

WellCare
Prior Authorization Protocols
2011

No Changes Made Since 8/2011

ABILIFY (aripiprazole)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the same class AND one lower tier traditional mood stabilizer. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine.</p> <p>Major Depressive Disorder (augmenting treatment): Documented continuous treatment with an antidepressant as monotherapy x 6 weeks AND documented treatment failure or intolerable side effects from treatment with at least one formulary medication within the same class. Members currently on fluoxetine require trial and failure of Symbyax and atypical quetiapine. Members not on fluoxetine require trial and failure of atypical antipsychotic quetiapine. Members not on an antidepressant require continuous trial with lower tier antidepressant including fluoxetine, paroxetine, sertraline, citalopram, bupropion, mirtazepine, venlafaxine.</p> <p>Autism: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p>
Age restrictions	<p>18 years or greater (Major Depressive Disorder – adjunctive treatment)</p> <p>13 years or greater (Schizophrenia)</p> <p>10 years or greater (Bipolar Disorder)</p> <p>6 -17 years (Autism)</p>
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ABILIFY DISCMELT (aripiprazole)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the same class AND one lower tier traditional mood stabilizer. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine.</p> <p>Major Depressive Disorder (augmenting treatment): Documented continuous treatment with an antidepressant as monotherapy x 6 weeks AND documented treatment failure or intolerable side effects from treatment with at least one formulary medication within the same class. Members currently on fluoxetine require trial and failure of Symbyax and atypical quetiapine. Members not on fluoxetine require trial and failure of atypical antipsychotic quetiapine. Members not on an antidepressant require continuous trial with lower tier antidepressant including fluoxetine, paroxetine, sertraline, citalopram, bupropion, mirtazepine, venlafaxine.</p> <p>Autism: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>For the use of the Abilify Discmelt, statement of swallowing difficulty must be included and trial and failure of risperidone ODT and risperidone oral solution for the diagnosis of schizophrenia or bipolar mania.</p>
Age restrictions	<p>18 years or greater (Major Depressive Disorder – adjunctive treatment)</p> <p>13 years or greater (Schizophrenia)</p> <p>10 years or greater (Bipolar Disorder)</p> <p>6 -17 years (Autism)</p>
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ACETYLCYSTEINE

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

ACTIMMUNE (interferon gamma-1b)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement indicating FDA approved diagnosis of chronic granulomatous disease or severe malignant osteopetrosis
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	<p>Public Health Advisory [Posted 03/09/2007] FDA notified healthcare professionals of the early termination of the INSPIRE clinical study of Actimmune for idiopathic pulmonary fibrosis (IPF). The study was stopped because an interim analysis showed that patients with IPF who received Actimmune did not benefit. The trial compared survival in patients getting Actimmune or an inactive injection (placebo). An analysis showed that 14.5% of patients treated with Actimmune died as compared to 12.7% of patients treated with placebo. Actimmune is not approved by the FDA to treat IPF. Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.</p>

ADAGEN (pegademase bovine)

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

ADCIRCA (tadalafil)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approve for members with a diagnosis of pulmonary hypertension and a negative response to the vagoactive stimulation test. Medical statement indicating diagnosis of pulmonary arterial hypertension.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Adcirca should not be used in combination with organic nitrates.

AFINITOR (everolimus)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved indication of advanced renal cell cancer. Stated failure, resistance, or intolerance to Sunitinib or Sorafenib.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ALBUTEROL SULFATE NEBULIZATION SOLUTION (albuterol sulfate)

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

ALDARA (imiquimod)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approve upon failure to an adequate trial of preferred treatment or approve if preferred treatment is contraindicated. Trial and failure of a preferred agent. Preferred agents include: For external perianal warts: Condylox gel For external genital warts: podofilox For basal cell CA: Fluorouracil topical For actinic keratosis: Fluorouracil topical
Age restrictions	12 years or older
Prescriber Restrictions	
Coverage Duration	16 weeks
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ALDURAZYME (Iaronidase)

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

ALIMTA (pemetrexed disodium)

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

AMIFOSTINE

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

**AMPHETAMINE SALT COMBO (amphetamine
/dextroamphetamine)**

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis of narcolepsy or attention-deficit hyperactivity disorder (ADHD)
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

ANADROL-50 (oxymetholone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Acquired Aplastic Anemia: 1. History of failure to erythropoietic stimulating agent: OR 2. Used in combination with antilymphocyte globulin or both antilymphocyte globulin and corticosteroid treatment.</p> <p>Hypoplastic Anemia: 1. Diagnosis of hypoplastic anemia due to myelotoxic drugs: AND 2. Failure to erythropoietic stimulating agent</p> <p>Pure Red Cell Aplasia: Failure of immunosuppressive therapy.</p> <p>Anemia of Chronic Renal Failure: Failure to an erythropoietic stimulating agent</p> <p>Preferred Erythropoietin Stimulating Agent: Procrit</p>
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

APOKYN (apomorphine hydrochloride)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Patient that has not been previously treated with standard dopaminergic therapy.
Required Medical Information	Advanced Parkinson's Disease: 1. Confirmed diagnosis of advanced Parkinson's disease AND 2. Unable to control "off" symptoms with adequate combinations of conventional oral therapy AND 3. Used in combination with a non-5-HT3 antagonist antiemetic for initial therapy AND 4. Not used in combination with 5-HT3 antagonists.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through Benefit Year
Other Criteria	Concomitant use of apomorphine with 5HT antagonists is contraindicated.

ARCALYST (rilonacept)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement indicating diagnosis is required: Approve for diagnosis cryopyrin-associated periodic syndromes (CAPS) including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
Age restrictions	12 years and older
Prescriber Restrictions	
Coverage Duration	Through Benefit Year
Other Criteria	

AVASTIN (bevacizumab)

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

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

BANZEL (rufinamide)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement indicating FDA approved diagnosis. Documentation that members current medication regimen is inadequate to control members disease.
Age restrictions	Age 4 years or greater
Prescriber Restrictions	
Coverage Duration	Through Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

BLEOMYCIN SULFATE

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

BONIVA (ibandronate sodium)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of gastrointestinal intolerance of oral bisphosphonate therapy. Preferred oral bisphosphonates: alendronate, Boniva (oral)
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

BUPHENYL (sodium phenylbutyrate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Cycle disorders: As adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC) or argininosuccinic acid synthetase (AAS). In all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). In patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. It is important that the diagnosis is made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a life threatening emergency.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

BUPRENORPHINE HCL INJECTION

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

BUPRENORPHINE HCL SUBLINGUAL TABLET

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approve sublingual tablets for diagnosis of opioid dependence.
Age restrictions	16 years old and greater
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

CALCITRIOL

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

CAMPATH (alemtuzumab)

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

CARIMUNE NANOFILTERED (immune globulin iv, ivig)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Statement indicating FDA approved diagnosis.</p> <p>Documented hypogammaglobulinemia (IgG less than 400 mg/dL).</p> <p>Idiopathic Thrombocytopenic Purpura (ITP)</p> <ol style="list-style-type: none"> 1. When there is an immediate need to increase the plt count (e.g., serious bleeding episodes) AND plt count less than 30,000 2. In preparation for splenectomy or other invasive procedures AND platelet count less than 20,000 3. In pregnant women at risk of bleeding AND a. Plt count less than 10,000 at any time during the pregnancy OR b. Plt count 10,000 to 30,000 in the second or third trimester OR c. Clinically significant bleeding 4. In chronic ITP not responding to steroids <p>Other applicable and relevant supporting medical information, such as failure or contraindication to immunosuppression or alternative therapy.</p>
Age restrictions	
Prescriber Restrictions	
Coverage Duration	<p>ITP: 5 days</p> <p>Primary Immune Deficiency Disorder: through benefit year</p>
Other Criteria	<p>Part B coverage is available for IVIG administered in the home for individuals whose diagnosis is primary immune deficiency disease.</p> <p>For Primary immunodeficiency diseases (e.g. agammaglobulinemia or hypogammaglobulinemia), Carimmune is covered under Medicare Part B.</p>

CELLCEPT (mycophenolate mofetil)

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

CEREDASE (alglucerase)

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

CEREZYME (imiglucerase)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis It is suggested that patients be monitored periodically for IgG antibody formation during their first year of treatment.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization except to verify Part B vs Part D coverage for therapy in neoplastic diseases. May Be Covered Under Medicare Part B

CERVARIX (human papillomavirus vaccine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Males
Required Medical Information	
Age restrictions	Females age 10 years old to 25 years of age
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

CHORIONIC GONADOTROPIN

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

COPAXONE (glatiramer acetate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Stated diagnosis from neurologist of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Statement may include a first MS attack with document MRI scan abnormalities characteristic of MS, OR evaluation documenting EITHER: history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, OR history of one focal neurological deficit which has resolved, and an MRI suggestive of MS: At least 3 total lesions, each at least 5mm: At least one lesion with contrast enhancement: At least 2 out of 3 lesions in either Periventricular white matter OR Brain stem (e.g. cerebellar peduncle, pons) OR Spinal cord.
Age restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Through the benefit year
Other Criteria	

CROMOLYN SODIUM INHALATION SOLUTION

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

CYCLOPHOSPHAMIDE

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

CYCLOSPORINE# M7 @CGDCF-B9`AC8 = -98

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

CYSTADANE (betaine (trimethylglycine))

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of diagnosis. Homocystinuria: The treatment of homocystinuria to decrease elevated homocysteine blood levels. Included within the category of homocystinuria are deficiencies or defects in: Cystathionine beta-synthase (CBS), 5,10-methylenetetrahydrofolate reductase (MTHFR), or Cobalamin cofactor metabolism (cbl).
Age restrictions	
Prescriber Restrictions	Urologist
Coverage Duration	Through the benefit year
Other Criteria	

CYSTAGON (cysteamine bitartrate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Cysteamine is contraindicated in patients who have demonstrated hypersensitivity to cysteamine or penicillamine hypersensitivity.
Required Medical Information	Statement of FDA approved diagnosis: Management of nephropathic cystinosis in children and adults
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Do not administer Intact cysteamine capsules to children less than 6 years old because of aspiration risk. Capsules may be administered by sprinkling contents over food.

