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Negative Tuberculin PPD test for initial authorization. For continued authorization, chart documentation must be submitted from the provider that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restriction

**Prescriber Restrictions:**

Confirming diagnosis by a rheumatologist or dermatologist based upon diagnosis.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

For the diagnosis of rheumatoid arthritis, and juvenile rheumatoid arthritis: member must have a diagnosis of moderate to severe rheumatoid arthritis or juvenile rheumatoid arthritis and for rheumatoid arthritis, if appropriate, member must have tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider, or, member has experienced significant side effects/toxicity of methotrexate (MTX) (approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy) and currently not using a Tumor Necrosis Factor (TNF) blocking agent or other biologic agent such as Kineret or Humira. For the diagnosis of psoriatic arthritis: member must have a diagnosis moderate to severe psoriatic arthritis, defined as affecting at least five joints and member must have tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider, or, member has experienced significant side effects/toxicity of methotrexate (Approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy.) and currently not using a TNF-blocking agent or other biologic agent such as Kineret or Humira. For the diagnosis of psoriasis: members with a diagnosis severe plaque psoriasis (greater than 10% BSA involvement), who are candidates for systemic therapy (members with plaque psoriasis of the palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement) and member must have either: tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider, or, experienced significant side effects/toxicity of methotrexate, or, documented medical contraindications, by the prescribing provider, to methotrexate therapy OR tried phototherapy (UVB) or photochemotherapy (psoralens with UVA [PUVA]) and currently not using a TNF-

blocking agent or other biologic agent such as Kineret or Humira. For the diagnosis of ankylosing spondylitis: chart documentation must be submitted showing that the member has tried and failed intensive conservative treatment measures, including when indicated, a trial with a DMARD, such as methotrexate or sulfasalazine, for at least 3-6 months with an inadequate response as reported by the prescribing provider, and member must currently not be using a TNF-blocking agent or other biologic agent such as Kineret or Humira.

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**Prior Authorization Group:****Epogen/Procrit****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D include CRF or ESRD renal dialy, CRF not requ dialy,zido treat anem HIV mem,chemo-ind anem, mem with Hg lss thn13 hi rsk for periop transf secon to sig,antic bld loss sche to undergo elec, ncard, nvas srg to red risk fr allogren bld transf,anem assoc w ribavirin use w Hg lss thn 12 or2 dec frm base,ane assoc w myelody syn w Hg ls thn12

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Hemoglobin level, iron studies, and diagnosis for initial auth. Continued authorization requires an increase in Hgb of 1gm/dl and a Hgb less thn or equal to 12gm/dl.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

1 month initially then every 6 months.

**Clinical Criteria Used in Determining Coverage:**

Member must have a ONE of the following: CRF or ESRD and on renal dialysis and laboratory values showing Hgb less than/equal to 11 g/Dl or CRF not requiring dialysis AND lab values showing Hgb less than or equal to 11 g/dl or zidovudine treatment-induced anemia in HIV members AND lab value showing Hgb less than or equal to 11g/Dl or chemotherapy-induced anemia, not due to iron or folate deficiencies, hemolysis or GI bleed AND lab value showing Hgb less than 11 g/Dl or anemic members with lab value showing Hgb less than 13g/Dl, who are at high risk for perioperative transfusions secondary to significant, anticipated blood loss and are schedule to undergo elective, noncardiac, nonvascular surgery to reduce the risk for allogenic blood transfusions or anemia associated with the use of ribavirinI Hgb less than 12.0 g/ Dl or a 2 g/ Dl decrease from baseline or anemia associated with myelodysplastic syndrome when Hgb less than 12.0 g/dl. Iron status must be evaluated by the provider for all members before and during treatment. Supplemental iron therapy is required for all members whose serum ferritin is below 100 mcg/L (less than 300 mcg/L in members with chronic kidney disease) or whose serum transferrin saturation is below 20%.Member must not have uncontrolled hypertension. Member must not have a known hypersensitivity to the active substance or any of the excipients of the product. Prescribed dose must be within the recommended dosing guidelines.

**Prior Authorization Group:****Fabrazyme****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Men with a diagnosis of Fabry disease based on clinical symptoms or by genetic testing. Women with presumed symptoms of Fabry disease (heterozygous carriers) based on family history and/or genetic testing.

**Prior Authorization Group:****Gardasil****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Men

**Required Medical Information:**

None

**Age Restrictions:**

Member must be between the ages of 9 and 26.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

3 doses per 365 days

**Clinical Criteria Used in Determining Coverage:**

Female gender and age 9 years of age through 26 years of age

**Prior Authorization Group:****Gleevec****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days.

**Clinical Criteria Used in Determining Coverage:**

Adult and pediatric Philadelphia positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, patients in Ph+ CML in blast crisis, accelerated phase or interferon-refractory chronic phase, pediatric Ph+ CML recurrence after stem cell transplant or interferon-alpha resistant, adult relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL), adult myelodysplastic disease/myeloproliferative disease (MDS/MPD) associated with PDGFR gene rearrangements, adult aggressive systemic mastocytosis (ASM) without D816V c-Kit mutation or c-Kit mutation unknown, adult hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) with platelet derived growth factor receptor (FIP1L1-PDGFR $\alpha$ ) fusion kinase positive, negative, or unknown, adult unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP), or patients with Kit cancer protein (CD117) unresectable and/or metastatic malignant GI stromal tumors.

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## **Prior Authorization Group:**

## **Growth Hormone**

### **Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

### **Exclusion Criteria:**

Children with constitutionally delayed growth and development (i.e., delayed skeletal maturation with normal growth velocities and rates of bone age advancement, members who are at the lowest 5% of the growth curve at age 3, steroid-induced growth failure, kidney transplant recipients, Down syndrome, Fanconi's syndrome, Bloom syndrome, chromosomal and genetic disorders. Adults with chronic fatigue syndrome, fibromyalgia, obesity, athletic performance enhancer, anti-aging treatment, sepsis, burns, trauma, surgery, ESRD, wasting associated with cancer or organ failure. No evidence of malignancy in adults.

### **Required Medical Information:**

Diagnosis, growth charts, growth hormone levels from stimulation tests, IGF-1 level, x-rays of left hand and wrist, pituitary hormone levels. For continued authorization, one of the following cannot be true: growth velocity while on therapy is less than 2.5

### **Age Restrictions:**

No Age Restrictions

### **Prescriber Restrictions:**

Endocrinologist, pediatric endocrinologist, or pediatric nephrologist dependent upon diagnosis.

### **Coverage Duration:**

180 days for children with extreme short stature and 365 days for other indications.

