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Blue Cross Blue Shield of Michigan - Medicare Part D, PPO Prior Authorization / Step Therapy Program 2010 Plan Year

BCBSM – Medicare Part D, PPO 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). 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)	Coverage is provided for the diagnosis of rheumatoid arthritis <u>AND</u> patient has tried and failed Enbrel <u>OR</u> Humira. All FDA- approved indications not otherwise excluded for Part D. Prescriber restrictions: must be a rheumatologist. Age restrictions = patients 18 years of age or older. Exclusion criteria = None Coverage duration = Lifetime.
Adcirca [™] (tadalafil)	Diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for tadalafil (Adcirca [™]) in combination with bosentan (Tracleer [®]), epoprostenol (Flolan [®]), treprostinil (Remodulin [®]) or iloprost (Ventavis [®]) is provided after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient's symptoms. All FDA-approved indications not otherwise excluded for Part D. Exclusion criteria = coverage is not provided for tadalafil (Adcirca [™]) in situations where patients are receiving Nitrate therapy .

(g) = generic available

MEDICATION/ DRUG CLASS	CRITERIA
	Coverage duration = Lifetime.
Advicor [®] (lovastatin/extended release niacin)	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.
Afinitor [®] (everolimus)	Initial requests require a diagnosis of Advanced Renal Cell Carcinoma <u>AND</u> the prescribing physician is an Oncologist <u>AND</u> documented failure of treatment, described as disease progression, with the use of Nexavar [®] OR Sutent [®] . Maximum dose = 20mg. Renewal of therapy is provided in patients who meet all of the following criteria: Confirmation that current medical necessity criteria are met <u>AND</u> the medication is effective. All FDA approved indications not otherwise excluded for Part D. Exclusion criteria: will not be covered in combination with Nexavar [®] or Sutent [®] and for unapproved or investigational indications. Initial and Renewal coverage duration = 12 months..
Alpha-1 Proteinase Inhibitors Aralast NP [®] Glassia [®] Prolastin [®] Zemaira [®]	Initial 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 are less than 80mg/dl and must have deteriorating pulmonary function, as demonstrated by a decline in the FEV1 (less than 65% of the predictive value). Renewal of therapy is provided in patients who demonstrate serum levels of alpha-1 antitrypsin above threshold of 80mg/dl. All FDA approved indications not otherwise excluded for Part D. Age restrictions = patients 18 years of age or older. Coverage duration = initial request approve for six months; renewal of therapy approve for one year.
Amitiza [®] (lubiprostone)	Following criteria are used in reviewing Amitiza: patient must be diagnosed with Chronic Idiopathic Constipation or Constipation-Irritable Bowel Syndrome <u>AND</u> documented failure within the last 12 months using lactulose. All FDA-approved indications not otherwise excluded for Part D. 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.

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	<p>Documentation of a 25 foot timed walk test must be provided. Renewal of therapy requires documentation of improvement in walking distance of a 25 foot timed walk test compared to pretreatment.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Prescriber restrictions = Prescribing physician is a neurologist.</p> <p>Exclusion criteria = Coverage will not be provided in the following situations, 1) Patients with a history of seizure 2) Moderate to severe renal impairment defined by a (creatinine clearance) CrCl of 50ml/min or less.</p> <p>Coverage duration = initial request approve for three months; renewal of therapy approve for one year.</p>
<p>Angiotensin II Receptor Blockers (ARBs): Avapro[®](irbesartan)/Avalide[®], Atacand[®](candesartan)/HCT, Diovan[®](valsartan)/HCT, Micardis[®](telmisartan)/HCT, Teveten[®](eprosartan)/HCT</p>	<p>Requires documentation that member has experienced failure of or intolerance to an ACE-Inhibitor such as Accupril[®] (g), Capoten[®] (g), Prinivil[®]/Zestril[®] (g), Vasotec[®] (g), etc.</p>
<p>Arcalyst[™] (rilonacept)</p>	<p>Requires diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). All FDA-approved indications not otherwise excluded for Part D.</p> <p>Age restrictions = patients 12 years of age and older.</p> <p>Coverage duration = 1 year.</p>
<p>Arzerra[™] (ofatumumab)</p>	<p>Requires diagnosis of Chronic Lymphocytic Leukemia (CLL) in patients who are refractory to fludarabine and alemtuzumab therapy. Must be prescribed by an Oncologist.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = 1 year.</p>
<p>Beriner[®] C1 inhibitor, human</p>	<p>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 inh (antigenic) level less than 150 mg, iii.) C1inhf (functional) level less than or equal to 84 percent.</p> <p>Age restrictions = At least 13 years of age</p> <p>All FDA-approved indications not otherwise excluded for Part D</p> <p>Coverage duration = 10 days</p>

