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Medicare Plus Blue PPO Vitality, Signature and Prescription Blue PDP Option A Prior Authorization / Step Therapy Program 2011 Plan Year

BCBSM – Medicare Plus Blue PPO Vitality, Signature and Prescription Blue PDP Option A monitors the use of certain medications to ensure our members receive the most appropriate and cost-effective drug therapy. **Prior authorization** (PA) for these drugs means that either clinical and/or administrative criteria must be met before coverage is provided. Drugs subject to **step therapy** (ST) may require previous treatment with one or more formulary drugs prior to coverage. Drugs that must meet clinical/administrative criteria are identified in the formulary list with (PA) or (ST). If drugs listed below have a **(g)** noted, the **PA** or **ST** criteria may also apply to the generic version of the drug. In some cases, the brand name drug is listed for reference and the generic drug is covered. Please refer to the Formulary to verify if your drugs are covered. Your physician can contact our pharmacy help desk to request prior authorization or step therapy for these drugs.

The clinical criteria for authorization are based on current medical information and the recommendations of the Blues' Pharmacy and Therapeutics Committee, a group of physicians, pharmacists and other experts.

Please call the Customer Service number on the back of your BCBSM ID card if you have questions about your drug coverage or a drug claim.

MEDICATION/ DRUG CLASS	CRITERIA
Actemra [®] (tocilizumab)	<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>Coverage is provided for the diagnosis of rheumatoid arthritis and has tried and failed Enbrel[®] and Humira[®].</p> <p><i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p><u>Prescriber restrictions:</u> must be a rheumatologist.</p> <p><u>Age restrictions:</u> patients 18 years of age or older.</p> <p><u>Coverage duration:</u> Lifetime.</p>

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Advicor[®] (lovastatin/extended release niacin)	Coverage requires documentation that the patient has had at least 1 month of treatment with lovastatin and niacin extended release as individual agents when used concomitantly. Coverage duration: Lifetime.
Alpha-1 Proteinase Inhibitors Aralast NP [®] Glassia [®] Prolastin [®] Zemaira [®]	<u>Initial</u> request requires documentation of a congenital deficiency of alpha-1 antitrypsin, demonstrated by a homozygous phenotype of AAT, <u>and</u> must be a nonsmoker, <u>and</u> must have symptomatic emphysema <u>and</u> serum levels of alpha-1 antitrypsin that are less than 80mg/dl <u>and</u> must have deteriorating pulmonary function, as demonstrated by a decline in the fev1 (less than 65% of predictive value). <u>Renewal</u> of therapy requests will be provided for patients who demonstrate serum levels of alpha-1 antitrypsin that are above threshold of 80mg/dl. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Age restrictions: patients 18 years of age or older. Coverage duration: <u>Initial</u> approval is for 6 months. <u>Reauthorization</u> is for 1 year.
Amitiza[®] (lubiprostone)	Coverage is provided for diagnosis of chronic idiopathic constipation or constipation-irritable bowel syndrome. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Age restrictions: patients 18 years of age or older. Coverage duration: Lifetime.
Ampyra[®] (dalfampridine)	Initial coverage is provided to improve walking distance in patients with a diagnosis of Multiple Sclerosis who have the ability to walk a timed 25 foot walk test. <u>Initial</u> requests require documentation of a 25 foot timed walk test. <u>Renewal</u> of therapy require documentation that the member has shown an improvement in walking distance of a 25 foot timed walk test compared to pretreatment. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Prescriber restrictions: prescribing physician is a neurologist. Exclusion criteria: patients with a history of seizure or moderate to severe renal impairment defined by a CrCl of 50ml/min or less. Coverage duration: <u>Initial</u> approval is for 3 months. <u>Reauthorization</u> is for 1 year.