### **Clinical Criteria Used in Determining Coverage:**

Child and Adults with Classic GHD must: doc fail to respond to 2 GH prov tests, defined as a serum GH level (peak level) less than 10ng/ml. Unless contra, 1 test must be ITT, others include levo, arg, clon, propr, glucagon. 1 ab GH test is sufficient in child with a history of irradiation or multiple pituitary hormone deficiency and IGF-I levels below normal for bone age/sex and at least 2 of the following: height is less than 5th percentile for age/sex, pretreatment growth velocity is less than 10th percentile for bone age and gender or less than 4.5cm/yr, comparison of skeletal age by x-ray of left hand and wrist is less than 2 standard deviations below the chronological age. Child with growth retardation due to Chronic Renal Insufficiency must: doc CRI up to time of renal transplant and at least one of: height is less than 5th percentile for age/sex, growth velocity is less than 10th percentile for bone age and gender or less than 4.5cm/yr. GH therapy in child must be prescribed by a pediatric endocrinologist or pediatric nephrologist. Turner syndrome in females/Noonan Syndrome must: doc diagnosis and at least one of the following: height is less than 5th percentile for age/sex, growth velocity is less than 10th percentile for bone age and gender or less than 4.5cm/yr. Child with Prader-Willi Syndrome must: doc diagnosis of Prader-Willi Syndrome and as previously stated with Turner's syndrome. Child with extreme short stature must: doc that includes specification of how basic ADLs affected, height SDS less than -2.25 cm/yr, documented growth rates are unlikely to permit attainment of adult height within target height range calculated based on parental heights, documented children with short stature born SGA have not shown catch-up growth by age 2 years. Adult

GHD–Child Onset must: diag w GHD during child whx have GHD reconfirmed as adult, GH treatment shxuld be stopped for 2-3 months aft compl of linear growth then GH levels shxuld be reasses by stim test and mem has biochem diag of GHD det by neg resp to std GH stim test def as peak GH level lss thn 3ng/ml, ITT is requ unless contra. GHRH-arg stim test res may be sub for mem w doc contra to ITT and mem has NOT reach adult peak bone mass (between 25 and 30 ys old).Ad GHD–Ad Onset must: diag w GHD, biochem diag GHD det by neg resp to std GH stim test def as pk GH level of lss thn 3ng/ml. The ITT is req unless contra. GHRH-arg stim test results may be sub for thxse w doc contr to ITT. If GHRH-arg test results nt avai, then results of 2 other stim tests, incl clon, L-Dopa, or arg, shxuld be sub OR if the cause of pit dis is known AND if 3 or more pit hxxrm are def (ACTH, TSH and gonadotropins), an IGF-1 level lss thn 84 ng/ml is suf to diag GHD. Add GH stim tsts are not req in these mem OR if cause of GHD is unknown, evid of hyp-pit ds, def as doc def in at least 2 of the fol: TSH, ACTH or gonadotropins, must be provd in addition to the GH levels from stiM test and if pit adenoma, doc subm that tumor sz has remained stab one-year prior to intng GH and mem does not have poorly cont diab or diab with unstbl prol ret.GH in adlts presc by endocrinologist. GH in children presc by endocrinologist or ped endocrinologist.

**Prior Authorization Group:****Human Chorionic Gonadotropin****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

Member must be at least 4 years of age for the treatment of cryptorchidism.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

Up to 365 days dependent upon treatment dosage.

**Clinical Criteria Used in Determining Coverage:**

Cryptorchidism: 4000 units IM 3 times weekly for 3 weeks OR 5000 units every second day for 4 doses OR 15 injections of 500 to 1000 units over a period of 6 wks OR 500 units 3 times weekly for 4 to 6 wks repeated 1 month later using 1000 units dose if ineffective. Hypogonadotropic hypogonadism, In male patients: 500 to 1000 units IM 3 times weekly for 3 weeks followed by 500 to 1000 units 2 times weekly for 3 weeks OR 4000 units 3 times weekly for 6 to 9 months, may reduce to 2000 units 3 times weekly for an additional 3 months.

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**Prior Authorization Group:****Humira****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Negative Tuberculin PPD for initial authorization. For continued authorization, chart documentation must be submitted from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

18 years of or older except for the diagnosis of Juvenile Idiopathic Arthritis in which patients must be 4 years of age or older.

**Prescriber Restrictions:**

Confirming diagnosis by a rheumatologist or a dermatologist or gastroenterologist based upon diagnosis.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

For the diag of rheumatoid arthritis (RA): mem must have a diag of mod to sev RA, if appropriate, member must have tried methotrexate (MXT) for at least 3-6 mths with an inadequate response as reported by the presc provider, or, mem has exp sig side effects/tox of MTX, (Approvals will be granted only upon doc med contraindications, by the presc provider, to MTX therapy) and currently not using a TNF-blocking agent or other biologic agent, such as Kineret or Enbrel. For the diag of psoriatic arthritis: mem must have a diag mod to sev psoriatic arthritis, defined as affecting at least five joints and mem must have tried MXT for at least 3-6 mths with an inadequate resp as reported by the presc provider, or, mem has exp sign side effects/toxicity of MTX, (Approvals will be granted only upon doc med contraindications, by the presc provider, to MXT) and currently not using a TNF-blocking agent or other biologic ag, such as Kineret or Enbrel. For the diag of ankylosing spondylitis: chart doc must be submitted showing that the mem has tried and failed intensive conservative treatm measures, incl when ind a trial with a DMARD, such as MXT or sulfasalazine, for at least 3-6 mths with an inadequate response as reported by the prescr provider and mem must currently not be using a TNF-blocking agent or other biologic agent such as Kineret or Humira. For the diag of Crohn's Ds: mem must have diag of mod to sev active crohn's dis, mem must have: tried conventional therapy including aminosalicylates (i.e., sulfasalazine, mesalamine), corticosteroids or immunomodulators (i.e., azathioprine, 6-mercaptopurine) and mem must currently not be using a TNF-blocking agent, such as Enbrel or Remicade or other biologic agent, such as Kineret. For the diag of Juvenile Idiopathic Arthritis: mem must have a diag of mod to sev active polyarticular juvenile idiopathic arthritis, member

must have: tried MXT for at least 3-6 months with an inadequate response as reported by the presc provider, or, exp sig side effects/tox of methotrexate, or, doc med contraindications, by the presc provider, to MXT therapy and currently not using a TNF-blocking agent, such as Enbrel or other biologic agent, such as Kineret, Orencia, or Rituxan. For the diag of plaque psoriasis: members with a diag severe plaque psoriasis (greater than 10% BSA involvement), who are candidates for systemic therapy (mem with plaque psoriasis of the palms, soles, head and neck, or genitalia are not requ to have a minimum body surface area involvement) and mem must have either: tried MXT for at least 3-6 mths with an inadequate response as reported by the prescr provider, or,exp sig side effects/toxicity of MXT, or, doc med contraindications, by the prescr provider, to MXT therapy OR tried phototherapy (UVB) or photochemotherapy (psoralens with UVA [PUVA]) and mem must currently not using a TNF-blocking agent such as Enbrel or Remicade or other biologic agent such as Kineret, Amevive, or Raptiva.