MEDICATION/ DRUG CLASS	CRITERIA
Bisphosphonates 1: Actonel [®] (risedronate) Actonel [®] with calcium (risedronate)	Actonel [®] requires trial and failure of or intolerance to Fosamax [®] (g). Coverage duration = Lifetime.
Bisphosphonates 2: Boniva [®] (ibandronate)	Boniva [®] requires trial and failure of or intolerance to Fosamax [®] (g) <u>AND</u> Actonel [®] . Coverage duration = Lifetime.
Byetta[®] (exenatide)	Approved as adjunctive therapy to improve glycemic control in patients who have a diagnosis of type II diabetes mellitus <u>AND</u> are currently taking metformin, a sulfonylurea, a thiazolidinedione, or a combination of metformin and a sulfonylurea or a combination of metformin and a thiazolidinedione <u>AND</u> documentation of HbA1c greater than 7%. All FDA-approved indications not otherwise excluded for Part D. Exclusion criteria = will not be covered for weight loss in patients with or without diabetes. Coverage duration = Lifetime.
Bystolic[®] (nebivolol)	Requires documentation that member has tried and failed or is intolerant to at least 2 of the formulary cardioselective beta blockers. Coverage duration = Lifetime.
Campral[®] (acamprosate calcium)	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 12-step facilitation, social skills training or a cognitive-behavioral therapy program. All FDA-approved indications not otherwise excluded for Part D. 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. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 1 month.
Chenodal[™] (chenodiol)	Requires the diagnosis of the FDA indicated use (gallstones) <u>AND</u> the trial and failure or intolerance of ursodiol <u>AND</u> the patient is not a candidate for surgery. Exclusion criteria = History of hepatocellular disease. Women who are or may become pregnant.

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	All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 2 years
Cholesterol-Lowering Therapies 1: Crestor® (rosuvastatin)	Crestor® 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). Coverage duration = Lifetime.
Cholesterol-Lowering Therapies 2: Zetia® (ezetimibe)	Zetia® requires documentation that member has trial and failure, intolerance, contraindication, or adverse reaction to Mevacor® (g), Pravachol® (g) or Zocor® (g); <u>OR</u> member is currently on statin therapy and unable to reach therapeutic target after trial at maximum tolerated dose (minimum 40mg of generic statin). Coverage duration = 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®. Coverage duration = Lifetime.
Cimzia® (certolizumab pegol)	Coverage will be provided for the treatment 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 or contraindicated or patient has been unable to taper or patient is experiencing breakthrough disease while stabilized on an immunomodulatory medication for at least two months <u>AND</u> 2) patient has previous trial/failure or contraindication to Remicade or Humira. Coverage will be provided for the treatment of rheumatoid arthritis when the following criteria are met: 1) Treatment failure or documented intolerance to adalimumab (Humira) <u>AND</u> etanercept (Enbrel). All FDA-approved indications not otherwise excluded for part D. Age restrictions = patients 18 years of age or older. Coverage duration = 1 year
Cinryze® (C1-inhibitor (human))	Initial requests require a diagnosis of Hereditary angioedema (HAE) established by an Immunologist or Hematologist and history of at least 2 HAE attacks per month. 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.) C1 inhF (functional) level less than or equal to 84 percent. Requires documentation if being used for short-term prophylaxis (i.e. patients scheduled to undergo dental work, invasive medical procedures, and surgical