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<p>Anabolic Steroids Oxandrin[®](g) (oxandrolone), Anadrol-50[®] (oxymetholone)</p>	<p>Oxandrin requires documentation that use is 1) for therapy to offset protein catabolism associated with prolonged use of corticosteroids. 2) for bone pain associated with osteoporosis. 3) as prophylactic therapy in patients with hereditary angioedema. Anadrol-50 requires documentation of:1) HIV associated wasting.2) prophylactic therapy for hereditary angioedema.3) clinically diagnosed anemia. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: One year.</p>
<p>Anti-diabetic Injectable Agents Byetta[®] (exenatide) Victoza[®] (liraglutide)</p>	<p>Coverage will be provided as adjunctive therapy to improve glycemic control in patients who have a diagnosis of type II diabetes mellitus and are currently taking or have tried and failed 2 of the following: metformin, a sulfonylurea, or a thiazolidinedione, or one of the following: a combination of metformin and a sulfonylurea or a combination of metformin and a thiazolidinedione. Documentation of HbA1c greater than 7% will be required. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Exclusion criteria: 1) Coverage will not be provided for weight loss in patients with or without diabetes. 2) Coverage will not be provided as concurrent therapy with insulin. Coverage duration: Lifetime.</p>
<p>Aromatase Inhibitors Aromasin[®] (g) (exemestane) Femara[®] (g) (letrozole)</p>	<p>Coverage is provided for female members. Coverage provided for male members with a diagnosis of ER-positive breast cancer. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: Lifetime.</p>
<p>Arzerra[™] (ofatumumab)</p>	<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. Coverage requires documentation of diagnosis of Chronic Lymphocytic Leukemia (CLL) in patients who are refractory to fludarabine and alemtuzumab therapy. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Prescriber restrictions: Must be prescribed by an oncologist. Coverage duration: 1 year.</p>

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Beriner[®] C1 inhibitor, human	Coverage is provided for the acute attacks of those with a diagnosis of hereditary angioedema (HAE) established by an immunologist or hematologist. Documentation of diagnosis confirmed with all of the following laboratory findings, i.) C4 level less than 14mg/l, ii.) C1 inha (antigenic) level less than 150 mg, iii.) C1inhf (functional) level less than or equal to 84 percent. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Age restrictions: At least 13 years of age Prescriber restrictions: Must be prescribed by an Immunologist or Hematologist Coverage duration: 10 days
Betaseron[®] (interferon beta-1b)	Coverage requires the trial and failure of Extavia [®] . Coverage duration: 1 year.
Bisphosphonates 1: Actonel [®] (risedronate) Atelvia [®] (risedronate)	Coverage requires trial and failure of or intolerance to Fosamax [®] (g). Coverage duration: Lifetime.
Bisphosphonates 2: Boniva [®] (ibandronate)	Coverage requires trial and failure of or intolerance to Fosamax [®] (g) and Actonel [®] . Coverage duration: Lifetime.
Campral[®] (acamprosate calcium)	Coverage is provided for maintenance of abstinence from alcohol in patients with alcohol dependence who have been abstinent at treatment initiation for at least 5 days post detoxification. Requires the patient to be enrolled in a comprehensive alcohol management program which includes psychosocial support, such as a 12-step facilitation, social skills training or a cognitive-behavioral therapy program. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 year.
Cayston[®] (aztreonam)	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. Coverage is provided for treatment to improve respiratory symptoms in cystic fibrosis patients with Pseudomonas aeruginosa. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 month.

MEDICATION/ DRUG CLASS	CRITERIA
Cholesterol-Lowering Therapies 1: Crestor [®] (rosuvastatin)	Coverage requires documentation that member has experienced failure (at doses greater than or equal to 40mg) or intolerance to at least one generic statin: Mevacor [®] (g), Pravachol [®] (g), Zocor [®] (g). <u>Coverage duration:</u> Lifetime.
Cholesterol-Lowering Therapies 2: Zetia [®] (ezetimibe)	Coverage requires documentation that member has trial and failure, intolerance, contraindication, or adverse reaction to Mevacor [®] (g), Pravachol [®] (g), Zocor [®] (g), or member is currently on statin therapy and unable to reach therapeutic target after trial at maximum tolerated dose (minimum 40mg). <u>Coverage duration:</u> Lifetime.
Cholesterol-Lowering Therapies 3: Altoprev [®] (lovastatin), Lescol/XL [®] (fluvastatin) Livalo [®] (pitavastatin)	Requires documentation that member has experienced failure (at doses greater than or equal to 40mg) or intolerance to at least one statin: (Mevacor (g), Pravachol (g) Zocor (g)), and trial/failure or intolerance to formulary brand agent Crestor. <u>Coverage duration:</u> Lifetime
Chorionic Gonadotropins	Coverage will be provided based on documentation of diagnosis. <i>All FDA-approved indications not otherwise excluded for Part D.</i> <u>Coverage duration:</u> 1 year.
Cryopyrin-Associated Periodic Syndromes (CAPS) Agents Arcalyst [™] (rilonacept)	Coverage will be provided based on documentation of diagnosis. <i>All FDA-approved indications not otherwise excluded for Part D.</i> <u>Age restrictions:</u> Arcalyst: patients 12 years of age and older. <u>Coverage duration:</u> 1 year.
Durable Medical Equipment (DME) Supply Drugs <i>Various products</i>	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. <u>Coverage duration:</u> Lifetime.
Erythropoiesis Stimulating Agents Aranesp [®] , Epogen [®] , Procrit [®]	These drugs 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. Coverage under Medicare Part D requires documentation diagnosis. Hemoglobin less than 13 for prophylactic use during some major surgeries for Epogen. Hemoglobin less than 12mg/dl for remaining covered uses. <i>All FDA-approved indications not otherwise excluded for Part D.</i>