CYTOVENE (ganciclovir)

PENDING CMS APPROVAL

DEXTROAMPHETAMINE SULFATE

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis of narcolepsy or attention-deficit hyperactivity disorder (ADHD) AND For the treatment of ADHD must have documented failure or adverse effect to two preferred alternatives including amphetamine salt combo, methylphenidate, or dexamethylphenidate.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

DRONABINOL

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For treatment of chemotherapy-induced nausea or vomiting refractory to conventional antiemetic agents: Failure of one preferred 5HT-3 receptor antagonist. Preferred alternatives include ondansetron and granisetron AND Failure of one of the following agents: dexamethasone, promethazine, or prochlorperazine. For treatment of anorexia associated with weight loss in patients with HIV: Documentation of trial and failure, contraindication, or intolerance to megestrol (Megace)
Age restrictions	18 years old and greater for the treatment of anorexia associated with weight loss in patients with HIV
Prescriber Restrictions	
Coverage Duration	For N/V - 6 months For anorexia in HIV positive patients - 3 months
Other Criteria	

ELAPRASE (idursulfase)

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

ELITEK (rasburicase)

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

EMCYT (estramustine phosphate sodium)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Prescriber statement that medication is being requested for palliative treatment of metastatic and/or progressive prostate cancer.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

EMEND (aprepitant)

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

EMSAM (selegiline)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Major depressive disorder: Failure of two (2) preferred antidepressants which should be from different classes of antidepressants, one of which should be mirtazapine orally disintegrating tablets for patients unable to swallow tablets/capsules Preferred agents include: Fluoxetine capsules, Paroxetine, Citalopram, Bupropion, Mirtazapine/ Mirtazapine ODT, Trazodone, Amitriptyline, or Venlafaxine.
Age restrictions	18 years old and greater
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ENBREL (etanercept)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Rheumatoid Arthritis: monotherapy or as adjunct therapy for the treatment of moderately to severely active RA in patients 18 years or older when the patient has failed an adequate trial (defined by the ACR) to at least one disease modifying antirheumatic drug (DMARD) and one NSAID. Preferred agents include: NSAIDS- ibuprofen, naproxen, ketoprofen, meloxicam. DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Psoriatic Arthritis: monotherapy or as adjunct therapy for the treatment of active arthritis in patients age 18 or older with moderate to severe psoriatic arthritis with documented intolerance, contraindication, or allergy to at least 2 different drug classes of preferred products OR clinical failure of adequate trial and dose of at least 2 different preferred drugs. Preferred agents include: NSAIDS- ibuprofen, naproxen, ketoprofen, meloxicam. DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Plaque Psoriasis: Failure of two oral agents including methotrexate and a steroid, OR PUVA treatment.</p> <p>Juvenile Rheumatoid Arthritis: For the treatment of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years old or greater when patient had inadequate response to methotrexate alone for the appropriate treatment period OR methotrexate is contraindicated AND one NSAID. Preferred NSAIDs include ibuprofen, naproxex, and meloxicam</p> <p>Ankylosing Spondylitis: Monotherapy for reducing signs and symptoms of active ankylosing spondylitis when patient hasn't responded to maximum tolerated doses of at least two NSAIDS. Preferred NSAIDs include ibuprofen, naproxex, and meloxicam.</p>
Age restrictions	18 years old and greater for uses other than juvenile idiopathic arthritis
Prescriber Restrictions	Rheumatologist- for RA, JRA, Psoriatic Arthritis, Anklyosing spondylitis Dermatologist for Plaque Psoriasis
Coverage Duration	Through the benefit year
Other Criteria	

ENGERIX-B (hepatitis b virus vaccine recombinant)

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

EXJADE (deferasirox)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical documentation of FDA approved diagnosis, serum ferritin and serum creatinine every 6 months. Exjade will be covered when a patient has evidence of chronic iron overload, such as the transfusion of approximately 100 mL/kg of packed red blood cells (approximately 20 units for a 40 kg patient) and a serum ferritin consistently greater than 1000 mcg/L. If the serum ferritin consistently falls below 500 mcg/L, consider temporarily interrupting therapy. Doses above 40 mg/kg are not covered.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	

EXTAVIA (interferon beta-1b)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Stated diagnosis from neurologist of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Statement may include a first MS attack with document MRI scan abnormalities characteristic of MS, OR evaluation documenting EITHER: history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, OR history of one focal neurological deficit which has resolved, and an MRI suggestive of MS: At least 3 total lesions, each at least 5mm: At least one lesion with contrast enhancement: At least 2 out of 3 lesions in either Periventricular white matter OR Brain stem (e.g. cerebellar peduncle, pons) OR Spinal cord.
Age restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Through the benefit year
Other Criteria	

FABRAZYME (agalsidase beta)

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

FANAPT (iloperidone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

FASLODEX (fulvestrant)

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

FAZACLO (clozapine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Refractory Schizophrenia/Schizoaffective Disorder: Fazaclo 12.5mg orally disintegrating tablet will be approved upon receipt of physician statement that member requires the use of an atypical antipsychotic for the treatment of refractory schizophrenia that has failed to respond adequately to appropriate courses of standard formulary antipsychotic agents or to reduce the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder AND is intolerant to oral solutions or unable to swallow other oral formulations.</p> <p>Formulary antipsychotics: clozapine (tablet), risperidone (orally disintegrating tablet, tablet, solution) and quetiapine (tablet)</p>
Age restrictions	18 years or older
Prescriber Restrictions	Part of a clozapine monitoring and distribution system
Coverage Duration	Through the benefit year
Other Criteria	<p>Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization</p> <p>Because of the significant risk of agranulocytosis, clozapine is available only through a monitoring and distribution system (composed of a contracting physician, pharmacy, and laboratory) that ensures compliance with the required white blood cell monitoring prior to delivery of the next supply of medication.</p> <p>Pharmacists may dispense the 7, 14, or 28 day supply of medication only upon the receipt of the appropriate laboratory results, appropriate forms must be filed with the clozapine registry of the manufacturer.</p>

FORTEO (teriparatide)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Approve for the following indications:</p> <ol style="list-style-type: none"> 1. Treatment of postmenopausal women with osteoporosis at high risk for fracture OR 2. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and, meet any of the following criteria: a. member had had at least one fracture OR b. member had BMD screening results of -2.5 or below OR c. member had previously used any of the following: Evista, Miacalcin Inj or NS, alendronate, Premarin, Prempro, Estradiol, Actonel, FemHRT 1/5, Boniva, or Reclast. 3. Treatment of men and women with osteoporosis associated with sustained systemic glyocorticoid therapy at high risk for fracture, and meet any of the following criteria: a. member has had at least one fracture, OR b. member has multiple risk factors for fracture, OR c. member had previously used any of the following: Evista, Miacalcin Inj or NS, alendronate, Premarin, Prempro, Estradiol, Actonel, FemHRT 1/5, Boniva, or Reclast. Preferred bisphosphonate agents include: alendronate or Boniva (PO or Inj).
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through benefit year but not more than 2 years total
Other Criteria	<p>Treatment failure is defined as documented continued bone loss after at least three months despite treatment with a bisphosphonate or SERM (Evista).</p> <p>Note: Since the effects of long-term treatment with teriparatide are not known at this time, therapy for more than 2 years duration is considered experimental and investigational. Because of an increased incidence of osteosarcoma, Forteo should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior radiation therapy involving the skeleton).</p>

FOSCARNET SODIUM

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Trial and failure to preferred agent or contraindication/intolerance to preferred medication.</p> <p>Indications for use: Treatment of cytomegalovirus (CMV) retinitis in immunocompromised patients. Combination therapy with foscarnet and ganciclovir is indicated for patients who have relapsed after monotherapy with either drug. For CMV, preferred alternative is Valcyte. Mucocutaneous acyclovir-resistant herpes simplex virus (HSV) infections. For HSV, preferred alternative is Famciclovir.</p>
Age restrictions	18 years old and greater
Prescriber Restrictions	
Coverage Duration	Herpes simplex- 21 days CMV Retinitis- through benefit year
Other Criteria	

GAMMAGARD LIQUID (immune globulin iv)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Documented hypogammaglobulinemia (IgG less than 400 mg/dL).</p> <p>Idiopathic Thrombocytopenic Purpura (ITP)</p> <ol style="list-style-type: none"> 1. When there is an immediate need to increase the plt count (e.g., serious bleeding episodes) AND plt count less than 30,000 2. In preparation for splenectomy or other invasive procedures AND platelet count less than 20,000 3. In pregnant women at risk of bleeding AND a. Plt count less than 10,000 at any time during the pregnancy OR b. Plt count 10,000 to 30,000 in the second or third trimester OR c. Clinically significant bleeding 4. In chronic ITP not responding to steroids <p>Kawasaki Disease</p> <ol style="list-style-type: none"> 1. Statement indicating diagnosis AND 2. Must be on concurrent aspirin therapy AND 3. Documented hypogammaglobulinemia (IgG less than 400 mg/dL). <p>Chronic Lymphocytic Leukemia (CLL)</p> <ol style="list-style-type: none"> 1. Statement indicating diagnosis 2. Documented hypogammaglobulinemia (IgG less than 400 mg/dL). Other applicable and relevant supporting medical information, such as failure or contraindication to immunosuppression or alternative therapy. <p>Other applicable and relevant supporting medical information, such as failure or contraindication to immunosuppression or alternative therapy.</p>
Age restrictions	
Prescriber Restrictions	
Coverage Duration	<p>ITP: 5 days</p> <p>Kawaski Syndrome: 4 days</p> <p>Primary Immune Deficiency Disorder: through benefit year</p>
Other Criteria	<p>Part B coverage is available for IVIG administered in the home for individuals whose diagnosis is primary immune deficiency disease.</p> <p>For primary immunodeficiency diseases (e.g. agammaglobulinemia or hypogammaglobinemia), Gammagard is covered under Medicare Part B.</p>

GARDASIL (human papillomavirus vaccine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Females: indicated for the prevention of diseases and precancerous or dysplastic lesions caused by Human Papillomavirus (HPV) Males: Indicated for the prevention of genital warts (condyloma acuminata) caused by HPV
Age restrictions	Females: 9 through 26 years old Males: 9 through 26 years old
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	Dosing 0.5 ml/dose IM. Give the first dose at an elected date, the second dose 2 months after the first, and the third dose 6 months after the first dose. The vaccine is not indicated for the treatment of HPV infection cervical neoplasia or cervical, vulvar, and vaginal pre-cancers and lesions including genital warts.