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**Prior Authorization Group:****Immune Globulins****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis, IgG level, platelet counts.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Prescribed by immunologist or in consultation with an immunologist for specific dependent upon diagnoses.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Primary immunodef if prescribed by an immunologist or in consultation with an immunologist. Children with ITP approved if platelet count is less than 20,000 and there is significant mucous membrane bleeding or if platelet count is less than 10,000 and minor purpura, if splenectomy is planned and platelet count is less than 30,000, if platelet count is less than 20,000 and inaccessibility or noncompliance is a concern, or if surgery, dental extractions, or other procedures likely to cause blood loss are needed. Adults with ITP approved if patient has tried a corticosteroid and the platelet count is less than 30,000 and there is acute bleeding, if ITP symptoms persist after treatment with glucocorticoids and splenectomy AND platelet count is less than 30,000 AND there is active bleeding, to increase platelet counts before major surgical procedures: dentistry less than/equal to 10,000, extractions less than/equal to 30,000, regional dental block less than/equal to 30,000, minor surgery less than/equal to 50,000, and major surgery less than/equal to 80,000, if the platelet count is less than/equal to 20,000 and the patient is considered to be at risk for intracerebral bleeding, if to defer splenectomy. For pregnant women with ITP if platelet count is less than/equal to 100,000, if past history of splenectomy, have previously delivered infants with autoimmune thrombocytopenia. For Kawasaki disease, one dose with aspirin approved in the acute phase within 7-10 days of illness. Second dose approved in patients who fail to respond to the initial therapy. For B-cell CLL, approve in patients with hypogammaglobulinemia and/or with previous history of a serious bacterial infection. Hypogammaglobulinemia for these patients is IgG less than 640 mg/dl. For CIDP, unequivocal CIDP AND impaired function by objective assessment AND trial and failure of or contraindications to steroid therapy for at least 2 months and/or plasma exchange.

**Prior Authorization Group:****Increlex/Iplex****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Member with closed epiphyses, presence of active or suspected neoplasia, or allergy to mecasecamin.

**Required Medical Information:**

Diagnosis, growth hormone levels from stimulation tests, IGF-1 level.

**Age Restrictions:**

Must be at least 2 years of age.

**Prescriber Restrictions:**

Must be prescribed by a pediatric endocrinologist and must be used with appropriate physician (pediatric endocrinologist) follow-up.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Two of the following must be present: present height less than 5th percentile for age/sex, pretreatment growth velocity is less than 10th percentile for age and gender or less than 4.5 cm/yr until age 10, and lower growth rates thereafter, comparison of skeletal (bone) age by x-ray of the left hand and wrist is greater than 2 standard deviations below the chronological age. Must have basal serum IGF-1 level which is low for age (greater than 3 standard deviations below the normal level for age and gender, as measured in clinical labs where appropriate normative data are available) and normal or elevated growth hormone (GH) shown by growth stimulation tests, except for members with GH gene deletion and cannot have secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. If thyroid or nutritional deficiencies exist, this should be corrected beforehand. For continued authorization, the member must have positive response to therapy as demonstrated through growth velocity increase, member has not reached expected final adult height and growth plates have not fused as proven through x-ray of left hand and wrist.

**Prior Authorization Group:****Invega****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a diagnosis of schizophrenia and member must have failed two atypical anti-psychotics as supported by physician chart documentation.

**Prior Authorization Group:****Iressa****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

Renewable every 180 days.

**Clinical Criteria Used in Determining Coverage:**

Monotherapy for locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based AND docetaxel-based chemotherapies who are benefiting or have benefited from Iressa.

**Prior Authorization Group:****Kuvan****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis, baseline serum phenylalanine level, and follow-up serum phenylalanine levels.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

1 month initially then annually.

**Clinical Criteria Used in Determining Coverage:**

The member must have a diagnosis of phenylketonuria (PKU) and a documented baseline serum phenylalanine level. Continuation/Discontinuation criteria: lab reassessment will be conducted after an initial one month trial to determine if authorization may be extended. Patients on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These patients will be approved for another one month trial at the higher dose. Patients on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment with Kuvan should be discontinued in these patients.

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**Prior Authorization Group:****Leflunomide Arava Kineret****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis for initial authorization. For continuation of authorization, chart documentation must be submitted by the provider stating that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Rheumatologist must be prescribing.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider or, member has experienced significant side effects/toxicity of methotrexate (approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy) and member must currently not be using another Tumor Necrosis Factor (TNF) blocking agent or biologic agent, such as Enbrel, Kineret, Humira, or Arava.

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**Prior Authorization Group:****Letairis****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis and confirmed diagnosis by right heart catheterization. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Cardiologist or pulmonologist

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member has a confirmed diagnosis of PAH with WHO functional class II or III symptoms AND member has had baseline liver function tests (ALT, AST) prior to initiation of therapy AND if a member is a woman of childbearing potential, she has had a baseline negative pregnancy test prior to initiation of therapy.

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**Prior Authorization Group:****Leuprolide and derivatives****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation is required from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 dys f pros/bs ca,cpp, 180 dys for endosis, 90 dys for ut leiomyomata, 60 dys f endometrial thin.

**Clinical Criteria Used in Determining Coverage:**

Diagnosis of prostate cancer or diagnosis of breast cancer. Diagnosis of endometriosis confirmed by laparoscopy OR if the diagnosis is not confirmed by surgery, then chart documentation of an adequate work-up and the clinical rationale for the diagnosis must be provided, for mild endometriosis, the member must have tried oral contraceptives and/or progestins. For the diagnosis of uterine leiomyomata (fibroids), member must have a diagnosis of uterine leiomyomata (fibroids), and the use of GnRh (gonadotropin-releasing hormone) agonist can be used in the treatment for fibroid in the following contexts: it may be used preoperatively to maximize preoperative hemoglobin in patients with documented preexisting anemia (Hemoglobin lss thn 11) or it may be used preoperatively to decrease the size of the fibroid uterus so a less invasive route of hysterectomy can be attempted. (i.e. from an abdominal hysterectomy to a vaginal hysterectomy or a laparoscopic hysterectomy) and clinical rationale for other use of GnRh agonist outside of the context of preoperative adjuvant in the surgical management of leiomyoma must be provided. For the diagnosis of central precocious puberty, the member must have a diagnosis of central precocious puberty with onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males. For endometrial thinning, the member must have a diagnosis of dysfunctional uterine bleeding and the member must be undergoing endometrial ablation.