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	<p>procedures): I.) History of attacks involving swelling of the face and airway or II.) Inadequate response or has a contraindication or intolerance to antifibrinolytic agents (epsilon aminocaproic acid, EACA) or attenuated androgens (i.e. danazol, stanozolol, and oxandrolone) or long term prophylaxis I.) Inadequate response or has a contraindication or intolerance to antifibrinolytic agents (epsilon aminocaproic acid, EACA) or attenuated androgens (i.e. danazol, stanozolol and oxandrolone) Renewal of therapy is provided in patients who meet all of the following criteria: objective data documenting at least 50% or greater in reduction of HAE attacks and/or severity (i.e., duration of attack, days of swelling) <u>AND</u> dose is ≤ 1000 units every 3-4 days. All FDA-approved indications not otherwise excluded for Part D. Age restrictions = patients ≥ 9 years of age. Coverage duration = initial request approve for one month; renewal of therapy approve for one month.</p>
<p>Cymbalta® (duloxetine)</p>	<p>Approved for treatment of <u>major depression</u> after trial and failure with two formulary antidepressants including a generic SSRI/SNRI OR <u>for generalized anxiety disorder</u> after trial and failure with two formulary anxiolytics or antidepressants OR <u>for fibromyalgia</u> characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance OR for <u>diabetic peripheral neuropathy</u>. All FDA-approved indications not otherwise excluded for Part D. Coverage duration is lifetime.</p>
<p>Durable Medical Equipment (DME) Supply Drugs <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. Coverage duration = lifetime.</p>
<p>Exforge HCT® (amlodipine/valsartan/hydrochlorothiazide)</p>	<p>Requires documentation that the patient has experienced treatment success for at least 3 months with Exforge®. Coverage duration = Lifetime.</p>
<p>Exalgo® (hydromorphone ER)</p>	<p>Coverage for Exalgo is provided when documentation is provided that the use is for moderate to severe pain in opioid tolerant patients requiring continuous around the clock opioid analgesia for an extended period of time. All FDA-approved indications not otherwise excluded for Part D. Exclusion Criteria = Coverage is not provided for the treatment of acute pain or for opioid naïve patients. Coverage duration = 1 year.</p>

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Fibricor[®] (fenofibric acid)	Requires documentation of trial and failure to gemfibrozil (g) and fenofibrate (g). Coverage duration = Lifetime
Flector[®] (diclofenac)	Requires the diagnosis of treatment in acute pain due to minor strains, sprains and contusions. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 1 month
Forteo[®] (teriparatide, rDNA origin)	Requires diagnosis of treatment of postmenopausal women with osteoporosis or men with primary or hypogonadal osteoporosis who are at high risk for fracture, <u>AND</u> 1) have tried and failed a bisphosphonate for 12 month period or have a documented intolerance, <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). All FDA-approved indications not otherwise excluded for Part D. Coverage duration = Two years
Growth Hormone (somatropin), Genotropin [®] , Humatrope [®] , Norditropin [®] , Norditropin Nordiflex [®] , Nutropin [®] (all), Omnitrope [®] , Saizen [®] , Serostim [®] , Tev-Tropin [®] , Zorbtive [™]	INITIAL requests for human growth hormone in pediatric patients: 1. For all indications, growth hormone must be prescribed by a pediatric endocrinologist, or pediatric nephrologist. <u>AND</u> 2. One of the following indications: Growth Hormone Deficiency (GHD), Prader-Willi Syndrome (PWS), Turner's Syndrome, Chronic Renal Insufficiency (CRI). <u>AND</u> 3. Initiating therapy in <u>children</u> (male less than 16, female less than 15): Initial height measurements less than 5 th percentile for age (based on initial evaluation), abnormal growth velocity for at least 6 months, initial subnormal growth hormone test. RENEWING treatment in <u>children</u> 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. 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 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. <u>AND</u> 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. <u>OR</u>