GENGRAF (cyclosporine)

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

GEODON (ziprasidone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the same class AND one lower tier traditional mood stabilizer. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine.</p>
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

GLEEVEC (imatinib mesylate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Stated diagnosis of one of the following:</p> <p>Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy</p> <p>Pediatric patients with Ph+ CML in chronic phase who are newly diagnosed or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy.</p> <p>Adult patients with relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)</p> <p>Adult patients with myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements</p> <p>Adult patients with aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown</p> <p>Adult patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown</p> <p>Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)</p> <p>Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). Or adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST</p>
Age restrictions	
Prescriber Restrictions	Oncologist
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

GRANISETRON HCL

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Nausea and vomiting due to chemotherapy, radiation therapy, or post-operative nausea/vomiting, AND intolerance or failure to preferred alternative, ondansetron. Preferred alternative: ondansetron (available as an oral solution, oral tablet, solution for injection, and orally disintegrating tablet)
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

HECTOROL (doxercalciferol)

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

HEXALEN (altretamine)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For the palliative treatment of recurrent or persistent ovarian cancer following first-line combination chemotherapy
Age restrictions	
Prescriber Restrictions	Oncologist
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

HUMATROPE (somatropin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Pediatric GHD</p> <ol style="list-style-type: none"> 1. Diagnosis of GH deficiency based on two GH stimulation tests or low Insulin-like growth factor 1 (IGF-1) levels: AND 2. Demonstrate growth failure based on growth velocity or height shorter than 2 standard deviations (SD) below the mean height for age. <p>Prader-Willi Syndrome or Small for Gestational Age:</p> <ol style="list-style-type: none"> 1. Diagnosis of PWS confirmed by appropriate genetic testing OR 2. Diagnosis of SGA confirmed by birth wt of less than 2500g at gestation of more than 37 wks or at birth weight or length below the 3rd percentile for gestational age who failed catch up by 2 y.o. <p>Turner Syndrome, Noonan Syndrome:</p> <ol style="list-style-type: none"> 1. Treatment of short stature in females with bone age less than 15 y. associated with TS or NS: OR 2. Treatment of short stature in males with bone age less than 17 y. associated with NS. <p>Growth Retardation assoc. with Chronic Renal Insufficiency:</p> <ol style="list-style-type: none"> 1. Diagnosis of chronic renal insufficiency: AND 2. Height shorter than or equal to 2 SD below the median age for children or where growth velocity falls to below 4.5 cm/year.
Age restrictions	
Prescriber Restrictions	Member under the care of, and prescribed by an endocrinologist.
Coverage Duration	Six months
Other Criteria	<p>Adult Onset Growth Hormone Deficiency:</p> <ol style="list-style-type: none"> 1. Patients with GHD alone or multiple hormone deficiencies because of pituitary disease or insult, hypothalamic disease, surgery, or radiation treatment: AND 2. IGF-1 level less than 77 mcg/L or 2 SD below the mean value, matched by age and gender. <p>Childhood Onset GH Deficiency in Adults:</p> <ol style="list-style-type: none"> 1. Childhood onset in patients who were GH deficient during childhood who have GH deficiency confirmed as an adult before replacement treatment with GH is started: AND 2. Persistent deficiency of GH documented by GH stimulation tests. <p>Isolated GH Deficiency in Adults: Documented deficiency of GH documented by 2 GH stimulation tests.</p>

	<p>Reauthorization for GHD in Children, PWS, SGA, TS, NS, GRCRF:</p> <ol style="list-style-type: none">1. Increase in growth velocity of at least 2 cm/year during previous year of treatment AND2. Males with bone age less than 17 yrs or females with bone age less than 15 yrs. <p>Reauthorization of ISS:</p> <ol style="list-style-type: none">1. Increase in growth velocity of at least 4.5 cm/year during previous year of treatment AND2. Males with bone age less than 17 yrs. Or females with bone age less than 15 yrs. <p>Reauthorization for GHD in Children, PWS, SGA, TS, NS, GRCRF:</p> <ol style="list-style-type: none">1. Increase in growth velocity of at least 2 cm/year during previous year of treatment AND2. Males with bone age less than 17 yrs or females with bone age less than 15 yrs. <p>Reauthorization of ISS:</p> <ol style="list-style-type: none">1. Increase in growth velocity of at least 4.5 cm/year during previous year of treatment AND2. Males with bone age less than 17 yrs. Or females with bone age less than 15 yrs.
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HUMIRA (adalimumab)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Rheumatoid Arthritis: monotherapy or as adjunct therapy for the treatment of moderately to severely active RA in patients 18 years or older when the patient has failed an adequate trial (defined by the ACR) to at least one disease modifying antirheumatic drug (DMARD) and one NSAID. Preferred agents include: NSAIDS- ibuprofen, naproxen, ketoprofen, meloxicam. DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Psoriatic Arthritis: monotherapy or as adjunct therapy for the treatment of active arthritis in patients age 18 or older with moderate to severe psoriatic arthritis with documented intolerance, contraindication, or allergy to at least 2 different drug classes of preferred products OR clinical failure of adequate trial and dose of at least 2 different preferred drugs. Preferred agents include: NSAIDS- ibuprofen, naproxen, ketoprofen, meloxicam. DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Plaque Psoriasis: Failure of two oral agents including methotrexate and a steroid, OR PUVA treatment.</p> <p>Juvenile Rheumatoid Arthritis: For the treatment of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years old or greater when patient had inadequate response to methotrexate alone for the appropriate treatment period OR methotrexate is contraindicated AND one NSAID. Preferred NSAIDs include ibuprofen, naproxex, and meloxicam</p> <p>Ankylosing Spondylitis: Monotherapy for reducing signs and symptoms of active ankylosing spondylitis when patient hasn't responded to maximum tolerated doses of at least two NSAIDS. Preferred NSAIDs include ibuprofen, naproxex, and meloxicam.</p> <p>Crohn's disease: For inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease AND patient has failed to respond to at least one steroidal therapy (Entocort EC, hydrocortisone, prednisone, prednisolone, methylprednisolone)</p>
Age restrictions	18 years old and greater for uses other than juvenile idiopathic arthritis

Prescriber Restrictions	Rheumatologist- for RA, JRA, Psoriatic Arthritis, Anklyosing spondylitis Dermatologist for Plaque Psoriasis Gastroenterologist for Crohn's disease
Coverage Duration	Through benefit year
Other Criteria	

INCRELEX (mecasermin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Contraindicated in neonates, patients with closed epiphyses, and suspected neoplasia.
Required Medical Information	Indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion that have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by: Height standard deviation score less than or equal to -3.0 and Basal IGF-1 standard deviation score not exceeding -3.0 and Normal or elevated growth hormone (GH) Severe Primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects as they are not GH deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment.
Age restrictions	Age 2 to 18 years of age
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	Not a substitute for GH treatment.

INTRON-A (interferon alfa-2b)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Type B viral Hepatitis (HBeAg positive): serum HBsAg positive for at least six months, AND elevated serum ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy. Type B Viral Hepatitis (HBeAg negative) HBsAG positive for at least 6 months AND BHV DNA level of 2000 IU/ml or more than 11,200 copies/ml AND One of the following: persistent ALT 2 times UNL or moderate to severe hepatitis or fibrosis on biopsy. Hepatitis C: Positive HCV antibody and HCV RNA. Condyloma acuminatum or perianal warts: member must have documentation of trial and failure to preferred alternative or intolerance/contraindication to preferred alternatives. For external perianal warts: Condylox gel, for external genital warts: podofilox, or imiquimod.
Age restrictions	For Hepatitis B- age 1 or older, All other diagnoses- 18 years or older
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization except to verify Part B vs Part D coverage for therapy in neoplastic diseases.