**Prior Authorization Group:****Lexapro****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

None

**Required Medical Information:**

Evidence of prior use of 2 generic selective serotonin reuptake inhibitors.

**Age Restrictions:**

None

**Prescriber Restrictions:**

None

**Coverage Duration:**

365 Days

**Clinical Criteria Used in Determining Coverage:**

None

**Prior Authorization Group:****Lidoderm Patch****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Diagnosis of post-herpetic neuralgia.

**Prior Authorization Group:****Low Dose Seroquel****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must be on total daily dose greater than 200mg or member with a diagnosis of schizophrenia or member with a diagnosis of bipolar I disorder.

**Prior Authorization Group:****Low-Dose Seroquel XR****Covered Uses:**

Pending CMS Approval

**Exclusion Criteria:**

Pending CMS Approval

**Required Medical Information:**

Pending CMS Approval

**Age Restrictions:**

Pending CMS Approval

**Prescriber Restrictions:**

Pending CMS Approval

**Coverage Duration:**

Pending CMS Approval

**Clinical Criteria Used in Determining Coverage:**

Pending CMS Approval

**Prior Authorization Group:****Lyrica**

<b>Covered Uses:</b>	Pending CMS Approval
<b>Exclusion Criteria:</b>	Pending CMS Approval
<b>Required Medical Information:</b>	Pending CMS Approval
<b>Age Restrictions:</b>	Pending CMS Approval
<b>Prescriber Restrictions:</b>	Pending CMS Approval
<b>Coverage Duration:</b>	Pending CMS Approval
<b>Clinical Criteria Used in Determining Coverage:</b>	Pending CMS Approval

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**Prior Authorization Group:****Myobloc**

<b>Covered Uses:</b>	All FDA-approved indications not otherwise excluded from Part D including cervical dystonia and spasmodic torticollis.
<b>Exclusion Criteria:</b>	No Exclusion Criteria
<b>Required Medical Information:</b>	Diagnosis. For continued authorization, chart documentation from the prescriber must be submitted indicating that the member's condition has improved as a result of therapy.
<b>Age Restrictions:</b>	No Age Restrictions
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	90 days initially then 365 days.
<b>Clinical Criteria Used in Determining Coverage:</b>	Not Applicable

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**Prior Authorization Group:****Naglazyme****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

Must be 5 years of age and older.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Not Applicable

**Prior Authorization Group:****Neulasta****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**Diagnosis for initial authorization. For continuation of authorization, documentation of improvement or ANC stabilization to maintain ANC greater than 1500 cells/ mm<sup>3</sup>.**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

90 days.

**Clinical Criteria Used in Determining Coverage:**

Not Applicable

**Prior Authorization Group:****Neupogen****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

History of hypersensitivity to E. coli-derived proteins, Filgrastim, or any component of the product.

**Required Medical Information:**

Diagnosis and neutrophil count. For continuation of therapy, documentation of improvement of ANC stabilization to maintain ANC greater than 1500 cells/ mm<sup>3</sup> is required.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

90 days.

**Clinical Criteria Used in Determining Coverage:**

Neupogen will be covered for cancer members receiving conventional chemotherapy which has a significant risk of severe neutropenia, secondary prophylaxis when the following criteria are met: member is receiving a chemotherapy regimen which has a significant risk of severe neutropenia AND member has a disease for which clinical data supports maintenance of chemotherapy dose-intensity, cancer members receiving high-dose chemotherapy, Bone Marrow Transplant (BMT) to reduce the duration of neutropenia and neutropenia-related clinical sequelae in members undergoing myeloablative chemotherapy followed by marrow transplantation, members undergoing peripheral blood progenitor cell (PBPC) collection and therapy, myeloid malignancies, congenital neutropenia with neutrophil count less than 1000 cells/mm<sup>3</sup>, drug-induced agranulocytosis for members with a neutrophil count less than 1000 cells/ mm<sup>3</sup> associated with fever or other evidence of serious infection, or members being treated with ganciclovir (for CMV) AND whose neutrophil counts are consistently less than 1000 cells/ mm<sup>3</sup>.

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**Prior Authorization Group:****Nexavar****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Advanced renal cell carcinoma or unresectable hepatocellular cancer (hepatoma).

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**Prior Authorization Group:****Noxafil****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Members on the following medications: terfenadine, astemizole, cisapride, pimozone, halofantrine, quinidine.

**Required Medical Information:**

Diagnosis.

**Age Restrictions:**

Must be greater than 13 years of age.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

120 days for dg of proph of Aspergillus and Candida infections, 30 days for tx of oroph candidiasis

**Clinical Criteria Used in Determining Coverage:**

Member must be severely immunocompromised and must have a diagnosis of prophylaxis of Aspergillus and Candida infections, or diagnosis of treatment of oropharyngeal candidiasis.

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**Prior Authorization Group:****Orencia****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

6 years of age or older for Juvenile Idiopathic Arthritis

**Prescriber Restrictions:**

Diagnosis must be confirmed by a rheumatologist.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a negative Tuberculin PPD (purified protein derivative) test. For a diagnosis of moderately to severely active rheumatoid arthritis, member must have tried and failed treatment with methotrexate, for at least 3 to 6 months with an inadequate response, unless the member has experienced significant side effects/toxicity to methotrexate or if the member has documented medical contraindications to methotrexate and member must have tried and failed treatment with Remicade for at least 3 to 6 months with an inadequate response, unless the member has experienced significant side effects/toxicity to Remicade or the member has documented medical contraindications to Remicade and the member must not be using a TNF-blocking agent such as Enbrel, Remicade, Humira, and Kineret. For Juvenile Idiopathic Arthritis, member must have tried and failed treatment with methotrexate, for at least 3 to 6 months with an inadequate response, unless the member has experienced significant side effects/toxicity to methotrexate or if the member has documented medical contraindications to methotrexate and the member must not be using a TNF-blocking agent such as Enbrel, Remicade, Humira, and Kineret.

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**Prior Authorization Group:**

**Orfadin**

**Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

The member has a confirmed diagnosis of Tyrosinemia type I and the drug is being used as an adjunct to diet therapy.

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## **Prior Authorization Group:**

## **Peg Interferons**

### **Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

### **Exclusion Criteria:**

Extended or Maintenance therapy for Hepatitis C. Autoimmune hepatitis or other conditions known to be exacerbated by interferon. Known hypersensitivity to drugs used to treat hepatitis C. Patients with decompensated liver disease.