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	<p>Exclusion criteria: Coverage is not provided in the following conditions: a. Anemia due to folate, vitamin b-12, and iron deficiencies, hemolysis, bleeding, or bone marrow fibrosis, b. Anemia associated with treatment of acute and chronic myelogenous leukemias (CML, AML).</p> <p>Coverage duration: Three months.</p>
<p>Exalgo[®] (hydromorphone hcl)</p>	<p>Coverage is provided for moderate to severe pain in opioid tolerant patients requiring continuous around the clock opioid analgesia for an extended period of time. <i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p>Exclusion criteria: Coverage is not provided for the treatment of acute pain or for opioid naïve patients.</p> <p>Coverage duration: 1 year.</p>
<p>Exforge HCT[®] (amlodipine/valsartan/hydrochlorothiazide)</p>	<p>Requires trial of Exforge.</p> <p>Coverage duration: Lifetime.</p>
<p>Fibrates Fibricor[®] (fenofibric acid) Trilipix[®] (fenofibric acid)</p>	<p>Coverage requires documentation of trial and failure to gemfibrozil (g) and fenofibrate (g).</p> <p>Coverage duration: Lifetime.</p>
<p>Gilenya (fingolimod hydrochloride)</p>	<p>Coverage requires the trial and failure of either glatiramer or an interferon beta product. <i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p>Prescriber restrictions: Must be prescribed by a neurologist.</p> <p>Coverage duration: 1 year.</p>
<p>Growth Hormone (somatropin), Genotropin[®], Humatrope[®], Norditropin[®], Norditropin Nordiflex[®], Nutropin[®] (all), Omnitrope[®], Saizen[®], Serostim[®], Tev-Tropin[®], Zorbtive[™]</p>	<p>Initial requests for human growth hormone in pediatric patients: 1) one of the following indications: growth hormone deficiency (GHD), Prader-Willi Syndrome (PWS), Turners Syndrome, chronic renal insufficiency (CRI). And 2.) Initiating therapy in children (male less than 16, female less than 15): initial height measurements less than 5th percentile for age (based on initial evaluation), abnormal growth velocity for at least 6 months, initial subnormal growth hormone test. Renewing treatment in children requires growth velocity of at least 2.5cm/yr during first 6 months and at least 4.5cm/yr for each succeeding 6 month period. May be continued until final height or epiphyseal closure is documented.</p> <p>Requests in adult patients: 1.) The diagnosis of growth hormone deficiency with hypopituitarism when one of the following criteria (a or b) are met: a. Two pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement</p>

g = generic available

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	<p>such as TSH, ACTH, gonadotropins and ADH and both of the following i and ii: i. At least one known cause for pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma or infiltrative disease (histoplasmosis, Sheehan Syndrome, autoimmune hypophysitis, or sarcoidosis) is documented. And ii. One provocative stimulation less than 5 ng/ml. The insulin tolerance test is the preferred testing method, but other secretagogues, such as arginine, GHRH, clonidine and l-dopa are acceptable. Or b. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement and an igf-1 level below 80 ng/ml. Coverage for serostim for the treatment of aids-related cachexia.</p> <p><i>All FDA approved indications not otherwise excluded for Part D.</i></p> <p><u>Prescriber restrictions:</u> Pediatric patients requires for all indications must be prescribed by a pediatric endocrinologist or pediatric nephrologist.</p> <p><u>Coverage duration:</u> Pediatrics equals one year. Adults equals lifetime.</p>
<p>Hepatitis Vaccine Comvax[®], Engerix-B[®], Pediatrix[®], Recombivax HB[®]</p>	<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><u>Coverage duration:</u> 1 year.</p>
<p>Horizant[®] (gabapentin enacarbil)</p>	<p>Requires trial and failure of or intolerance to Requip (g) and Mirapex (g).</p> <p><u>Coverage duration:</u> Lifetime.</p>
<p>Immunosuppressive Therapy for an Organ Transplant <i>Various products</i></p>	<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><u>Coverage duration:</u> Lifetime.</p>
<p>Ilaris[®] (canakinumab)</p>	<p>Coverage requires diagnosis of cryopyrin-associated periodic syndromes (CAPS) including familial cold auto-inflammatory syndrome (FCAS) and Muckle–Wells syndrome (MWS) AND a patient age of 4 years or older. As new FDA approved indications become available plan will consider coverage accordingly.</p> <p><u>Age restrictions:</u> Patients 4 years or older.</p> <p><u>Coverage duration:</u> 1 year.</p>