INVEGA (paliperidone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Schizophrenia/Schizoaffective Disorder: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

INVEGA SUSTENNA (paliperidone palmitate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documented treatment failure or intolerable side effects from treatment with Risperdal Consta in patients with schizophrenia.
Age restrictions	18 years or older
Prescriber Restrictions	Psychiatrist
Coverage Duration	Through the benefit year
Other Criteria	Members who newly enroll in the plan and are stable on Invega Sustenna before joining the plan, are not required to meet the prior authorization criteria

IPRATROPIUM BROMIDE SOLUTION

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

IPRATROPIUM BROMIDE/ALBUTEROL SULFATE SOLUTION

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

ITRACONAZOLE

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Aspergillosis, histoplasmosis, or blastomycosis: Approve Onychomycosis: Stated trial, failure, or contraindication to two preferred products including: terbinafine tablets, griseofulvin, and topical ciclopirox Oropharyngeal/esophageal candidiasis: Stated trial, failure, or contraindication to two preferred products including: amphotericin B, and fluconazole
Age restrictions	
Prescriber Restrictions	
Coverage Duration	90 days
Other Criteria	

IXEMPRA KIT (ixabepilone)

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

KINERET (anakinra)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Medical statement indicating diagnosis and a negative TB test is required.</p> <p>Rheumatoid Arthritis: For reducing the signs and symptoms and slowing the progression of structural damage of moderately to severely active rheumatoid arthritis in patients who have failed at least one preferred disease modifying antirheumatic drugs (DMARDs) AND one preferred TNF.</p> <p>Preferred DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Preferred TNF-alpha inhibitors: Humira or Simponi</p>
Age restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Throughout benefit year
Other Criteria	<p>Higher doses do not result in increased response.</p> <p>Kineret may be given alone or in combination with other DMARDs.</p> <p>Kineret is contraindicated in combination with TNF-alpha inhibitors.</p>

KUVAN (sapropterin dihydrochloride)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement indicating diagnosis is required: Approve for indication to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria (PKU). This medication is to be used in conjunction with a Phe-restricted diet. Discontinue sapropterin therapy if blood Phe concentrations do not decrease after 1 month of treatment at 20 mg/kg/day.
Age restrictions	4 years and older
Prescriber Restrictions	
Coverage Duration	Throughout benefit year
Other Criteria	

LATUDA (lurasidone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Schizophrenia/Schizoaffective Disorder: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

LETAIRIS (ambrisentan)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Pulmonary arterial hypertension (PAH) with WHO class II or III symptoms and stated trial and failure or contraindication to preferred alternative Adcirca. Treat women of child-bearing potential only after a negative pregnancy test and treat only women who are using two reliable methods of contraception OR have had a tubal sterilization OR a Copper T 380A IUD or LNG 20 IUD inserted.
Age restrictions	18 years old and greater
Prescriber Restrictions	Available only to those enrolled in the Letairis Education Access Program (LEAP).
Coverage Duration	Through benefit year
Other Criteria	Black box warning for potential liver injury.

LEUKINE (sargramostim)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Medical statement indicating diagnosis AND trial and failure of preferred agent neupogen AND Absolute Neutrophil Count less than 10,000/mm³ and CBC with differential.</p> <p>Approved indications:</p> <p>Use following induction chemotherapy in older adult patients with acute myelogenous leukemia (AML).</p> <p>Use for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.</p> <p>Use for acceleration of myeloid recovery in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's disease undergoing autologous bone marrow transplantation (BMT).</p> <p>Use for acceleration of myeloid recovery in patients undergoing allogeneic BMT from HLA-matched related donors.</p> <p>Use for patients who have undergone allogeneic or autologous bone marrow transplantation (BMT) in whom engraftment is delayed or has failed.</p>
Age restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	2 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

LIDODERM PATCH (lidocaine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Lidoderm/Lidocaine patch therapy is not considered medically necessary for members with the following concomitant conditions: Generalized (non neuropathic) pain disorder.
Required Medical Information	Must have documented trial or failure of preferred medication gabapentin OR documented allergy, contraindication or intolerance to preferred medication Preferred alternative is Gabapentin - FDA indicated for postherpetic neuralgia up to maximum dosage of 1800 mg/day.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	

LUMIZYME (alglucosidase alfa)

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

LUPRON DEPOT (leuprolide acetate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (Category X)
Required Medical Information	<p>Medical statement of FDA approved diagnosis</p> <p>Approve for the treatment of preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata with concomitant with iron therapy.</p> <p>For the treatment of central precocious puberty submission of pubertal gonadal sex steroid levels (in boys, testosterone levels greater than 30 ng/dL and in girls, estradiol levels greater than 20 pg/mL) AND a pubertal LH increase in response to stimulation by native GnRH, AND pelvic ultrasound assessment in girls is required for approval along with notes indicating premature development of secondary sexual characteristics at or before the age of 8 years in girls and 9 years in boys and significant advancement of bone age and/or a poor adult height prediction. Magnetic resonance imaging or CT-scanning of the brain is recommended to detect hypothalamic or pituitary tumors, or anatomical changes associated with increased intracranial pressure. Other causes of sexual precocity, such as congenital adrenal hyperplasia, testotoxicosis, testicular tumors and/or other autonomous feminizing or masculinizing disorders must be excluded by proper clinical hormonal and diagnostic imaging examinations.</p> <p>For the treatment of prostate cancer, patient must have stated failure or intolerance to Trelstar.</p> <p>For the treatment of endometriosis, patient must have stated failure or intolerance to at least two of the following preferred medications. Preferred medications include danazol, medroxyprogesterone, Synarel, and norethindrone acetate.</p>
Age restrictions	For precocious puberty: 11 years or less in males and 10 years or less in females
Prescriber Restrictions	
Coverage Duration	Through Benefit Year for the diagnosis of prostate cancer Six months for other indications
Other Criteria	<p>This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.</p> <p>Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.</p>

LYRICA (pregabalin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Seizure disorder: Approve for adjunctive therapy</p> <p>Post herpetic neuralgia: Trial and failure of preferred alternative, gabapentin, is required. Gabapentin is the preferred alternative at a dosage of greater than or equal to 1800mg unless a documented allergy or side effects with previous gabapentin therapy.</p> <p>Fibromyalgia: Must submit one of the following - Documentation of the number and location of tender points as defined by ACR guidelines, or Chart notes documenting the history of the condition. Patient must have widespread pain (on the left and right side of the body and above and below the waist) AND axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) present for AT LEAST 3 months AND pain in at least 11 of 18 specific tender point sites after digital palpation with an approximate force of 4 kg. Tender point sites are bilateral and include the following: occiput, low cervical, trapezius, supraspinatus, second rib, lateral epicondyle, gluteal, greater trochanter, or knee</p>
Age restrictions	18 years or greater
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

METHITEST (methyltestosterone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Use for treatment of erectile dysfunction is excluded by Medicare Part D.
Required Medical Information	Pretreatment testosterone level below normal physiological value of 280 ng/dl or below normal reference level provided by the laboratory
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

METHOTREXATE SODIUM

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

MIACALCIN (calcitonin,salmon)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Postmenopausal Osteoporosis- trial and failure of one bisphosphonate or selective estrogen-receptor modulator (SERM) AND Failure of Calcitonin Nasal Spray AND History of vertebral compression fractures, or fractures of the hip or distal radius resulting from minimal trauma, or T score of -2.5 or less. Paget's Disease History of failure or intolerance to oral bisphosphonates. Preferred bisphosphonate agents include: Alendronate, Boniva. Preferred SERM: Evista
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

MITOXANTRONE HYDROCHLORIDE

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

MYCAMINE (micafungin sodium)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of FDA approved diagnosis For the treatment of Candida albicans, patient must have stated failure or intolerance to fluconazole.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

MYFORTIC (mycophenolate sodium)

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

MYOZYME (alglucosidase alfa)

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

NAGLAZYME (galsulfase)

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

NEUMEGA (oprelvekin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	<p>Medical statement of FDA approved diagnosis AND platelet levels less than 50,000 cells/microliter.</p> <p>Neumega is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia. Efficacy was demonstrated in patients who had experienced severe thrombocytopenia following the previous chemotherapy cycle. Neumega is not indicated following myeloablative chemotherapy.</p> <p>Dosing should be initiated six to 24 hours after the completion of chemotherapy. Platelet counts should be monitored periodically to assess the optimal duration of therapy. Dosing should be continued until the post-nadir platelet count is greater than or equal to 50,000/microliter. In controlled clinical trials, doses were administered in courses of 10 to 21 days. Dosing beyond 21 days per treatment course is not recommended.</p> <p>Treatment with Neumega should be discontinued at least two days before starting the next planned cycle of chemotherapy.</p>
Age restrictions	18 years and older
Prescriber Restrictions	Certified hematologist and/or oncologist
Coverage Duration	6 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

NEUPOGEN (filgrastim)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Medical documentation of FDA approved diagnosis, and concurrent chemotherapy treatment, if applicable. Absolute Neutrophil Count and CBC with differential.</p> <p>Chemo-induced Neutropenia, initiate therapy 24-72 hrs after chemotherapy for 7 to 14 days. Initial dose should be 5 mcg/kg/day, adjust dose according to ANC goal of 1,500 to 10,000/mm³.</p> <p>Cytotoxic Chemo-Induced Neutropenia after Bone Marrow Transplantation, initiate therapy 24 hrs after cytotoxic chemotherapy. Initial dose should be 10 mcg/kg/day, adjust dose according to ANC: reduce dose to 5 mcg/kg/day if ANC greater than 1,000 for 3 consecutive days, and discontinue therapy if ANC greater than 1,000 for 3 consecutive days if already at 5 mcg/kg/day. Severe chronic neutropenia, initiate therapy when severe neutropenic (ANC less than 500mm³), initial dose should be 6 mcg/kg SC twice a day, adjust dose if ANC greater than 10,000/mm³. Peripheral blood stem cell mobilization, start 4 days before the first leukaphoresis procedure and continue until the last leukaphoresis procedure. Initial dose should be 10 mcg/kg/day, adjust dose if ANC greater than 10,000/mm³. Target ANC goal between 1,500/mm³ and 10,000/mm³. DC use of Neupogen if ANC is greater than 10,000/mm³.</p>
Age restrictions	
Prescriber Restrictions	
Coverage Duration	2 months
Other Criteria	May be covered under Part B.