### **Required Medical Information:**

Diagnosis, Hepatitis C genotype and baseline quantitative hepatitis C virus titer. For retreatment, liver biopsy needed.

### **Age Restrictions:**

18 years of age and older.

### **Prescriber Restrictions:**

Must be prescribed by an infectious disease physician, gastroenterologist, hepatologist, or a transplant physician or in consultation with these physicians.

### **Coverage Duration:**

48 wks for all ind except for Hep C Geno 2 and 3 is 24 wks, Hep C Gento 1 is 16wks thn total 48 wks

### **Clinical Criteria Used in Determining Coverage:**

For Initial Treatment of Chronic Hepatitis C Genotype 1, treatment with peginterferon alfa is authorized for up to 16 weeks (the initial authorization is for 12 weeks with an additional 4 weeks granted for the prescriber to obtain the quantitative HCV RNA). After 12 weeks of therapy, a quantitative HCV RNA is required to continue therapy. If the member has attained an early virologic response as defined by the achievement of at least a 100-fold (2 log 10) decrease in serum HCV RNA from pretreatment baseline and/or clearance of the HCV RNA, continued treatment for a maximum of 48 weeks is authorized. If the member has not attained an early virologic response as indicated by the achievement of at least a 100-fold (2 log 10) decrease in serum HCV RNA from pretreatment baseline, further treatment with peginterferon is considered not medically necessary and should not be authorized. Consideration for continuation will be individualized based on severity of disease, demonstration of some virologic response, and tolerability of treatment. For Initial Treatment of Chronic Hepatitis C Genotypes 2 and 3 who have not been previously treated with interferon, treatment with peginterferon alfa is authorized for 24 weeks. For Treatment of HIV-Infected Member for all genotypes, treatment with peginterferon will be authorized for up to 48 weeks. For Treatment of Members with Renal Disease for all genotypes, treatment with peginterferon alfa-2A at a dose of 135mcg/week for members who are on hemodialysis will be authorized for up to 48 weeks. For Liver Transplant Members, authorization will be evaluated on a case-by-case basis using the initial treatment criteria for up to 48 weeks. Treatments will be authorized if the member has a history of treatment

prior to the transplant, as this would not constitute retreatment. Upon medical review, extended treatment with peginterferon alfa beyond the treatment course of 24-48 weeks may be considered medically necessary for persons with cryoglobulinemia and for liver transplant recipients with recurrent hepatitis C infections. Furthermore, retreatment with peginterferon will be approved for nonresponders or relapsers who have significant fibrosis or cirrhosis and who have undergone previous regimens of treatment using pegylated and non-pegylated interferons. A liver biopsy will be required to determine the progression of disease. Requests for maintenance therapy will not be authorized. For indications other than hepatitis C authorization for treatment will be given for the following conditions: For interferon alfa-2b: hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, AIDS-Related Kaposi's Sarcoma, chronic hepatitis B (1 year of age or older) For interferon alfa-2a: hairy cell leukemia or Philadelphia chromosome positive CML. For peginterferon alfa-2a: chronic hepatitis B (adult).

**Prior Authorization Group:****Prevacid Naprapac****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Member currently taking a COX-II inhibitor regardless of whether he/she meets the criteria.

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a prior history of a gastric ulcer or be at high risk for a gastric ulcer, member must require the use of a non-steroidal anti-inflammatory drug for the treatment of rheumatoid arthritis, osteoarthritis, or ankylosing spondylitis, member must have tried and failed omeprazole and an Rx strength nonsteroidal anti-inflammatory drug (NSAID) for at least 2 weeks or have a contraindication to omeprazole.

**Prior Authorization Group:****Promacta****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Platelet counts and diagnosis

**Age Restrictions:**

18 years of age or older

**Prescriber Restrictions:**

Hematologist or oncologist

**Coverage Duration:**

3 months initially and then every 6 months thereafter.

**Clinical Criteria Used in Determining Coverage:**

For initial approval, diagnosis of ITP and platelet count less than  $30 \times 10^9/L$ . Discontinue if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum daily dose of 75 mg. Discontinue if ALT levels increase to greater than or equal to 3 times upper limit of normal and progressive, or persistent for greater than or equal to 4 weeks or accompanied by increased direct bilirubin or accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation. Utilization of the lowest dose of eltrombopag to achieve and maintain platelet count  $\geq 50 \times 10^9/L$ . Dosing adjustments to follow the prescribing information. Authorization may be extended at 6 month intervals based upon chart documentation from the provider that the member's disease has improved based upon the prescriber's assessment and documented improvement in platelet count from baseline.

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**Prior Authorization Group:****Provigil****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D including diagnosis of chronic fatigue due to Multiple Sclerosis AND the member has had a previous trial of a amantadine.

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

6 months for the diagnosis of Shift-work sleep disorder. 365 days for other approvable indications.

**Clinical Criteria Used in Determining Coverage:**

For narcolepsy: documentation of diagnosis through sleep study and trial/failure of a CNS stimulant (i.e., methylphenidate, Dexedrine, generic Adderall) documented in pharmacy claims or through physician chart documentation. For Obstructive sleep apnea: documentation of diagnosis through sleep study and documentation/compliance report from physician that the member is using a CPAP machine on a regular basis, defined by at least 4 hours a night on at least 70% of the nights and symptoms still persist. For Shift-work sleep disorder (SWSD): must meet the International Classification of Sleep Disorders (ICSD)-10 criteria for chronic SWSD (which are consistent with the American Psychiatric Association DSM-IV criteria for Circadian Rhythm Sleep Disorder: Shift Work Type). The criteria includes either a primary complaint of excessive sleepiness or insomnia which is temporarily associated with a work period (a minimum of 5 night shifts per month) that occurs during the habitual sleep phase, OR polysomnography and the Multiple Sleep Latency Test (MSLT) demonstrate loss of a normal sleep-wake pattern and no other medical or mental disorder accounts for the symptoms and the symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g., time zone change [jet lag] syndrome). For chronic fatigue due to Multiple Sclerosis: the member has had a previous trial of a amantadine.

## UPMC *for Life*: Prior Authorization Criteria 2010

<b>Prior Authorization Group:</b>	<b>Relistor</b>
<b>Covered Uses:</b>	All FDA approved indications unless otherwise restricted from Part D coverage
<b>Exclusion Criteria:</b>	No Exclusion Criteria
<b>Required Medical Information:</b>	Diagnosis and previous agents tried and failed for constipation.
<b>Age Restrictions:</b>	No Age Restrictions
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	4 months initially
<b>Clinical Criteria Used in Determining Coverage:</b>	Member must have a diagnosis of opioid-induced constipation AND member must have advanced, life-limiting illness AND trial and failure of a course of traditional laxatives for treatment of the constipation.