MEDICATION/ DRUG CLASS	CRITERIA
Immune Thrombocytopenic Purpura (ITP) Agents Promacta [®] (eltrombopag olamine)	Promacta requires a diagnosis of chronic immune thrombocytopenia (ITP) and persistent thrombocytopenia. Requires inadequate response or patient must not be a candidate for corticosteroids, immunoglobulins or splenectomy. Documentation of a current platelet count less than 50,000mcl. Renewal of therapy is provided in patients who meet all of the following criteria: recent platelet count between 30,000 - 150,000 mcl. <i>All FDA-approved indications not otherwise excluded for Part D</i> Prescriber restrictions: Must be prescribed by hematologist or in consultation with a hematologist. Age restrictions: patients 18 years of age or older. Coverage duration: <u>Initial</u> request approve for 3 months. <u>Renewal</u> of therapy approve for 12 months.
Inhaled Nasal Steroids 1: Nasacort AQ [®] (triamcinolone)	Coverage requires trial and failure of or intolerance to Nasarel [®] (g)/ Nasalide [®] (g) or Flonase [®] (g). Coverage duration: Lifetime.
Inhaled Nasal Steroids 2: Beconase AQ [®] (beclomethasone), Nasonex [®] (mometasone), Omnaris [®] (ciclesonide), Rhinocort Aqua [®] (budesonide), Veramyst [®] (fluticasone)	Coverage requires trial and failure of or intolerance to Nasacort AQ [®] <u>and</u> either Nasalide [®] (g) / Nasarel [®] (g) or Flonase [®] (g). Coverage duration: Lifetime.
Innohep[®] (tinzaparin)	Coverage is provided for the diagnosis and treatment of acute symptomatic DVT, with or without pulmonary embolism (PE), when administered in conjunction with warfarin. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Exclusion criteria: Documentation of history of heparin- induced thrombocytopenia. Coverage duration: 1 month.
Intravenous Immune Globulin (IVIG) <i>Various products</i>	These drugs 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. Coverage under Medicare Part D requires documentation of diagnosis of Inflammatory

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	<p>Demyelinating Polyneuropathy (acute or chronic), chronic ITP and Kawasaki syndrome. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: Lifetime.</p>
<p>Jevtana[®] (cabazitaxel)</p>	<p>Coverage requires documentation of diagnosis. Coverage is provided for the treatment of patients, in combination with prednisone, with hormone-refractory metastatic prostate cancer previously treated with a docetaxel- containing treatment regimen. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 year.</p>
<p>Kalbitor[®] (ecallantide)</p>	<p>Coverage is provided for a diagnosis of acute attacks of Hereditary Angioedema (HAE) that have been confirmed by an Immunologist or Hematologist. Documentation of diagnosis confirmed with all of the following laboratory findings, i.) C4 level less than 14mg/l, ii.) C1 inha (antigenic) level less than 150 mg, iii.) C1inhf (functional) level less than or equal to 84 percent. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Age restriction: Patients 16 years and older. Prescriber restrictions: Must be prescribed by an Immunologist or Hematologist. Coverage duration: 10 days.</p>
<p>Lotronex[®] (alosetron hydrochloride)</p>	<p>Coverage is provided for the diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS), and unresponsive to a trial of conventional IBS therapy such as Benty[®] (g). Also required is documentation of patient-physician agreement for Lotronex and physician attestation of qualifications and acceptance of responsibilities signatures have been attained as recommended in product labeling. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Age restriction: Greater than or equal to 18 years of age. Coverage duration: 1 year.</p>
<p>Lyrica[®] (pregabalin)</p>	<p>Coverage is provided for the diagnosis and treatment of 1) seizures/epilepsy. 2) diabetic peripheral neuropathy. 3) fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months. 4) post-herpetic neuralgia after a 30 day trial of gabapentin. For off-label uses: trigeminal neuralgia: patient must try and fail carbamazepine and gabapentin. For chemotherapy induced peripheral neuropathy: patient must try and fail gabapentin.</p>