NEUTREXIN (trimetrexate glucuronate)

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

NEXAVAR (sorafenib tosylate)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of FDA approved diagnosis with failure of one course of radiation treatment and/or prior systemic chemotherapy.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

OCTREOTIDE ACETATE

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Acromegaly: Documentation of inadequate response to surgery and/or radiotherapy, or documentation that patient is not a candidate for surgery and/or radiotherapy. Reauthorization will require statement indicating growth hormone (GH) levels are stabilized at less than 5.0ng/mL, IGF-1 levels are normalized as matched by age and gender, or the patient has a documented clinical response defined by a reduction of tumor mass, a reduction in the signs and symptoms of acromegaly, or an improvement in significant co-morbidities.</p> <p>Carcinoid tumors: Diagnosis of metastatic carcinoid tumors with severe diarrhea or flushing and documentation of response to octreotide injection.</p> <p>Vasoactive Intestinal Peptide Tumors: Statement indicating diagnosis of metastatic vasoactive peptide tumor, for symptomatic treatment of diarrhea associated with VIP</p>
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Initial therapy: 6 months. Reauthorization: 12 months
Other Criteria	

OFORTA (fludarabine phosphate)

PENDING CMS APPROVAL

ONDANSETRON HCL; SODIUM CHLORIDE

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

ONDANSETRON ORAL SOLUTION

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement that member has swallowing difficulties and cannot tolerate Ondansetron tablets or Ondansetron orally disintegrating tablets. Trial and failure of Ondansetron tablets or Ondansetron orally disintegrating tablets.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ONDANSETRON HCL INJECTION

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

ONTAK (denileukin diftitox)

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

ORFADIN (nitisinone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of diagnosis of hereditary tyrosinemia type 1 (HT-1) AND current patient weight as dose must be within FDA approved dosing range: maximum dosage for all patients is 2 mg/kg/day. When initiating therapy, Serum tyrosine should be below 500 mmol/L to avoid toxic effects, and urinary succinylacetone levels should be undetectable.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	

OXANDROLONE

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement indicating use to offset the protein catabolism associated with prolonged administration of corticosteroids, or a diagnosis of bone pain due to osteoporosis
Age restrictions	
Prescriber Restrictions	
Coverage Duration	4 weeks. Reauthorization required beyond initial therapy
Other Criteria	

PAMIDRONATE DISODIUM

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

PEGASYS (peginterferon alfa-2a)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Major, uncontrolled depressive illness
Required Medical Information	<p>Chronic Hepatitis C (HCV): Diagnosis of HCV with compensated liver disease AND no signs or symptoms of jaundice, ascites, active gastrointestinal bleeding, and encephalopathy</p> <p>Required Information for HCV:</p> <p>Baseline serum HCV RNA</p> <p>Statement indicating Hepatitis C genotype</p> <p>Platelets greater than or equal to 90,000/mm³ (as low as 70,000/mm³ in patients with HCV and HIV)</p> <p>ANC greater than or equal to 1,500/mm³</p> <p>SCr less than 1.5 x ULN</p> <p>TSH and T4 WNL or adequately controlled thyroid function</p> <p>Baseline Hgb greater than 12 g/dl for women and 13 g/dl for men in monoinfected patients</p> <p>In coinfecting HIV pts: CD4 T-cell count greater than 100/mm³, baseline Hgb greater than 11g/dL for women and 12g/dL in men</p> <p>Chronic Hepatitis B (HBV): Documentation in adult patients with HBeAg positive and negative HBV who have compensated liver disease and evidence of viral replication and liver inflammation</p> <p>Required information for HBV: HBV DNA more than 20,000 IU/ml and an ALT concentration greater than 2 times normal</p>
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	<p>HBV: 1 year.</p> <p>HCV Initial approval: 16 weeks</p>
Other Criteria	<p>For HCV re-approval in genotypes 2 and 3:</p> <p>Documentation must be submitted indicating at least a 2-log (100 fold) decrease in viral load at week 12 for re-approval at week 16. Patients will be approved for a total of 24 weeks</p> <p>For HCV re-approval in genotypes 1 and 4:</p> <p>Documentation must be submitted indicating at least a 2-log (100 fold) decrease in HCV RNA at week 12 for re-approval at week 16</p> <p>Patients with an undetectable HCV RNA by week 12 will be approved for a total of 48 weeks</p> <p>Patients with a 2-log decrease in HCV RNA with detectable HCV RNA at week 12 will be approved for a total of 28 weeks</p> <p>At week 28, patients with an undetectable HCV RNA will be approved for a total duration of 48 weeks</p>

PENTOSTATIN

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of FDA approved diagnosis AND current height and weight to determine dose is within FDA approved dosing range. Max dosage: 4 mg/m ² IV as a single dose once every other week
Age restrictions	18 years old or greater
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization except to determine Part B vs Part D coverage

PROCRIT (epoetin alfa)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Patients with ESRD on Dialysis, coverage will be under Part B.
Required Medical Information	Documented FDA approved diagnosis AND No active gastrointestinal bleed AND Transferrin saturation should be at least 20% and ferritin at least 100 ng/mL AND For patients with uncontrolled hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy. Lab data within 30 days of DER request. Doses greater than 60,000 units will not be covered unless patient has normal iron saturation and has received an adequate 4 weeks trial at a lower dose with other sources of anemia ruled out. Labs for review: Hemoglobin, Ferritin, Iron Saturation. Anemia in neoplastic disease, due to chemotherapy, the hgb level prior to initiation of treatment is less than 10 g/dL (or the hct is less than 30%). Must be receiving concomitant chemotherapy for a min. of 2 mths. Maintenance of ESA therapy is the starting dose if the hgb remains below 10 g/dL (or hct is less than 30%) 4 wks after initiation of therapy and the rise in hgb is more than 1g/dL (hct greater than 3%).
Age restrictions	
Prescriber Restrictions	For patients with cancer: prescribers must be under the ESA APPRISE Oncology program
Coverage Duration	2 months
Other Criteria	In patients whose hgb rises less than 1 g/dl (hct rise less than 3%) compared to pretreatment baseline over 4 weeks of treatment and whose hgb level remains below 10 g/dL after the 4 weeks of treatment (or the hct is below 30%), the FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hgb rises more than 1 g/dl (hct rise less 3%) compared to pretreatment baseline by 8 wks of treatment or if there is a rapid rise in hgb more than 1 g/dl (hct less than 3%) over 2 wks of treatment unless the hgb remains below or falls to less than 10g/dL (or hct is less tha 30%). Continuation and reinstatement of ESA therapy must include a dose reduction of 25% from the previously administered dose. Treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. For cont. of therapy hgb level must be less than 12 g/dL. Anemia of chronic renal failure- Hgb 10g/dL or less. For cont of therapy hgb level must be

	less than/equal 12 g/dL. Anemia related to zidovudine therapy, Hgb below 10.0 g/dL. Must have serum erythropoietin levels less/equal 500 mUnits/mL, and be receiving a dose of zidovudine of less than or equal to 4200 mg/wk. For continuation of therapy hgb level must be under 12 g/dL. Reduction of allogeneic blood transfusion for elective, noncardiac, nonvascular surgery in anemic patients, Hgb of more than 10 to less than or equal to 13g/dL
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PROGRAF (tacrolimus)

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

PROLASTIN / PROLASTIN-C (alpha-1 proteinase inhibitor)

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

PROLEUKIN (aldesleukin)

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

PROLIA (denosumab)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Male gender
Required Medical Information	<p>Medical documentation indicating need for the treatment of postmenopausal women with osteoporosis at high risk for fracture and meet any of the following criteria:</p> <p>a. member had had at least one osteoporotic fracture OR</p> <p>b. member had BMD screening results of -2.5 or below OR</p> <p>c. member had previously failed/intolerant to any of the following: Evista, Miacalcin Inj or NS, alendronate, Premarin, Prempro, Estradiol, Actonel, Jinteli 1/5, Boniva, or Reclast.</p> <p>OR</p> <p>d. statement of gastrointestinal intolerance of or contraindication to oral bisphosphonate therapy</p> <p>Prior to initiation of therapy hypocalcemia must be corrected. Only approve when dosed every 6 months, for a total of 2 doses per year.</p>
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through benefit year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

PROMACTA (eltrombopag olamine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Stated failure to respond sufficiently to corticosteroids, immunoglobulins, or splenectomy. Platelet counts from within the past 30 days should be provided and should be less than 50,000/mm ³ .
Age restrictions	18 years or older
Prescriber Restrictions	Any prescriber enrolled in PROMACTA CARES program
Coverage Duration	6 months
Other Criteria	PROMACTA is only available through a restricted distribution program called PROMACTA CARES. This is a risk management program intended to perform risk-benefit decisions prior to initiation of therapy. All prescribers, pharmacists, and patients must be enrolled in PROMACTA CARES in order to prescribe, dispense and receive the medication. This service also offers optional reimbursement services to all patients prescribed PROMACTA. A copy of the patient's enrollment should be forwarded to WellCare.

PROVIGIL (modafinil)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Narcolepsy: Submission of sleep study indicating diagnosis of narcolepsy as defined by the International Classification of Sleep Obstructive Sleep Apnea/Hypopnea Syndrome AND documented failure or contraindication/intolerance to two of the preferred medications is required. Preferred medications include methylphenidate ER, methylin ER, amphetamine salts. Reauthorization requires statement of symptomatic relief of hypersomnolence with Provigil use.</p> <p>Obstructive sleep apnea/hypopnea syndrome: Statement indicating member is currently receiving treatment for underlying condition AND member is receiving continuous positive airway pressure and a maximal effort to treat with CPAP or is contraindicated prior to initiating Provigil.</p> <p>Shift work sleep disorder: Statement indicating member is a night shift worker AND no other disorder accounts for the symptoms and that sleep disturbance causes significant distress or impairment AND documentation member is not receiving sedative/hypnotics Reauthorization for shift work sleep disorder requires statement that patient is experiencing relief of excessive sleepiness with use of Provigil.</p>
Age restrictions	16 years old or greater
Prescriber Restrictions	Sleep specialist, ENT specialist, Neurologist, Pulmonologist
Coverage Duration	Narcolepsy: Benefit Year OSAHS, SWSD: 3 months Reauthorization for OSAHS, SWSD: benefit year
Other Criteria	

PULMOZYME (dornase alfa)

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

RANEXA (ranolazine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis and trial and failure of the use of two lower tier preferred alternatives. Preferred alternatives include: Amlodipine, Atenolol, Diltiazem, Isosorbide Dinitrate, Isosorbide Mononitrate, Metoprolol, Nadolol, Nifedipine, Nitroglycerin, Propranolol, and Verapamil
Age restrictions	18 years or older
Prescriber Restrictions	Cardiologist
Coverage Duration	Through the benefit year
Other Criteria	Ranexa should not be used with strong CYP3A inhibitors (i.e. ketoconazole, indinavir, etc.) or inducers (i.e. rifampin, phenytoin, etc.)