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	<p>b. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement <u>AND</u> an IGF-1 level below 80 ng/ml.</p> <p>2. Coverage for Serostim[®] for the treatment of AIDS-related cachexia. As new FDA approved indications become available plan will consider coverage accordingly.</p> <p>Age restrictions = pediatric male patients less than 16; pediatric female patients less than 15. Prescriber restrictions = pediatric patients requires for all indications must be prescribed by a pediatric endocrinologist or pediatric nephrologist.</p> <p>Coverage duration = pediatrics-one year; adults-lifetime.</p>
<p>Hepatitis Vaccine Comvax[®], Engerix-B[®], Recombivax HB[®], Pediarix[®], Twinrix[®]</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>Coverage duration = 1 year</p>
<p>HP Acthar Gel[®] (repository corticotropin)</p>	<p>Requires documentation of indication for use (is it being used for a diagnostic test or a specific medical condition). Documentation of FDA approved use in medical condition along with the documentation of response to corticosteroid therapy (which is considered to be treatment of choice).</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration for diagnostic testing = 1 month Coverage duration for FDA approved indications = 6 months</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>Coverage duration = Lifetime.</p>
<p>Ilaris[®] (canakinumab)</p>	<p>Requires diagnosis of cryopyrin-associated periodic syndromes (CAPS) including familial cold auto-inflammatory syndrome (FCAS) and Muckle–Wells syndrome (MWS) <u>AND</u> a patient age of 4 years or older. As new FDA approved indications become available plan will consider coverage accordingly.</p> <p>Coverage duration = 1 Year</p>
<p>Increlex[®] (mecasermin)</p>	<p>For all indications, Increlex[®] must be prescribed by a pediatric endocrinologist and requires the diagnosis of one of the following: severe <u>primary igf-1 deficiency</u> or <u>growth hormone gene deletion</u> or <u>genetic mutation of growth hormone receptor</u> (i.e. laron syndrome) and all of the following must be met: 1) current height measurement at less than the 3rd percentile for age and sex, and 2) igf-1 level greater than or equal to 3 standard deviations below normal (based on lab reference range for age</p>

MEDICATION/ DRUG CLASS	CRITERIA
	<p>and sex), and 3) normal or elevated growth hormone levels based on lab reference range for age and sex following at least one growth hormone stimulation test (insulin tolerance test, arginine or GHRH), and 4) open growth plates. Exclusion Criteria: Growth velocity is less than 2.5 cm/year or bone age in males exceeds 16 0/12 years of age or bone age in females exceeds 14 0/12 years of age. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 1 Year</p>
<p>Inhaled Nasal Steroids 1: Nasocort AQ[®] (triamcinolone)</p>	<p>Nasocort AQ[®] requires trial and failure of or intolerance to Flonase[®] (g), Nasalide[®] (g) OR Nasarel[®] (g). Coverage duration = Lifetime</p>
<p>Inhaled Nasal Steroids 2: Beconase AQ[®] (beclomethasone), Nasonex[®] (mometasone), Omnaris[®] (ciclesonide), Rhinocort Aqua[®] (budesonide), Veramyst[®] (fluticasone)</p>	<p>Beconase AQ[®], Nasonex[®], Omnaris[®], Rhinocort Aqua[®] and Veramyst[®] require trial and failure of or intolerance to Flonase[®] (g) or Nasalide[®] (g) / Nasarel[®] (g) <u>AND</u> Nasacort AQ[®]. Coverage duration = Lifetime</p>
<p>Innohep[®] (tinzaparin)</p>	<p>Requires diagnosis for treatment of acute symptomatic DVT, with or without pulmonary embolism (PE), when administered in conjunction with warfarin. Exclusion criteria: documentation of history of heparin- induced thrombocytopenia. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 1 month</p>
<p>Intravenous Immune Globulin (IVIG) <i>Various products</i></p>	<p>Approved under Medicare Part B if given for Primary Immune Deficiency disease. Approved under Medicare Part D for documentation of Inflammatory Demyelinating Polyneuropathy (acute or chronic), chronic ITP and Kawasaki syndrome. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = Lifetime</p>
<p>Janumet[®] (sitagliptin/metformin)</p>	<p>Requires documentation that the patient has experienced treatment success for at least 3 months with Januvia[®] (sitagliptin) <u>AND</u> Glucophage[®] (metformin) as individual agents when taken concurrently as evidenced by improvement in HbA1c and lack of adverse effects. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = lifetime.</p>
<p>Jevtana[®] (cabazitaxel)</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>