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	<p><i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 year or lifetime.</p>
<p>Migraine Combination Products Treximet® (sumatriptan/naproxen sodium)</p>	<p>Coverage requires documentation of medical necessity. Trial and failure of naproxen and either Maxalt® or sumatriptan, and documentation as to why use of the individual agents (naproxen and sumatriptan) is harmful to the patient. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: Lifetime.</p>
<p>Miscellaneous Vaccine: BCG Live Vaccine, Hepatitis A Vaccine, Measles Virus Vaccine, Rabies Vaccine, Tetanus Toxoid Vaccine <i>Various products</i></p>	<p>Approved under Medicare Part B if given to treat an injury or as a result of direct exposure to a disease or condition Approved under Medicare Part D for prophylactic use. Coverage duration: 1 year.</p>
<p>Mozobil® (plerixafor)</p>	<p>Coverage requires documentation of diagnosis and is provided in combination with granulocyte colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-hodgkin's lymphoma (NHL) and multiple myeloma (MM). Documentation of G-CSF prior to initiation of Mozobil® for 4 days is also required. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 month.</p>
<p>Narcolepsy Agents Nuvigil® (armodafinil) Provigil® (modafinil)</p>	<p>Provigil requires documentation of diagnosis of narcolepsy, obstructive sleep apnea, or shift work sleep disorder. Nuvigil requires documentation of diagnosis of narcolepsy, obstructive sleep apnea, or shift work sleep disorder and has tried and failed Provigil. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: Lifetime.</p>
<p>Narcotic analgesics (fentanyl citrate) Abstral® Actiq® Fentora® Onsolis®</p>	<p>Coverage is provided for breakthrough pain only in patients diagnosed with cancer currently receiving a long acting narcotic with documented tolerance to high dose narcotics. Documentation of medical diagnosis and tolerance to high dose narcotics is required. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 year.</p>

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Nplate[®] (romiplostim)	Requires a diagnosis of chronic immune thrombocytopenia (ITP) and persistent thrombocytopenia. Documentation of platelet count less than 150,000 mcL for greater than or equal to 2 months and a current platelet count less than 30,000 mcL. Must be prescribed by Hematologist or in consultation with a hematologist. Requires inadequate response or patient must not be a candidate for corticosteroids, immunoglobulins or splenectomy. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Age restrictions: Patients 18 years of age or older. Prescriber restrictions: Must be prescribed by a Hematologist or in consultation. Coverage duration: 3 months.
Nuedexta[®] (dextromethorphan hbr/quinidine)	Coverage is provided for the treatment of pseudobulbar affect in patients with underlying neurologic conditions. Requires diagnosis of pseudobulbar affect (PBA). <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 year.
Oleptro[®] (trazodone ER)	Coverage is provided for the treatment of major depressive disorder and requires the trial and failure of immediate release trazodone and documentation that the continued use of immediate release trazodone will adversely affect the member's health. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: Lifetime.
Oral Anti-emetics Agents <i>Various products</i>	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. Coverage duration: 1 year.
Oral Chemotherapeutic Agents <i>Various products</i>	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. Coverage duration: Lifetime.

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Osteoporosis Agents Forteo [®] (teriparatide, rDNA origin)	Coverage requires documentation of diagnosis: postmenopausal women with osteoporosis, glucocorticoid induced osteoporosis, or men with primary or hypogonadal osteoporosis, all of who are at high risk for fracture <u>and</u> 1) have tried and failed, or have a documented intolerance, to a bisphosphonate for a 12 month period <u>and</u> 2) have a bone mineral density that is 2.5 standard deviations or more below the mean (t-score at or below -2.5). <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 2 years.
Parenteral Nutrition <i>(Numerous ingredients may be reflected in various products)</i>	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. Coverage duration: Lifetime.
Prolia[®] (denosumab)	Requires diagnosis of postmenopausal osteoporosis, who have a high risk for fracture. Requires a 12 month trial and failure, or have a documented intolerance, to a bisphosphonate. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Exclusion criteria: Coverage is not provided for Hypocalcemia. Coverage duration: Lifetime.
Pulmonary Arterial Hypertension (PAH) agents Adcirca [®] (tadalafil) Letairis [®] (ambrisentan), Revatio [®] (sildenafil citrate), Revatio [®] IV (sildenafil citrate), Tracleer [®] (bosentan)	<u>Adcirca[®] and Revatio[®] (oral):</u> coverage is provided for a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for Revatio [®] or Adcirca [®] is also provided if used in combination with bosentan (Tracleer [®]), epoprostenol (Flolan [®]), treprostinil (Remodulin [®]) or iloprost (Ventavis [®]) after monotherapy with one of these agents has been found to be inadequate in the treatment of the patients symptoms. <u>Revatio[®] IV:</u> coverage is provided for the continued treatment of patients with Pulmonary Arterial Hypertension who are currently prescribed Revatio [®] tablets but who are temporarily unable to take oral medication. <u>Tracleer[®]:</u> coverage is provided for the diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with world health organization (WHO) class ii to iv symptoms. <u>Letairis[®]:</u> coverage is provided for the diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO class ii or iii symptoms. <i>All FDA-approved indications not otherwise excluded for Part D.</i>