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**Prior Authorization Group:****Remicade****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis for initial authorization. For continued authorization, chart documentation submitted from the provider showing that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Confirming diagnosis by a rheumatologist or a dermatologist or gastroenterologist based upon diagnosis.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

For the diag of rheumatoid arthritis (RA), mem must have a diagnosis of mod to sev RA and mem must have tried methotrexate (MXT) for at least 3-6 months with an inadequate response as reported by the prescribing provider unless mem has experienced sig side effects/tox of MXT or meM must have doc medical contraindications, by the presc provider, to MXT therapy and mem must not currently be using another Tumor Necrosis Factor (TNF) blocking agent or other biologic agent such as Enbrel, Kineret or Humira. For Chron's disease: mem must have tried conventional therapy including corticosteroids, or 5-ASA (i.e., Sulfasalazine, Mesalamine) and mem must currently not be using a TNF-blocking agent or other biologic agent, such as Enbrel, Kineret, or Humira. Response must be shown by week 14 in order to continue Remicade. For psoriatic arthritis: mem must have active psoriatic arthritis, defined as affecting at least five joints, member must have tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider, or, member has experienced significant side effects/toxicity of methotrexate. (Approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy.) AND member must currently not be using a TNF-blocking agent or other biologic agent, such as Enbrel, Kineret, or Humira. For severe ankylosing spondylitis who have had an inadequate response to conventional treatment: chart doc must be submitted showing that the member has tried and failed intensive conservative treatment measures, including when indicated, a trial with a DMARD, such as methotrexate or sulfasalazine, for at least 3-6 months with an inadequate response as reported by the prescribing provider and mem must currently not be using a TNF-blocking agent or other biologic agent, such as Enbrel, Kineret, or Humira. For ulcerative colitis: mem must have tried conventional therapy including

corticosteroids, or 5-ASA (i.e., Sulfasalazine, Mesalamine) for at least 3-6 months with inadequate response and mem must currently not be using a TNF-blocking agent or other biologic agent, such as Enbrel, Kineret, or Humira.

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**Prior Authorization Group:**

**Remodulin**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis and confirmed diagnosis by right heart catheterization. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Cardiologist or pulmonologist.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member has a confirmed diagnosis of PAH with WHO functional class II-IV symptoms.

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**Prior Authorization Group:****Revatio****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis and confirmed diagnosis by right heart catheterization. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Cardiologist or pulmonologist

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member has a confirmed diagnosis of PAH with WHO functional class I-IV symptoms AND member is NOT currently taking a nitrate product.

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**Prior Authorization Group:****Revlimid****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days

**Clinical Criteria Used in Determining Coverage:**

Myelodysplastic syndrome transfusion-dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or with out other cytogenetic abnormalitie or combination therapy with dexamethasone for multiple myeloma patients who have received at least one prior therapy or combination therapy with dexamethasone for multiple myeloma patients as first-line therapy.

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**Prior Authorization Group:****Rituxan****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis. Re-treatment will be authorized upon review of chart documentation from the prescriber indicating that the member's condition has improved as a result of therapy.

**Age Restrictions:**

Member must be 18 years of age or older.

**Prescriber Restrictions:**

Rheumatologist must be prescribing.

**Coverage Duration:**

1 course within 16 week period.

**Clinical Criteria Used in Determining Coverage:**

This criterion is for non-antineoplastic use only. For the treatment of cancer diagnoses, the medication will be covered under either the Part B or Part D plan in accordance with CMS regulations. Member must have a diagnosis of moderate to severe rheumatoid arthritis and member must have tried methotrexate and a Tumor Necrosis Factor (TNF) blocking agent for at least 3-6 months each with an inadequate response as reported by the prescribing provider unless member has experienced significant side effects/toxicity of TNF blocking/ MTX agents or member must have documented medical contraindications, by the prescribing provider, to TNF blocking agents and member must currently be on methotrexate therapy unless documented contraindication and must currently not be using a TNF-blocking agent or other biologic agent, such as Kineret, Enbrel, or Humira.

**Prior Authorization Group:****Savella**

<b>Covered Uses:</b>	Pending CMS Approval
<b>Exclusion Criteria:</b>	Pending CMS Approval
<b>Required Medical Information:</b>	Pending CMS Approval
<b>Age Restrictions:</b>	Pending CMS Approval
<b>Prescriber Restrictions:</b>	Pending CMS Approval
<b>Coverage Duration:</b>	Pending CMS Approval
<b>Clinical Criteria Used in Determining Coverage:</b>	Pending CMS Approval

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**Prior Authorization Group:****Serostim**

<b>Covered Uses:</b>	All FDA approved indications not otherwise excluded from Part D
<b>Exclusion Criteria:</b>	No Exclusion Criteria
<b>Required Medical Information:</b>	Diagnosis
<b>Age Restrictions:</b>	No Age Restrictions
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	Up to 48 weeks per year.
<b>Clinical Criteria Used in Determining Coverage:</b>	Member has failed at least 2 treatments with other medications used for AIDS wasting (i.e., Marinol, Megace, and Oxandrin) unless contraindications exist AND member must be compliant with his/her antiretroviral medication and follows Serostim treatment guidelines. Member will be approved for up to 48 weeks per year. Therapy continuation will be authorized with documentation from the prescriber of weight stabilization or weight gain.

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**Prior Authorization Group:****Simponi****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Negative Tuberculin PPD test for initial authorization. For continued authorization, chart documentation must be submitted from the provider that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

18 years of age or older

**Prescriber Restrictions:**

Confirming diagnosis by a rheumatologist or dermatologist based on diagnosis.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Must have a diagnosis of moderate to severely active rheumatoid arthritis and must have an adequate trial of at least 3 months of methotrexate with an inadequate response and must be on concurrent methotrexate therapy and must currently not be using a TNF-blocking agent or other biologic agents in combination with Simponi and have no evidence of infection OR must have a diagnosis of active ankylosing spondylitis and if dominant axial disease, member must have an adequate trial of at least 3 months with at least 2 NSAIDs at anti-inflammatory target dose, with an inadequate response, sig side effects or toxicity, or have a contraindication to these therapies. If dominant peripheral disease, member must have an adequate trial of at least 3 months with at least one NSAID at anti-inflammatory target dose, with an inadequate response, significant side effects or toxicity, or have a contraindication to these therapies AND member must have an adequate trial of one conventional systemic therapy (sulfasalazine or methotrexate) with an inadequate response, sig side effects or toxicity, or have a contraindication to this therapy and must currently not be using a TNF-blocking agent or other biologic agents in combination with Simponi and have no evidence of infection OR must have a diagnosis of active ankylosing spondylitis and if dominant axial disease, member must have an adequate trial of at least 3 months with at least 2 NSAIDs at anti-inflammatory target dose, with an inadequate response, significant side effects and toxicity, or have a contraindication to these therapies. If dominant peripheral disease, member must have an adequate trial of at least 3 months with at least one NSAID at anti-inflammatory target dose, with an inadequate response, significant side effects and toxicity, or have a contraindication to these therapies AND member must have an adequate trial of one conventional systemic therapy (sulfasalazine or methotrexate) with an inadequate response, significant side effects /toxicity, or

have a contraindication to this therapy and member must currently not be using a TNF-blocking agent or other biologic agents in combination with Simponi and have no evidence of infection.