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	<p>Coverage is provided under Medicare Part D for the treatment of patients, in combination with prednisone, with hormone-refractory metastatic prostate cancer previously treated with a docetaxel- containing treatment regimen. Documentation of diagnosis is required.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>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.</p> <p>Age restriction = patients 16 years and older</p> <p>All FDA approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = 10 days</p>
<p>Letairis[®] (ambrisentan)</p>	<p>Diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class II or III symptoms.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = Lifetime.</p>
<p>Lotronex[®] (alosetron hydrochloride)</p>	<p>Requires diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS), and unresponsive to a trial of conventional IBS therapy such as Levsin[®] or Bentyl[®].</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Age restriction = Greater than or equal to 18 years of age.</p> <p>Coverage duration = 1 year</p>
<p>Lyrica[®] (pregabalin)</p>	<p>Approved for treatment of seizures/epilepsy OR neuropathic pain associated with diabetic peripheral neuropathy OR fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance OR neuropathic pain associated post-herpetic neuralgia after a 30 day trial of gabapentin. <u>Off-label uses:</u> trigeminal neuralgia - regardless of age, patient must try/fail formulary preferred agents carbamazepine and gabapentin. Chemotherapy induced peripheral neuropathy - regardless of age, patient must try/fail formulary preferred agent gabapentin.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = Lifetime or one year</p>
<p>Miscellaneous Vaccine: BCG Live Vaccine, Hepatitis A Vaccine, Measles</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</p>

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Virus Vaccine, Rabies Vaccine, Tetanus Toxoid Vaccine <i>Various products</i>	Approved under Medicare Part D for prophylactic use. Coverage duration = 1 year
Mozobil® (plerixafor)	Requires documentation that being used 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) after the patient has received G-CSF (10 mcg/kg) once daily in the morning for 4 days. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 1 month.
Non-Sedating Antihistamines 2 (NSA's): Xyzal® (levocetirizine), Clarinex (desloratadine)/D® (12hr and 24hr)	Requires step therapy with OTC loratadine or loratadine-D <u>OR</u> cetirizine or cetirizine-D <u>AND</u> Allegra® (fexofenadine). Coverage duration = Lifetime.
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. All FDA-approved indications not otherwise excluded for Part D. Age restrictions = patients 18 years of age or older. Coverage duration = 3 months.
Oleptro® (trazodone ER)	Coverage is provided for the treatment of major depressive disorder and requires the trial and failure of immediate release trazadone and documentation that the continued use of immediate release trazodone will adversely affect the member's health. All FDA-approved indications not otherwise excluded for Part D. 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 = One 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.

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	Coverage duration = Lifetime.
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.
Prandimet[®] (repaglinide/metformin)	Prandimet requires documentation that the patient has experienced treatment success (documented improvement in HbA1c and lack of adverse events) for at least 3 months with metformin and Prandin as individual agents when taken concurrently or documentation that supports use of individual agents may cause harm to patient. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = Lifetime.
Prolia[®] (denosumab)	Requires diagnosis of postmenopausal osteoporosis, for those who have a high risk for fracture. Requires a 12 month trial and failure, or have a documented intolerance, to a bisphosphonate. All FDA-approved indications not otherwise excluded for Part D. Exclusion criteria = Coverage is not provided for patients with hypocalcemia. Coverage duration = Lifetime.
Promacta[®] (eltrombopag)	Patient 18 years of age or older, requires a diagnosis of chronic immune thrombocytopenia (ITP) and persistent thrombocytopenia. Documentation of a current platelet count less than 50,000mcl. 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. Renewal of therapy is provided in patients who meet all of the following criteria: recent platelet count between 30,000 - 150,000 mcl and dose is less than or equal to 75 mg/day. All FDA-approved indications not otherwise excluded for Part D. Age restrictions = patients 18 years of age or older. Coverage duration = initial request approve for 3 months; renewal of therapy approve for 12 months.
Proton Pump Inhibitors (PPI's): Aciphex [®] (rabeprazole)	Requires trail and failure of or intolerance to 2 of the following formulary preferred alternatives; Prilosec OTC or Prilosec [®] (g) <u>AND</u> Prevacid [®] OR Protonix [®] . Coverage duration = Lifetime.
Erythropoiesis Stimulating Agents Epogen [®] , Procrit [®] , Aranesp [®]	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