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	<p>Exclusion criteria: Coverage is not provided for sildenafil (Revatio[®]) and tadalafil (Adcirca[®]) in situations where patients are receiving nitrate therapy.</p> <p>Coverage duration: Injectable agents for 3 months. Oral agents for Lifetime.</p>
<p>Relistor[®] (methylnaltrexone)</p>	<p>Requires a diagnosis of opioid induced constipation in members with advanced illness who are receiving palliative care when response to laxative therapy has not been sufficient. A member must be stable on opioid therapy for greater than 2 weeks. <i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p>Exclusion criteria: Coverage is not provided for patients with known or suspected mechanical gastrointestinal obstruction.</p> <p>Coverage duration: 3 months.</p>
<p>Renal Cell Carcinoma Agents Afinitor[®] (everolimus) 5mg, 10mg Votrient[®] (pazopanib)</p>	<p>Afinitor[®]: <u>Initial</u> requests require the diagnosis of advanced renal cell carcinoma and the documented failure of treatment, described as disease progression, with the use of Nexavar[®] or Sutent[®]. Maximum dose equals 20mg. <u>Renewal</u> of therapy is provided in patients who meet all of the following criteria: confirmation that current medical necessity criteria are met and the medication is effective.</p> <p>Votrient[®]: <u>Initial</u> requests require the diagnosis of advanced renal cell carcinoma. <u>Renewal</u> of therapy is provided in patients who meet all of the following criteria: confirmation that current medical necessity criteria are met and the medication is effective. <i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p>Prescriber restrictions: Must be prescribed by an oncologist.</p> <p>Exclusion criteria: Will not be covered in combination with Nexavar[®] or Sutent[®]. Will not be covered for unapproved or investigational indications.</p> <p>Coverage duration: <u>Initial</u> and <u>Renewal</u> requests approve for 12 months.</p>
<p>Savella[®] (milnacipran)</p>	<p>Coverage is provided for the diagnosis of fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance. <i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p>Coverage duration: requested duration or lifetime.</p>

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Sedative Hypnotics (ST): Rozerem [®] (ramelteon)	Coverage requires trial and failure of or intolerance to Ambien [®] (g), <u>or</u> Sonata [®] (g). Coverage duration: Lifetime.
Select Cholesterol Combination Products: Simcor [®] (simvastatin + niacin extended release)	Coverage requires documentation that the member has had at least 1 month of treatment with simvastatin or Vytorin [®] and either niacin extended release or Advicor [®] , as individual agents when used concomitantly. Coverage duration: Lifetime.
Selective Reuptake Inhibitor – antidepressants (SRI 1): Lexapro [®] (escitalopram)	Coverage requires step therapy with at least one of the following formulary alternatives: Celexa [®] (g), Effexor [®] (g), Effexor XR [®] (g), Luvox [®] (g), Paxil [®] /CR (g), Prozac [®] (g), Remeron [®] (g), Venlafaxin OSM [®] (g), Wellbutrin [®] /SR/XL (g), or Zoloft [®] (g). Coverage duration: Lifetime.
Selective Reuptake Inhibitor – antidepressants (SRI 2): Pristiq [®] (desvenlafaxine) Viibryd [®] (vilazodone)	Coverage requires step therapy with at least two formulary agents. Coverage duration: Lifetime.
Somavert[®] (pegvisomant)	Coverage is provided for patients diagnosed with acromegaly who have had an inadequate response to surgery or radiation therapy. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 1 year.
Stelara[®] (Ustekinumab)	Coverage is provided for the diagnosis of moderate to severe plaque psoriasis and requires the trial and failure of PUVA and either Enbrel [®] or Humira [®] . <i>All FDA-approved indications not otherwise excluded for Part D.</i> Prescriber restrictions: prescribing physician is a dermatologist. Age restrictions: patients 18 years of age or older. Coverage duration: Lifetime.
Strattera[®] (atomoxetine)	<u>For members age 5-21:</u> Coverage requires documentation that member has experienced failure of or intolerance to both Ritalin [®] (g) <u>and</u> Adderall [®] (g). <u>For members age greater than 21:</u> Coverage requires documentation that the member has experienced failure of or intolerance to either Ritalin [®] (g) <u>or</u> Adderall [®] (g). Approvable when stimulants are contraindicated by medical history.