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**Prior Authorization Group:**

**Sporanox**

**Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

90 days/year for onychomycosis. For other diagnoses, dependent upon recommended duration of therapy

**Clinical Criteria Used in Determining Coverage:**

Sporanox will be approved for onychomycosis in a diabetic, transplant, or immunocompromised member, or, onychomycosis causing severe debilitating foot pain (supported by chart documentation), or fungal infections on trunk of body such as tinea that are too large to treat with topical cream, or, diagnosis of oral thrush that has not responded to oral nystatin, or diagnosis of esophageal candidiasis.

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**Prior Authorization Group:**

**Sprycel**

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days

**Clinical Criteria Used in Determining Coverage:**

Adults with chronic, accelerated, or myeloid or lymphoid blast phase Chronic Myeloid Leukemia (CML) resistant or intolerant to prior therapy including imatinib (Gleevec) or Ph+ chromosome-positive ALL resistant or intolerant to prior therapy.

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**Prior Authorization Group:****Suboxone and Subutex****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continuation therapy, recent drug-free urine testing required.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Prescriber must have DATA 2000 waiver and Unique Identification Number and DEA number.

**Coverage Duration:**

90 days initially then annually.

**Clinical Criteria Used in Determining Coverage:**

Covered initially for 90 days. For continuation, member must be compliant with therapy for the previous 3 months, member must have a recent drug-free urine testing, member be enrolled and consistently participating in formal behavioral health counseling and member must not have attempted to fill any opioid prescriptions during this initial period as indicated by their drug claim history.

**Prior Authorization Group:****Sucraid****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

5 months or older.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Must have a confirmed diagnosis of sucrase-isomaltase deficiency.

**Prior Authorization Group:****Sutent****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days.

**Clinical Criteria Used in Determining Coverage:**

Gastrointestinal (GI) stromal tumors refractory to imatinib (Gleevec) or in patients intolerant to imatinib (Gleevec) or advanced renal cell carcinoma.

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**Prior Authorization Group:****Synagis****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis.

**Age Restrictions:**

Under 24 months at the start of RSV season.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

Maximum of 6 doses per RSV season.

**Clinical Criteria Used in Determining Coverage:**

Synagis will be covered for children under the age of 24 months at the beginning of Respiratory Syncytial Virus (RSV) season with Chronic Lung Disease (CLD) who have required medical treatment such as oxygen, bronchodilator, diuretic or corticosteroid therapy, for CLD within 6 months before the start of RSV season or children under the age of 24 months at the beginning of RSV season with Congenital Heart Disease, Congestive Heart Failure (CHF), severe pulmonary hypertension, cyanotic heart disease) or premature infants recommendations are based upon gestational age a) less than 28 weeks, 0 days gestational age and 12 months of age or less at the start of RSV season OR b) 28 weeks, 1 day – 32 weeks, 0 days gestational age and 6 months of age or less at the start of RSV season OR c) 32 weeks, 1 day – 35 weeks, 0 days gestational age and 6 months of age or less at the start of RSV season with TWO or more of the following risk factors: day care attendance, exposure to tobacco smoke/environmental pollutants at home, school aged siblings, diagnosis of neuromuscular disease, or diagnosis of congenital abnormality of airways.

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<b>Prior Authorization Group:</b>	<b>Tarceva</b>
<b>Covered Uses:</b>	All FDA-approved indications not otherwise excluded from Part D
<b>Exclusion Criteria:</b>	No Exclusion Criteria.
<b>Required Medical Information:</b>	Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.
<b>Age Restrictions:</b>	No Age Restrictions
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	180 days.
<b>Clinical Criteria Used in Determining Coverage:</b>	Locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen or first-line treatment in combination with gemcitabine (Gemzar) in patients with locally advanced, unresectable or metastatic pancreatic cancer.

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**Prior Authorization Group:****Targretin****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days

**Clinical Criteria Used in Determining Coverage:**

Cutaneous manifestations of T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.

**Prior Authorization Group:****Tasigna****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

180 days

**Clinical Criteria Used in Determining Coverage:**

Adult Ph+ CML in chronic phase or accelerated phase resistant to or intolerant to prior therapy including imatinib (Gleevec).

**Prior Authorization Group:****Tracleer****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis and confirmed diagnosis by right heart catheterization. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

Cardiologist or pulmonologist.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member has a confirmed diagnosis of PAH with WHO functional class II, III or IV symptoms AND member is NOT currently taking glyburide or cyclosporine AND member has had baseline liver function tests (ALT, AST) prior to initiation of therapy AND if a member is a woman of childbearing potential, she has had a baseline negative pregnancy test prior to initiation of therapy.

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<b>Prior Authorization Group:</b>	<b>Tykerb</b>
<b>Covered Uses:</b>	All FDA-approved indications not otherwise excluded from Part D
<b>Exclusion Criteria:</b>	No Exclusion Criteria.
<b>Required Medical Information:</b>	Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.
<b>Age Restrictions:</b>	No Age Restrictions
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	180 days
<b>Clinical Criteria Used in Determining Coverage:</b>	Combination therapy with capecitabine (Xeloda) for treatment of advanced or metastatic breast cancer whose tumors overexpress (HER2) AND who have had prior therapy with: anthracycline, taxane, or trastuzumab (Herceptin).

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**Prior Authorization Group:****Tysabri****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Member must not have or have had progressive multifocal leukoencephalopathy (PML).

**Required Medical Information:**

Diagnosis.

**Age Restrictions:**

Must be greater than 18 years of age.

**Prescriber Restrictions:**

Must be prescribed by a neurologist or gastroenterologist dependent upon the diagnosis who is registered with the TOUCH Prescribing program.

**Coverage Duration:**

90 days initially for Crohn's disease and 365 days for MS.