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MEDICATION/ DRUG CLASS	CRITERIA
	<p>of the drug to make the determination Approved for use in the following conditions with a hemoglobin <u>less than 12mg/dl</u>: anemia of chronic renal disease (not yet on dialysis) OR anemia secondary to active chemotherapy of solid tumors OR anemia secondary to active zidovudine (AZT) therapy OR anemia in myelodysplastic disorders. Approved for a hemoglobin <u>less than 13</u> when used for prophylactic use during some major surgeries. <u>Coverage is not provided in the following conditions:</u> 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), or erythroid cancers, c. Anemia due to cancer treatment in patients with uncontrolled hypertension, d. Anemia not associated with cancer treatment or renal disease under inclusion criteria, e. Anemia associated only with radiotherapy, f. Prophylactic use to prevent chemotherapy induced anemia, g. Prophylactic use to reduce tumor hypoxia, and h. Patients with erythropoietin type resistance due to neutralizing antibodies. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 3 months.</p>
<p>Relistor[®] (methylnaltrexone)</p>	<p>Requires a diagnosis of Opioid Induced Constipation in members, 18 years or older, 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. All FDA-approved indications not otherwise excluded for Part D. Exclusion criteria = Patient's with known or suspected mechanical gastrointestinal obstruction. Age restrictions = patients 18 years of age or older. Coverage duration = 3 months.</p>
<p>Revatio[®] injectable (sildenafil citrate)</p>	<p>Revatio injection is for the continued treatment of patients with Pulmonary Arterial Hypertension (PAH) who are currently prescribed Revatio[®] tablets but who are temporarily unable to take oral medication. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 3 months</p>
<p>Revatio[®] oral (sildenafil citrate)</p>	<p>Diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for sildenafil (Revatio[®]), if used in combination with bosentan (Tracleer[®]), epoprostenol (Flolan[®]), treprostinil (Remodulin[®]) or iloprost (Ventavis[®]), is provided after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient's</p>

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	<p>symptoms. As new FDA approved indications become available plan will consider coverage accordingly. Exclusion criteria = coverage is not provided for sildenafil (Revatio®) in situations where patients are receiving Nitrate therapy. Coverage duration = Lifetime.</p>
<p>Sancuso® (granisetron)</p>	<p>Approved for use in the prevention and/or treatment of nausea/vomiting associated with chemotherapy and/or radiation therapy. Requires treatment failure with generic ondansetron and generic granisetron. Patient must not be a candidate for IV granisetron. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 3 months.</p>
<p>Sandostatin® (G) (octreotide acetate)</p>	<p>Requires diagnosis of acromegaly in patients who have failed or are not candidates for surgery or radiation, <u>OR</u> in patients with diagnosis of metastatic carcinoid tumors to control the associated severe diarrhea and flushing, <u>OR</u> in patients with diagnosis of vasoactive intestinal peptide tumors (VIPomas) to control the associated profuse watery diarrhea. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = One year</p>
<p>Sandostatin® LAR Depot (octreotide acetate LAR)</p>	<p>Requires diagnosis of acromegaly in patients who have failed or are not candidates for surgery or radiation and responded to and tolerated immediate release octreotide injection, <u>OR</u> in patients with diagnosis of metastatic carcinoid tumors to control the associated severe diarrhea and flushing and responded to and tolerated immediate release octreotide injection, <u>OR</u> in patients with diagnosis of vasoactive intestinal peptide tumors (VIPomas) to control the associated profuse watery diarrhea and responded to and tolerated immediate release octreotide injection. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = 1 year</p>
<p>Savella® (milnacipran)</p>	<p>Diagnosis of fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance. All FDA-approved indications not otherwise excluded for Part D. Coverage duration = requested duration or lifetime.</p>
<p>Sedative Hypnotics: Rozerem® (ramelteon)</p>	<p>Rozerem® requires trial and failure of or intolerance to Ambien® (g) <u>OR</u> Sonata®. Coverage duration = Lifetime.</p>