RAPAMUNE (sirolimus)

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

REBIF (interferon beta-1a)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Stated diagnosis from neurologist of definite or probable relapsing-remitting MS, secondary progressive MS with relapses, or progressive relapsing MS. Statement may include a first MS attack with document MRI scan abnormalities characteristic of MS, OR evaluation documenting EITHER: history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, OR history of one focal neurological deficit which has resolved, and an MRI suggestive of MS: At least 3 total lesions, each at least 5mm: At least one lesion with contrast enhancement: At least 2 out of 3 lesions in either Periventricular white matter OR Brain stem (e.g. cerebellar peduncle, pons) OR Spinal cord.
Age restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Through the benefit year
Other Criteria	

RECOMBIVAX HB (hepatitis b virus vaccine recombinant)

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

REGANEX (becaplermin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement indicating patient is undergoing debridement at least once weekly, and at least two of the following are present: Stage III or IV wound: Wound at least 1 cm x 1 cm: Long-standing wound that does not heal with standard care: Patients at high risk for amputation (peripheral neuropathy, peripheral vascular disease, skin or nail abnormalities, previous foot ulcer amputation)
Age restrictions	Greater than 16 years old
Prescriber Restrictions	
Coverage Duration	3 months initial, Reauthorization needed for continuation of therapy
Other Criteria	

REMICADE (infliximab)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Rheumatoid Arthritis: monotherapy or as adjunct therapy for the treatment of moderately to severely active RA in patients 18 years or older when the patient has failed an adequate trial (defined by the ACR) to at least one disease modifying antirheumatic drug (DMARD) OR NSAID AND one preferred TNF (Humira or Simponi) [Preferred NSAIDs: ibuprofen, naproxen, ketoprofen, meloxicam Preferred DMARDs: methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide]</p> <p>Psoriatic Arthritis: monotherapy or as adjunct therapy for the treatment of active arthritis in patients age 18 or older with moderate to severe psoriatic arthritis with adequate trial and failure to preferred TNF Humira and Simponi.</p> <p>Plaque Psoriasis: Failure of methotrexate, OR a steroid, OR PUVA treatment AND preferred TNF Humira.</p> <p>Ankylosing Spondylitis: Monotherapy for patients 18 years or older for reducing signs and symptoms of active ankylosing spondylitis when patient hasn't responded to maximum tolerated doses of preferred TNF Humira and Simponi.</p> <p>Crohn's disease: For inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease AND patient has failed to respond to at least one steroidal therapy (Entocort EC, hydrocortisone, prednisone, prednisolone, methylprednisolone) AND preferred TNF Humira.</p> <p>Ulcerative Colitis: Diagnosis of moderate to severe ulcerative colitis. Stated failure of two conventional therapy regimens as outlined by the American Gastroenterology Association including corticosteroid treatment (hydrocortisone, prednisone, prednisolone, methylprednisolone), balsalazide, mesalamine or sulfasalazine.</p>
Age restrictions	6 years old or greater
Prescriber Restrictions	<p>Rheumatologist- for RA, Psoriatic Arthritis, Anklyosing spondylitis</p> <p>Dermatologist for Plaque Psoriasis</p> <p>Gastroenterologist for Crohn's disease, Ulcerative Colitis</p>
Coverage Duration	Through the benefit year
Other Criteria	

REVATIO (sildenafil citrate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approve for members with a diagnosis of pulmonary hypertension and a negative response to the vagoactive stimulation test. Medical statement indicating diagnosis of pulmonary arterial hypertension AND stated trial and failure or contraindication to preferred alternative Adcirca.
Age restrictions	18 years old and greater
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Revatio should not be used in combination with organic nitrates.

REVLIMID (lenalidomide)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Myelodysplastic syndrome (MDS): Karyotype results indicating 5q (del) abnormality must be submitted for diagnosis of MDS. CBC with Platelet Count- within last 30 days. Absolute Neutrophil Count- within last 30 days. 2 Negative Pregnancy Tests- within last 14 days. Multiple myeloma (MM): Statement indicating need for the treatment of multiple myeloma in combination with dexamethasone in patients who have failed to respond to at least one prior therapy.
Age restrictions	18 years or older
Prescriber Restrictions	Registered in RevAssist®
Coverage Duration	Through the Benefit Year
Other Criteria	Prescribers, pharmacists, and patients must be registered in RevAssist® in order to prescribe, dispense, or receive lenalidomide. Information about the drug and the program can be obtained by calling 1-888-423-5436.

RISPERDAL CONSTA (risperidone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Patient must begin at lowest available dose and may titrate the dose as needed every two weeks. The manufacturer states some adult patients not responding to the 25 mg dose may benefit from 37.5 mg or 50 mg IM once every 2 weeks.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Must have failed at least 2 weeks of oral Risperidone or quetiapine or provide documentation of non compliance, or inability to swallow or take oral medications. The maximum dose should not exceed 50 mg every 2 weeks. Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

RITUXAN (rituximab)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Non-Hodgkin's Lymphoma (NHL): Medical statement showing one of the following: Dx of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma and use in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, Dx of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy, Dx of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy, Dx of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.</p> <p>Chronic lymphocytic leukemia (CLL): Medical statement showing use in combination with fludarabine and cyclophosphamide, for the treatment CLL.</p> <p>Rheumatoid Arthritis (RA): Medical statement indicating diagnosis of moderately to severely active RA AND concurrent use of methotrexate AND trial and failure of an adequate trial of at least two preferred alternatives one being a preferred TNF of Humira or Simponi. Preferred agents include ibuprofen, naproxen, ketoprofen, meloxicam, methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p>
Age restrictions	18 years or older
Prescriber Restrictions	RA- Rheumatologist
Coverage Duration	For NHL- 8 courses For RA- 2 courses
Other Criteria	<p>Reauthorization for Rheumatoid Arthritis: requires medical statement indicating: At least 20% improvement in the tender and swollen joint count and, at least 20% improvements in 3 of the following: Patient global assessment, Physician global assessment, Patient's assessment of pain, Degree of disability, Acute phase reactant and, At least 16 weeks since last Rituxan treatment.</p> <p>Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization except to determine Part B vs Part D coverage</p>

SABRIL (vigabatrin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Previously tried and failed two medications for the diagnosis of refractory complex partial seizures including carbamazepine, clonazepam, diazepam, ethosuximide, felbamate, fosphenytoin, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, pregabalin, primidone, tiagabine, topiramate, valproic acid, divalproex sodium, zonisamide.
Age restrictions	Age 16 years or greater
Prescriber Restrictions	Neurologist registered with the SHARE program
Coverage Duration	Initial approval- 3 months Reauthorization- through the benefit year.
Other Criteria	Register with SHARE (Support, Help and Resources for Epilepsy). The potential benefits must outweigh the potential risk for developing permanent vision loss. Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization

SAPHRIS (asenapine maleate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the same class AND one lower tier traditional mood stabilizer. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine.</p>
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

SIMPONI (golimumab)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Rheumatoid Arthritis: monotherapy or as adjunct therapy for the treatment of moderately to severely active RA in patients 18 years or older when the patient has failed an adequate trial (defined by the ACR) to at least one disease modifying antirheumatic drug (DMARD) and one NSAID. Preferred agents include: NSAIDS- ibuprofen, naproxen, ketoprofen, meloxicam. DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Psoriatic Arthritis: monotherapy or as adjunct therapy for the treatment of active arthritis in patients age 18 or older with moderate to severe psoriatic arthritis with documented intolerance, contraindication, or allergy to at least 2 different drug classes of preferred products OR clinical failure of adequate trial and dose of at least 2 different preferred drugs. Preferred agents include: NSAIDS- ibuprofen, naproxen, ketoprofen, meloxicam. DMARD's- methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide</p> <p>Ankylosing Spondylitis: Monotherapy for reducing signs and symptoms of active ankylosing spondylitis when patient hasn't responded to maximum tolerated doses of at least two NSAIDS. Preferred NSAIDs include ibuprofen, naproxex, and meloxicam.</p>
Age restrictions	18 years old and greater
Prescriber Restrictions	Rheumatologist
Coverage Duration	Through the Benefit Year
Other Criteria	

SOMATULINE DEPOT (lanreotide acetate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1. Diagnosis of acromegaly 2. Inadequate response to surgery and/or radiotherapy, or for patients unable to tolerate surgery or radiation 3. Stated trial and failure of preferred agents. Preferred agents: bromocriptine, octreotide
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through Benefit Year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

SOMAVERT (pegvisomant)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement indicating use for the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum IGF-I levels. High Insulin like growth factor-I (IGF-I) levels as compared to normal reference values by age and gender. Growth hormone test during oral glucose tolerance test (must NOT decline below 1ng/ml). LFTs should be less than 3 times the upper limit of normal before initiating therapy. The maximum daily maintenance dose should not exceed 30 mg.
Age restrictions	18 years or older
Prescriber Restrictions	Member under the care of, and prescribed by an endocrinologist.
Coverage Duration	Through the Benefit Year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

SPRYCEL (dasatinib)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Chronic myelogenous leukemia (CML): Statement indicating approved diagnosis Acute lymphocytic leukemia (ALL): Statement indicating diagnosis of Philadelphia chromosome-positive (Ph+) ALL and failure, resistance, or intolerance to Imatinib (Gleevec)
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

SUBOXONE (buprenorphine hydrochloride; naloxone hydrochloride dihydrate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approve for diagnosis of opioid dependence.
Age restrictions	Greater than 16 years old
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

SUTENT (sunitinib malate)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis. CBCs with platelet count and serum chemistry including phosphate should be performed at the beginning of each treatment cycle. For GIST member must have documented trial and failure, disease progression or contraindication/intolerance to preferred agent, Gleevec (imatinib).
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

SYLATRON (peginterferon alfa-2b)