**Clinical Criteria Used in Determining Coverage:**

For MS, member must have a diagnosis of relapsing forms of multiple sclerosis, member must have previously had an inadequate response or cannot tolerate other multiple sclerosis therapies, including interferon beta-1a, interferon beta-1b, and glatiramer acetate, member must not have or have had progressive multifocal leukoencephalopathy (PML), member should not be receiving chronic immunosuppressant or immunomodulatory therapy (including interferon beta-1a, interferon beta-1b, and glatiramer acetate since natalizumab is indicated as monotherapy) or have systemic medical conditions resulting in significant compromised immune system function. For Chron's disease, member must have a diagnosis of moderately to severely active Crohn's disease with evidence of inflammation, member must have previously had an inadequate response or cannot tolerate conventional therapies such as aminosalicylates (i.e., sulfasalazine, mesalamine), corticosteroids or immunomodulators (i.e., azathioprine, 6-mercaptopurine) AND TNF-alpha inhibitors, member must not have or have had progressive multifocal leukoencephalopathy (PML), member should not be receiving chronic immunosuppressant or immunomodulatory therapy (including 6-mercaptopurine, azathioprine, cyclosporine, methotrexate, or inhibitors of TNF-alpha) or have systemic medical conditions resulting in significant compromised immune system function.

**Prior Authorization Group:**

**Vimpat**

**Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

No Exclusion Criteria.

**Required Medical Information:**

Diagnosis of partial-onset seizures.

**Age Restrictions:**

17 years of age or older.

**Prescriber Restrictions:**

Neurologist or in consultation with a neurologist.

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Vimpat (lacosamide) must be prescribed by or in consultation with a neurologist AND member must be 17 years of age or older AND member must have a diagnosis of partial-onset seizures AND member must be using Vimpat (lacosamide) as adjunctive therapy to other anti-epileptic drugs (AEDs).

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**Prior Authorization Group:****Xenazine****Covered Uses:**

All FDA approved indications unless otherwise restricted from Part D coverage

**Exclusion Criteria:**

Member must not be actively suicidal or have uncontrolled depression or currently using a monoamine oxidase inhibitor or reserpine.

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

18 years of age or older

**Prescriber Restrictions:**

Neurologist

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Member must have a diagnosis of chorea associated with Huntington's Disease. Authorizations may be extended at one-year intervals based upon chart documentation from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy and documentation that the member is being monitored for depression and suicidal ideation. Requests for doses above 50mg/day will also require documentation from the prescriber showing inadequate efficacy of lower doses and slow titration of tetrabenazine dose with close monitoring of side effects.

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**Prior Authorization Group:****Xolair****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis, IgE level, positive skin or RAST test to a perennial aeroallergen for initial authorization. For continued authorization, chart documentation from the provider must be submitted to indicate that the member's disease has improved based upon

**Age Restrictions:**

12 years of age or older

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Xolair will be approved for adults and adolescents (12 years of age and older) with moderate to severe persistent asthma on concomitant asthma therapy within the past year, and have a positive skin or RAST test to a perennial aeroallergen. An IgE (greater than 30 IU/ml or more) level must be provided.

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**Prior Authorization Group:****Xyrem****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis and sleep studies for initial authorization. For continued authorization, chart documentation from the provider must be submitted to indicate that the member's disease has improved based upon the provider's assessment while on therapy.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Xyrem will be covered for a diagnosis of cataplexy associated with narcolepsy demonstrated by supporting chart documentation or sleep studies OR a diagnosis of excessive daytime sleepiness (EDS) associated with narcolepsy demonstrated by polysomnographic evaluation or chart documentation supporting clinical history of narcolepsy.

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**Prior Authorization Group:****Xyzal****Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis.

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

For the diagnosis of allergic rhinitis, the member must have had an inadequate response as documented in pharmacy claims or physician chart documentation of 1 of the following non-sedating antihistamines: loratadine, fexofenadine, cetirizine AND an intranasal corticosteroid. For the diagnosis of urticaria, the member must have tried at least 2 of the following medications with an inadequate response as documented in pharmacy claims or physician chart documentation: loratadine, fexofenadine, and cetirizine.

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**Prior Authorization Group:****Zavesca****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

No Age Restrictions

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

365 days

**Clinical Criteria Used in Determining Coverage:**

Zavesca will be approved for a diagnosis of mild to moderate non-neuronopathic Gaucher's disease when enzyme replacement is not an option.

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<b>Prior Authorization Group:</b>	<b>Zolinza</b>
<b>Covered Uses:</b>	All FDA-approved indications not otherwise excluded from Part D
<b>Exclusion Criteria:</b>	No Exclusion Criteria
<b>Required Medical Information:</b>	Diagnosis. For continued authorization, chart documentation from the provider must be submitted to show that the member's disease has improved based upon the prescriber's assessment while on therapy.
<b>Age Restrictions:</b>	No Age Restrictions
<b>Prescriber Restrictions:</b>	No Prescriber Restrictions
<b>Coverage Duration:</b>	180 days
<b>Clinical Criteria Used in Determining Coverage:</b>	Cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following 2 systemic therapies.

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**Prior Authorization Group:****Zorbtive****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

Members with active malignancy.

**Required Medical Information:**

Diagnosis

**Age Restrictions:**

Must be at least 18 year of age.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

4 weeks.

**Clinical Criteria Used in Determining Coverage:**

Member must be at least 18 years of age. However, members under the age of 18 with a confirmed diagnosis of short bowel syndrome will be considered on a case-by-case basis in consultation with the Medical Director. Chart documentation must be submitted indicating that the member has a diagnosis of short bowel syndrome, defined as follows: member must have documented malabsorption from the small intestine that is marked by diarrhea, malnutrition, and steatorrhea and that results from resection of the small intestine and member must have a small intestine less than 200 cm in length and member must have an intact stomach and duodenum as well as greater than or equal to 30% of functioning colon with at least 15 cm of intact jejunum and/or ileum or member must have an intact stomach and duodenum as well as less than 30% functioning colon with at least 90 cm intact jejunum and/or ileum. Member should also be receiving adequate nutritional support as determined by their Provider.

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# UPMC *for Life*: Prior Authorization Criteria 2010

**Prior Authorization Group:****Zostavax****Covered Uses:**

All FDA approved indications not otherwise excluded from Part D

**Exclusion Criteria:**

No Exclusion Criteria

**Required Medical Information:**

None

**Age Restrictions:**

Must be 60 years of age or older.

**Prescriber Restrictions:**

No Prescriber Restrictions

**Coverage Duration:**

1 dose per 365 days

**Clinical Criteria Used in Determining Coverage:**

Not Applicable

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