MEDICATION/ DRUG CLASS	CRITERIA
	<p><u>Age restrictions:</u> 5 -21 years old and greater than 21 years old. <u>Coverage duration:</u> Lifetime.</p>
<p>Suboxone® (buprenorphine hcl/naloxone hcl)</p>	<p>Coverage is provided for the treatment of clinically diagnosed opioid dependence with documented use of validated screening tools to identify patients who may have an opioid use problem. <i>All FDA-approved indications not otherwise excluded for Part D.</i> <u>Prescriber restrictions:</u> Physicians must be certified with a data 2000 waiver. <u>Age restrictions:</u> 16 years of age or older. <u>Exclusion criteria:</u> coverage is not provided for pain management. <u>Coverage duration:</u> 6 months.</p>
<p>Subutex® (g) (buprenorphine hcl)</p>	<p>Coverage is provided for the treatment of clinically diagnosed opioid dependence with documented use of validated screening tools to identify patients who may have an opioid use problem. <i>All FDA-approved indications not otherwise excluded for Part D.</i> <u>Prescriber restrictions:</u> Physicians must be certified with a data 2000 waiver. <u>Age restrictions:</u> 16 years of age or older. <u>Exclusion criteria:</u> coverage is not provided for pain management. <u>Coverage duration:</u> 1 month.</p>
<p>Tekturna® (aliskiren): Tekturna®, Tekturna HCT®</p>	<p>Requires trial of an ace inhibitor and an angiotensin receptor blocker. <u>Coverage duration:</u> Lifetime.</p>
<p>TNF agents 1: Enbrel® (etanercept), Humira® (adalimumab)</p>	<p><u>Following criteria are used in reviewing Enbrel:</u> 1. Diagnosis of psoriatic arthritis. 2. Diagnosis of rheumatoid arthritis or juvenile arthritis, which requires a trial on two concurrent nonbiologic disease modifying anti-rheumatic drugs (dmards), one of which must be methotrexate unless contraindicated. 3. Diagnosis of plaque psoriasis, requires a trial with a topical steroid and treatment with puva (unless puva contraindicated). 4. Diagnosis of ankylosing spondylitis. <u>The following criteria are used in reviewing Humira:</u> 1. For diagnosis of psoriatic arthritis or 2) for diagnosis of rheumatoid arthritis or juvenile arthritis requires a trial on two concurrent nonbiologic disease modifying anti-rheumatic drugs (dmards), one of which must be methotrexate unless contraindicated. 3. For diagnosis of moderately to severely active crohn's disease for patients with a with a history of inadequate</p>