PENDING CMS APPROVAL

SYMBYAX (fluoxetine hcl; olanzapine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the atypical antipsychotic class AND one lower tier traditional mood stabilizer in conjunction with a preferred antidepressant. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine, lower tier antidepressants include fluoxetine, paroxetine, sertraline, citalopram, bupropion, mirtazepine, venlafaxine.</p> <p>Major Depressive Disorder (treatment resistant): Documented continuous treatment with a preferred antidepressant as monotherapy x 6 weeks AND documented treatment failure or intolerable side effects from treatment with one formulary medication within the atypical antipsychotics class. Members on an antidepressant require trial and failure of quetiapine. Members not on an antidepressant require two separate continuous trials with lower tier antidepressants including fluoxetine, paroxetine, sertraline, citalopram, bupropion, mirtazepine, venlafaxine.</p>
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

SYMLIN/SYMLINPEN (pramlintide acetate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement indicating patient has been diagnosed with type 1 diabetes and is currently on insulin, OR diagnosed with type 2 diabetes and is currently on insulin and metformin or a sulfonylurea, AND patient has been compliant with current therapy for a minimum of 3 months. Preferred diabetic agents: metformin, glyburide, glimepiride, glipizide, Novolin, Novolog, Lantus Submission of HgbA1C drawn within past 90 days. Those with a HgbA1C greater than 9% are not considered candidates for therapy with pramlintide.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	

SYNAREL (nafarelin acetate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (Category X)
Required Medical Information	<p>Medical statement indicating diagnosis is required: Approve for members with a diagnosis of endometriosis in adult females or central precocious puberty (CPP) in children. The diagnosis of central precocious puberty (CPP) is suspected when premature development of secondary sexual characteristics occurs at or before the age of 8 years in girls and 9 years in boys, and is accompanied by significant advancement of bone age and/or a poor adult height prediction. The diagnosis should be confirmed by pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH. Pelvic ultrasound assessment in girls usually reveals enlarged uterus and ovaries, the latter often with multiple cystic formations. Magnetic resonance imaging or CT-scanning of the brain is recommended to detect hypothalamic or pituitary tumors, or anatomical changes associated with increased intracranial pressure. Other causes of sexual precocity, such as congenital adrenal hyperplasia, testotoxicosis, testicular tumors and/or other autonomous feminizing or masculinizing disorders must be excluded by proper clinical hormonal and diagnostic imaging examinations.</p>
Age restrictions	For endometriosis: Females 18 years and older
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	

TABLOID (thioguanine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis.
Age restrictions	
Prescriber Restrictions	Hematologist/Oncologist
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

TARCEVA (erlotinib)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of approved FDA diagnosis AND total bilirubin laboratory value within six months prior to initiation of Tarceva Tarceva should be interrupted or discontinued if total bilirubin is greater than 3 times ULN and/or transaminases are greater than 5 times ULN in the setting of normal pretreatment values.
Age restrictions	
Prescriber Restrictions	Oncologist
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

TARGRETIN (bexarotene)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Medical statement of approved FDA diagnosis Negative pregnancy Test taken within 2 weeks of request. Documented early stage disease treatment in patients who have not tolerated other therapies or who have refractory or persistent disease.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the Benefit Year
Other Criteria	

TASIGNA (nilotinib)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of diagnosis of Ph+ chronic or accelerated phase CML.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

TESTIM (testosterone)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Statement indicating diagnosis of hypogonadism in men with a testosterone level below the normal physiological value of 280ng/dL before the start of treatment, or below the normal reference level provided by the testing laboratory.
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	

TESTOSTERONE CYPIONATE (testosterone cypionate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Statement indicating diagnosis of hypogonadism in men with a testosterone level below the normal physiological value of 280ng/dL before the start of treatment, or below the normal reference level provided by the testing laboratory.
Age restrictions	IM- 12 years or older
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	

TESTOSTERONE ENANTHATE (testosterone enanthate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Statement indicating diagnosis of hypogonadism in men with a testosterone level below the normal physiological value of 280ng/dL before the start of treatment, or below the normal reference level provided by the testing laboratory.
Age restrictions	IM- 12 years or older
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	

TEV-TROPIN (somatropin)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Pediatric GHD 1. Diagnosis of GH deficiency based on two GH stimulation tests or low Insulin-like growth factor 1 (IGF-1) levels: AND 2. Demonstrate growth failure based on growth velocity or height shorter than 2 standard deviations (SD) below the mean height for age. Prader-Willi Syndrome or Small for Gestational Age:</p> <p>1. Diagnosis of PWS confirmed by appropriate genetic testing OR 2. Diagnosis of SGA confirmed by birth wt of less than 2500g at gestation of more than 37 wks or at birth weight or length below the 3rd percentile for gestational age who failed catch up by 2 y.o.</p> <p>Turner Syndrome, Noonan Syndrome: 1. Treatment of short stature in females with bone age less than 15 y. associated with TS or NS: OR 2. Treatment of short stature in males with bone age less than 17 y. associated with NS. Growth Retardation assoc. with Chronic Renal Insufficiency: 1. Diagnosis of chronic renal insufficiency: AND 2. Height shorter than or equal to 2 SD below the median age for children or where growth velocity falls to below 4.5 cm/year.</p>
Age restrictions	
Prescriber Restrictions	Member under the care of, and prescribed by an endocrinologist.
Coverage Duration	6 months
Other Criteria	<p>Adult Onset Growth Hormone Deficiency: 1. Patients with GHD alone or multiple hormone deficiencies because of pituitary disease or insult, hypothalamic disease, surgery, or radiation treatment: AND 2. IGF-1 level less than 77 mcg/L or 2 SD below the mean value, matched by age and gender. Childhood Onset GH Deficiency in Adults: 1. Childhood onset in patients who were GH deficient during childhood who have GH deficiency confirmed as an adult before replacement treatment with GH is started: AND 2. Persistent deficiency of GH documented by GH stimulation tests. Isolated GH Deficiency in Adults: Documented deficiency of GH documented by 2 GH stimulation tests. Reauthorization for GHD in Children, PWS, SGA, TS, NS, GRCRF: 1. Increase in growth velocity of at least 2 cm/year during previous year of treatment AND 2. Males with bone age less than 17 yrs or females with bone age less than 15 yrs. Reauthorization of ISS: 1. Increase in growth velocity of at least 4.5 cm/year during previous year of treatment AND 2. Males with bone age less than 17 yrs. Or females with bone age less than 15 yrs.</p>

THALOMID (thalidomide)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	<p>Statement indicating use for FDA approved diagnosis. Negative Pregnancy Test. WBC with differential - Treatment should not be initiated if patient has an absolute neutrophil count (ANC) below 750/mm³.</p> <p>Multiple Myeloma (MM): Statement indicating newly diagnosed MM with concurrent use of dexamethasone or conventional dose chemotherapy, or combination treatment with high dose chemotherapy or stem cell rescue, or use as salvage therapy in refractory or relapsed MM after primary therapy, or use in combination with dexamethasone, doxorubicin, cyclophosphamide and etoposide as part of induction regimen in preparation for autologous transplant.</p> <p>Aphthous stomatitis or ulcers: Statement indicating one of the following: aphthous ulcer of the mouth in immunocompetent and HIV-infected patients or aphthous ulcers of the esophagus in HIV patients, OR recurrent aphthous stomatitis in immunocompromised patients.</p> <p>Crohn's disease: Statement indicating failure of two of the standard treatment regimens, including corticosteroids and Humira.</p> <p>GVHD: Statement indicating diagnosis of chronic or refractory GVHD and failure of two of the following treatment options: Corticosteroids, Azathioprine, Tacrolimus, Cyclosporine and Atithymocyte globulin.</p> <p>Primary Brain Tumors: Statement indicating use as adjuvant therapy to current cytotoxic therapies or previous failure of cytotoxic therapies and/or tumor resection.</p> <p>HIV associated wasting syndrome: Statement indicating diagnosis of AIDS wasting or cachexia, nutritional evaluation and hypogonadism screening, failure to respond to hormone replacement therapy in patients with hypogonadism, and failure, contraindication or intolerance to megestrol for the treatment of HIV associated wasting syndrome.</p>
Age restrictions	Greater than 12 years old
Prescriber Restrictions	Candidates must follow S.T.E.P. program requirements. Provider and pharmacy must be registered with this program.
Coverage Duration	<p>ENL, MM: Through Benefit Year AS: 1 month</p> <p>GVHD, Primary Brain Tumors: 6 months</p> <p>Other uses: 3 months</p>

Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.
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THYMOGLOBULIN (anti-thymocyte globulin (rabbit))

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of FDA approved diagnosis, CBC with differential, Platelets, WBC Recommended for all patients on Thymoglobulin prior to initiation therapy: Hematologic tests including CBC w/ differential and platelet counts. Blood chemistries- including renal and liver function tests.
Age restrictions	18 years old and greater
Prescriber Restrictions	
Coverage Duration	2 months
Other Criteria	

TRACLEER (bosentan monohydrate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Pulmonary arterial hypertension (PAH) with WHO class II through IV symptoms AND stated trial and failure or contraindication to preferred alternatives Adcirca and Letairis (for WHO class II and III only). Lab work- LFTs, CBC, and negative pregnancy tests
Age restrictions	Greater than 12 years of age
Prescriber Restrictions	Available only to those enrolled in the Tracleer Access Program (T.A.P.)
Coverage Duration	Through the benefit year
Other Criteria	

TREANDA (bendamustine hydrochloride)

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

TRELSTAR (triptorelin pamoate)

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

TRISENOX (arsenic trioxide)

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

TYKERB (lapatinib ditosylate)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approve if used in combination with : 1. Xeloda (capecitabine) for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. OR 2. Femara (letrozole) for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

TYZEKA (telbivudine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Hepatitis B: Labs indicating hepatitis B infection, evidence of viral replication, and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease AND trial and failure of preferred agent in patients with no documented resistance. Preferred agent is Epivir HBV (lamivudine HBV)
Age restrictions	16 years old or greater
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	

VALCYTE (valganciclovir hydrochloride)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Renal failure, hemodialysis
Required Medical Information	Documented FDA approved diagnosis AND laboratory values including serum creatinine, absolute neutrophil count (ANC) greater than 500/mm ³ , platelet count greater than 25,000/mm ³ , AND hemoglobin greater than or equal to 8 g/dl. For the use of the Valcyte oral solution, statement of swallowing difficulty must be included.
Age restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Valcyte should not be used in patients who received a liver transplant.