(g) = generic available

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Select Cholesterol Combination Products: Simcor [®] (simvastatin + niacin extended release)	Requires documentation that the member has had at least 1 month of treatment with simvastatin <i>or</i> Vytorin [®] and niacin extended release <i>or</i> Advicor [®] , as individual agents when used concomitantly. Coverage duration = Lifetime.
Selective Reuptake Inhibitor – antidepressants (SRI 1): Lexapro [®]	Lexapro [®] require 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), Venlafaxine OSM [®] , Wellbutrin/SR/XL [®] (g), or Zoloft [®] (g). Coverage duration = Lifetime.
Selective Reuptake Inhibitor – antidepressants (SRI 2): Pristiq [®] (desvenlafaxine)	Requires prior authorization/step therapy with at least two formulary agents. Coverage duration = Lifetime.
Selective Reuptake Inhibitor – antidepressants (SRI 3): Aplenzin [®] (bupropion), Luvox CR [®] (fluvoxamine), Pexeva [®] (paroxetine)	<u>Aplenzin[®]</u> requires prior authorization/step therapy with at least two formulary antidepressant agents plus documentation that continued use of Wellbutrin (g) will adversely affect the member's health. <u>Luvox CR[®]</u> requires prior authorization/step therapy with at least two formulary antidepressant agents plus documentation that continued use of Luvox (g) will adversely affect the member's health. <u>Pexeva[®]</u> requires prior authorization/step therapy with at least two formulary antidepressant agents plus documentation that continued use of Paxil (g) will adversely affect the member's health.
ST B VS D Methotrexate: Rheumatrex [®] (oral), Trexall [®] (oral)	If a member had a transplant covered by Medicare, in many cases, methotrexate coverage will now be available under Medicare Part B. Coverage is available under Medicare Part D for members with a prior claim for a rheumatoid arthritis drug. Coverage duration = Lifetime.
Strattera[®] (atomoxetine)	<u>For members age 5-21:</u> Requires documentation that member has experienced failure of or intolerance to <u>BOTH</u> a methylphenidate product (such as Concerta [®] or Ritalin [®] (g) <u>AND</u> an amphetamine (such as Adderall [®] (g)). <u>For members age >21:</u> Requires documentation that the member has experienced failure of or intolerance to <u>EITHER</u> a methylphenidate product <u>OR</u> an amphetamine. Approvable when stimulants are contraindicated by medical history. Age restrictions = 5 -21 years old and greater than 21 years old. Coverage duration = Lifetime.
Stelara[®] (Ustekinumab)	Coverage is provided for the diagnosis of moderate to severe plaque psoriasis AND the member has tried and failed PUVA and Enbrel [®] or Humira [®] . All FDA-approved indications not otherwise excluded for Part D.

(g) = generic available

MEDICATION/ DRUG CLASS	CRITERIA
	<p>Prescriber restrictions: requires therapy is being supervised by Dermatologist. Age restrictions = 18 years of age or older Coverage duration = Lifetime.</p>
<p>Sumavel™ DosePro™ (sumatriptan)</p>	<p>Requires the trial and failure of injectable sumatriptan and oral Maxalt -MLT®. Coverage duration is lifetime.</p>
<p>Tekturna® (aliskiren): Tekturna®, Tekturna HCT®</p>	<p>Requires documentation that member has experienced therapeutic failure at standard effective doses or intolerance to an ACE inhibitor <u>AND</u> documentation of therapeutic failure at standard effective doses or intolerance to an ARB.</p>
<p>Thiazolidinediones (TZDS) combo: Avandamet® (rosiglitazone/metformin) ActoPlus Met® (pioglitazone/metformin) Avandaryl® (rosiglitazone/glimepiride) Duetact® (pioglitazone/glimepiride)</p>	<p><u>Avandamet®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with metformin <u>AND</u> Avandia® as individual agents when taken concurrently. <u>ActoPlus Met®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with metformin <u>AND</u> Actos® as individual agents when taken concurrently. <u>Avandaryl®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with Avandia® <u>AND</u> glimepiride as individual agents when taken concurrently. <u>Duetact®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with Actos® <u>AND</u> glimepiride as individual agents when taken concurrently. All FDA-approved indications not otherwise excluded for Part D. Required medical information = documented improvement in HbA1c and lack of adverse events. Coverage duration = Lifetime.</p>
<p>TNF-alpha agents: Enbrel® (etanercept) Humira® (adalimumab) Kineret® (anakinra)</p>	<p>1. <u>Following criteria are used in reviewing Enbrel®</u>: Diagnosis of psoriatic arthritis. 2. Diagnosis of rheumatoid arthritis or juvenile arthritis which requires a three month trial on two concurrent nonbiologic disease modifying anti-rheumatic drugs (DMARDS), one of which must be methotrexate unless contraindicated. 3. For diagnosis of plaque psoriasis, a minimum of 3 months of previous treatment with a topical steroid and 3 months treatment with PUVA (unless PUVA contraindicated). 4. For diagnosis of ankylosing spondylitis. 2. <u>The following criteria are used in reviewing Humira®</u>: 1. For diagnosis of psoriatic arthritis 2) For diagnosis of rheumatoid arthritis or juvenile arthritis requires a three month trial on two concurrent nonbiologic disease modifying anti-rheumatic drugs (DMARDS), one of which must be methotrexate unless contraindicated. 2. For</p>