MEDICATION/ DRUG CLASS	CRITERIA
	<p>response to entocort ec. 4. For diagnosis of ankylosing spondylitis. 5. For diagnosis of plaque psoriasis, requires a trial with a topical steroid and treatment with puva (unless puva contraindicated).</p> <p><i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p><u>Prescriber restrictions:</u> for ankylosing spondylitis, requires therapy is being supervised by rheumatologist. For moderate to severe psoriasis, requires therapy is being supervised by dermatologist</p> <p><u>Age restrictions:</u> 18 years or older for crohn's disease.</p> <p><u>Coverage duration:</u> Lifetime.</p>
<p>TNF agents 2: Kineret[®] (anakinra) Simponi[®] (golimumab)</p>	<p><u>Following criteria are used in reviewing Kineret[®]:</u> For diagnosis of rheumatoid arthritis, Kineret[®] requires treatment failure or contraindication to Enbrel[®] and Humira[®].</p> <p><u>Following criteria are used in reviewing Simponi[®]:</u> 1. For the treatment of rheumatoid arthritis or psoriatic arthritis when there has been treatment failure or a contraindication to both adalimumab (Humira[®]) and etanercept (Enbrel[®]). 2. For ankylosing spondylitis, requires treatment failure or contraindication to both adalimumab (Humira[®]) and etanercept (Enbrel[®]).</p> <p><i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p><u>Prescriber restrictions:</u> For ankylosing spondylitis, requires therapy is being supervised by Rheumatologist.</p> <p><u>Age restrictions:</u> 18 years or older.</p> <p><u>Coverage duration:</u> Lifetime.</p>
<p>TNF agents 3: Cimzia[®] (certolizumab pegol)</p>	<p>Coverage will be provided for the diagnosis of acute exacerbation of moderate to severe Crohn's disease when <u>both</u> of the following criteria are met: 1) treatment with adequate course of systemic corticosteroids has been ineffective, contraindicated, patient has been unable to taper, or is experiencing breakthrough disease while stabilized on an immunomodulatory medication for at least two months <u>and</u>, 2) patient has had previous trial and failure or contraindication to Humira[®].</p> <p>Coverage is provided for the diagnosis of moderate to severe rheumatoid arthritis when there has been the trial and failure or contraindication of Humira[®] and Enbrel[®]</p> <p><i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p><u>Age restrictions:</u> 18 years or older.</p> <p><u>Coverage duration:</u> 1 year.</p>

MEDICATION/ DRUG CLASS	CRITERIA
Topical Anti-emetics Sancuso [®] (granisetron)	Coverage is provided for use in the prevention and/or treatment of nausea/vomiting associated with chemotherapy and/or radiation therapy and requires treatment failure with generic ondansetron and generic granisetron. Patient must not be a candidate for IV granisetron. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: 3 months.
Triptans 1 (Maxalt [®] , Maxalt MLT [®])	Coverage requires trial and failure with sumatriptan. Coverage duration: Lifetime.
Triptans 2 (Axert [®] , Frova [®] , Relpax [®] , Zomig [®] , Zomig ZMT [®])	Requires trial and failure with sumatriptan and Maxalt. Coverage duration: Lifetime.
Tysabri[®] (natalizumab)	These drugs 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. Coverage under Medicare Part D requires documentation diagnosis. Coverage is provided for the following 1) diagnosis of a relapsing-remitting form of Multiple Sclerosis and has had a trial of Copaxone [®] and at least one other interferon beta product unless contraindicated. 2) diagnosis of Crohn's disease with an elevated baseline c-reactive protein (CRP) levels and has had a trial and failure of Humira [®] <u>and</u> either Simponi [®] or Cimzia [®] unless contraindicated. Documentation of c-reactive protein levels in patients with Crohn's. <i>All FDA-approved indications not otherwise excluded for Part D.</i> Coverage duration: Crohn's disease: 1 year; relapsing-remitting Multiple Sclerosis: 6 months.
Uloric[®] (febuxostat)	Coverage requires treatment failure, intolerance or contraindication with allopurinol. Coverage duration: Lifetime
Vytorin[®] (simvastatin/ezetimibe)	Requires trial with Zocor (g) or Simcor, and Zetia, as individual agents when used concomitantly. Coverage duration: Lifetime.

g = generic available

MEDICATION/ DRUG CLASS	CRITERIA
Xenazine® (tetraabenazine)	<p>Coverage requires a diagnosis of chorea associated with Huntington's disease. Documentation of the CYP2D6 genotype of the patient will be required for doses above 50mg per day.</p> <p><i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p><u>Exclusion criteria:</u> coverage will not be provided in the following situations, 1) hepatic function impairment, 2) actively suicidal or who have untreated or inadequately treated depression, 3) taking monoamine oxidase inhibitors or Reserpine®, 4) treatment of tardive dyskinesia.</p> <p><u>Coverage duration:</u> 1 year.</p>
Xiaflex® (collagenase clostridium histolyticum)	<p>Coverage is provided for the treatment of adult patients with Dupuytren's contracture with a palpable cord.</p> <p><i>All FDA-approved indications not otherwise excluded for Part D.</i></p> <p><u>Prescriber restrictions:</u> Physician must have completed the Xiaflex Xperience™ training and their facility is currently enrolled as a healthcare site to receive Xiaflex orders.</p> <p><u>Age restrictions:</u> 18 years and older.</p> <p><u>Coverage duration:</u> 1 month.</p>