VANCOCIN HCL (vancomycin hydrochloride)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Antibiotic-associated pseudomembranous colitis caused by Clostridium difficile: Stool culture report within the previous 30 days indicating positive C. difficile toxin AND documented trial and failure or contraindication to preferred agent, metronidazole. Staphylococcus aureus (including methicillin-resistant strains) enterocolitis: Approve
Age restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 14 days Patients with multiple relapses: 6 weeks
Other Criteria	

VANCOMYCIN HCL INJECTION

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

VANDETANIB (vandetanib)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Stated diagnosis from oncologist of treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

VELCADE (bortezomib)

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

VFEND (voriconazole)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation of invasive aspergillosis, bronchopulmonary aspergillosis, serious Candida infections, infections caused by the emerging pathogens <i>Scedosporium</i> sp. and <i>Fusarium</i> sp., or rare and refractory fungal infections should be provided. Preferred alternative for Candida: oral fluconazole
Age restrictions	12 years or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

VIDAZA (azacitidine)

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

VIMPAT TABLETS (lacosamide)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approved as adjunctive therapy in the treatment of partial seizures in patients with epilepsy. Documentation indicating current seizure regimen requires optimization in order to control seizure activity.
Age restrictions	17 years old or greater
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

VIMPAT ORAL SOLUTION (lacosamide)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Approved as adjunctive therapy in the treatment of partial seizures in patients with epilepsy. Documentation indicating current seizure regimen requires optimization in order to control seizure activity. For use of oral solution a statement that member has swallowing difficulties or cannot tolerate Vimpat tablets must be included.
Age restrictions	17 years old or greater
Prescriber Restrictions	
Coverage Duration	Through the benefit year
Other Criteria	Trial and failure of Vimpat tablets. Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

VOTRIENT (pazopanib hydrochloride)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

XENAZINE (tetrabenazine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Statement of FDA approved diagnosis.
Age restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Through the benefit year
Other Criteria	

XOLAIR (omalizumab)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Weight between 30 - 150 kg (current weight must be provided). Stated diagnosis of moderate to severe persistent asthma (NAEPP/NIH guideline). Peak flow rate less than 80% of predicted with at least a 30% variability. Current use of a medium-dose inhaled corticosteroid and adjunctive therapy (a long acting beta agonist or a leukotrine inhibitor) as recommended by the NIH without disease control. Positive skin test or in vitro reactivity to a perennial aeroallergen. IgE level of 30 IU/ml to 700 IU/ml only. Guidelines developed by WellCare Healthplans (In addition to above criteria) May be covered under Part B. Continuous use of an inhaled corticosteroids with a long acting beta-agonist or leukotriene inhibitor for 6 months without disease control. Three or more episodes in the past twelve months where appropriate controller medication has failed to control the patient's symptoms, emergency room (or urgent care center or clinical office) visit for acute treatment, or hospital admission. Enrolled in Asthma Case Management Program for at least 6 months (if applicable as part of the member's Benefit with WellCare Health Plans) RAST or Allergy skin test.</p> <p>Preferred Inhaled Corticosteroids and Leukotriene Inhibitors include- Advair or Flovent, Qvar, Asmanex (in combination with Serevent) and Singulair</p>
Age restrictions	12 years or older
Prescriber Restrictions	Pulmonologist or Allergist
Coverage Duration	Through the benefit year
Other Criteria	

XYREM (sodium oxybate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>1. Treatment of excessive daytime sleepiness in patients with narcolepsy: a. Submission of sleep study confirming the diagnosis of narcolepsy, as defined by the International Classification of Sleep Disorders (1997), AND b. Patient is currently NOT taking any sedative hypnotic agents or other CNS depressants, AND c. Patient and Physician is enrolled in the Xyrem Success Program AND e. Patient has experienced inadequate response or intolerable side effects to two of the following preferred products modafinil, methylphenidate, or dextroamphetamine AND f. The requested dose does not exceed the FDA indicated maximum (9gm/night)</p> <p>2. Treatment of cataplexy in patients with narcolepsy: a. Submission of sleep study confirming the diagnosis of narcolepsy, as defined by the International Classification of Sleep Disorders (1997), AND b. Patient is currently NOT taking any sedative hypnotic agents or other CNS depressants, AND c. does not have sleep apnea, AND d. Patient and Physician is enrolled in the Xyrem Success Program, AND e. The dose does not exceed the FDA indicated maximum (9gm/night).</p>
Age restrictions	Greater than 16 years old
Prescriber Restrictions	
Coverage Duration	3 months initial, reauthorization needed for continuation of therapy
Other Criteria	

ZAVESCA (miglustat)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Medical statement of approved diagnosis: mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).
Age restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	

ZOLINZA (vorinostat)

Covered uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Cutaneous T-Cell Lymphoma (CTCL): diagnosis of progressive, persistent, or recurrent disease and has failed or is intolerant to two systemic therapies.</p> <p>Must try and fail at least two systemic therapies for CTCL. Examples of systemic therapies include oral retinoids (e.g., bexarotene (Targretin®), photopheresis, fusion proteins (e.g., denileukin diftitox (Ontak®), interferon, and systemic chemotherapy, topical methclorethamine, topical carmustine, Psoralen + ultraviolet A (PUVA), methotrexate, gemcitabine, cyclophosphamide, chlorambucil, doxorubicin, isotretinoin, pentostatin, fludarabine, cladarabine, glucocorticoids (e.g., prednisone, dexamethasone)</p>
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through the benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ZOMETA (zoledronic acid monohydrate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (Category D)
Required Medical Information	<p>Medical statement indicating diagnosis is required AND trial and failure of preferred oral bisphosphonates AND Boniva Injectable for the diagnosis of osteoporosis and osteoporosis prophylaxis. Preferred oral bisphosphonates: alendronate, Boniva (oral)</p> <p>Approve for the indications of:</p> <ol style="list-style-type: none"> 1. Hypercalcemia of malignancy 2. Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy <p>Important limitation of use: The safety and efficacy of Zometa has not been established for use in hyperparathyroidism or nontumor-related hypercalcemia.</p>
Age restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Through Benefit Year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

ZORTRESS (everolimus)

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

ZYPREXA (olanzapine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the same class AND one lower tier traditional mood stabilizer. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine.</p> <p>Major Depressive Disorder (augmenting treatment): Documented continuous treatment with an antidepressant as monotherapy x 6 weeks AND documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Members currently on fluoxetine require trial and failure of Symbyax and atypical quetiapine. Members not on fluoxetine require trial and failure of atypical antipsychotic quetiapine. Members not on an antidepressant require continuous trial with lower tier antidepressant including fluoxetine, paroxetine, sertraline, citalopram, bupropion, mirtazepine, venlafaxine.</p>
Age restrictions	<p>18 years or older (adjunctive treatment for Major Depressive Disorder)</p> <p>13 years or older (Schizophrenia and Bipolar Disorder)</p>
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ZYPREXA RELPREVV (olanzapine)

PENDING CMS APPROVAL

ZYPREXA ZYDIS (olanzapine)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Schizophrenia: Documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Formulary atypical antipsychotics include risperidone and quetiapine.</p> <p>Bipolar mania: Documented treatment failure or intolerable side effects from treatment with one formulary medication within the same class AND one lower tier traditional mood stabilizer. Formulary atypical antipsychotics include risperidone and quetiapine, lower tier traditional mood stabilizers include lithium, divalproex sodium, lamotrigine or carbamazepine.</p> <p>Major Depressive Disorder (augmenting treatment): Documented continuous treatment with an antidepressant as monotherapy x 6 weeks AND documented treatment failure or intolerable side effects from treatment with two formulary medications within the same class. Members currently on fluoxetine require trial and failure of Symbyax and atypical quetiapine. Members not on fluoxetine require trial and failure of atypical antipsychotic quetiapine. Members not on an antidepressant require continuous trial with lower tier antidepressant including fluoxetine, paroxetine, sertraline, citalopram, bupropion, mirtazepine, venlafaxine.</p> <p>For the use of the Zyprex Zydis, statement of swallowing difficulty must be included and trial and failure of risperidone ODT and risperidone oral solution for the diagnosis of schizophrenia or bipolar mania.</p>
Age restrictions	<p>18 years or older (adjunctive treatment for Major Depressive Disorder)</p> <p>13 years or older (Schizophrenia and Bipolar Disorder)</p>
Prescriber Restrictions	
Coverage Duration	Through the Benefit Year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ZYTIGA (abiraterone acetate)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy (category X)
Required Medical Information	Stated diagnosis from oncologist of treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel in combination with prednisone.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	Through benefit year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

ZYVOX (linezolid)

Covered uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	<p>Statement of FDA approved indication. Recent Culture and Sensitivity report indicating sensitivity to linezolid (Zyvox) and resistance to preferred agents. Approve for diagnosis of MRSA or VRE.</p> <p>Community Acquired Pneumonia -Trial and failure of two preferred medications. Preferred agents include: Amoxicilin/Clavulanate, Azithromycin, Cephalexin, Clarithromycin, Levaquin. Skin/structure infection other than MRSA: Amoxicillin/clavulanate, Cephalexin, Ciprofloxacin, Clindamycin, Levaquin, Trimethoprim/Sulfamethoxazole, Dicloxacillin.</p>
Age restrictions	
Prescriber Restrictions	
Coverage Duration	28 Days
Other Criteria	