MEDICATION/ DRUG CLASS	CRITERIA
	<p>diagnosis of moderately to severely active Crohn's disease for patients age 18 years or older, with a history of inadequate response to Entocort EC[®]. 3. For diagnosis of ankylosing spondylitis. 4. For diagnosis of plaque psoriasis, a minimum of 3 months of previous treatment with a topical steroid and 3 months treatment with PUVA (unless PUVA contraindicated).</p> <p>3. <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>Prescriber restrictions: For ankylosing spondylitis, requires therapy is being supervised by Rheumatologist. For moderate to severe psoriasis, requires therapy is being supervised by Dermatologist.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = Lifetime.</p>
<p>Tracleer[®] (bosentan)</p>	<p>Diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO class II to IV symptoms.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = Lifetime.</p>
<p>Treximet[®] (Sumatriptan/naproxen sodium)</p>	<p>Requires trial and failure of naproxen <u>and</u> Maxalt[®] or sumatriptan and documentation as to why use of the individual agents (naproxen and sumatriptan) is harmful to the patient.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = Lifetime.</p>
<p>Trilipix[®] (fenofibric acid)</p>	<p>Requires documentation of trial and failure to gemfibrozil (g) <u>and</u> fenofibrate (g).</p>
<p>Triptans 1 (Maxalt[®], Maxalt MLT[®])</p>	<p>Requires trial and failure with sumatriptan.</p> <p>Coverage duration = Lifetime.</p>
<p>Triptans 2 (Amerge[®], Axert[®], Frova[®], Relpax[®], Zomig[®], Zomig ZMT[®])</p>	<p>Requires trial and failure with sumatriptan and Maxalt[®].</p> <p>Coverage duration = Lifetime.</p>
<p>Uloric[®] (febuxostat)</p>	<p>Requires treatment failure, intolerance or contraindication with allopurinol.</p> <p>Coverage duration = Lifetime.</p>
<p>Victoza[®] (liraglutide)</p>	<p>Approved 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</p>

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	<p>metformin and a sulfonylurea or a combination of metformin and a thiazolidinedione. Documentation is required of HbA1c greater than 7%. All FDA-approved indications not otherwise excluded for Part D.</p> <p>Exclusion Criteria = 1) Coverage is not provided for weight loss in patients with or without diabetes. 2) Will not be covered as concurrent therapy with insulin.</p> <p>Coverage duration = Lifetime.</p>
<p>Vytorin[®] (simvastatin/ezetimibe)</p>	<p>Requires documentation that the patient has had at least 1 month of treatment with Zocor[®] (g) or Simcor,[®] and Zetia[®], as individual agents when used concomitantly and has had trial and failure of Crestor.[®]</p> <p>Coverage duration = Lifetime.</p>
<p>Vyvanse[®] (lisdexamfetamine)</p>	<p>ADHD in patients 6 years of age and older who have had treatment failure with both an amphetamine and methylphenidate product. Maximum dose shall be 70mg/day. All FDA-approved indications not otherwise excluded for Part D.</p> <p>Exclusion criteria = contraindications to amphetamine shall be considered contraindications to lisdexamfetamine.</p> <p>Age restrictions = patients 6 years of age and older.</p> <p>Coverage duration = 1 year.</p>
<p>Xenazine[®] (tetrabenazine)</p>	<p>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. All FDA-approved indications not otherwise excluded for Part D.</p> <p>Exclusion criteria = 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, 5) Treatment of Tourette's.</p> <p>Coverage duration = 1 year.</p>
<p>Xiaflex[®] (collagenase clostridium histolyticum)</p>	<p>Coverage is provided for the treatment of adult patients with Dupuytren's contracture with a palpable cord. All FDA-approved indications not otherwise excluded for Part D.</p> <p>Prescriber Restrictions = Physician must have completed the Xiaflex Xperience™ training and their facility is currently enrolled as a healthcare site to receive Xiaflex orders.</p> <p>Age restrictions = 18 years and older</p> <p>Coverage duration = 1 month</p>