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## Blue Cross Blue Shield of Michigan - Medicare Part D Prior Authorization / Step Therapy Program January 1, 2009

BCBSM – Medicare Part D 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
<b>Adcirca</b> <sup>TM</sup> (tadalafil)	Diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for tadalafil (Adcirca <sup>TM</sup> ) <b>in combination</b> with bosentan (Tracleer <sup>®</sup> ), epoprostenol (Flolan <sup>®</sup> ), treprostinil (Remodulin <sup>®</sup> ) or iloprost (Ventavis <sup>®</sup> ) <b>is provided</b> after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient's symptoms. As new FDA approved indications become available plan will consider coverage accordingly. Exclusion criteria = coverage is <b>not provided</b> for tadalafil (Adcirca <sup>TM</sup> ) in situations where patients are receiving <b>Nitrate therapy</b> . Coverage duration = lifetime.
<b>Afinitor</b> <sup>®</sup> (everolimus)	<b>Initial</b> requests require a diagnosis of Advanced Renal Cell Carcinoma, AND the prescribing physician is an Oncologist, AND documented failure of treatment, described as disease progression, with the use of Nexavar <sup>®</sup> OR Sutent <sup>®</sup> . Maximum dose = 20mg. All FDA approved indications not otherwise excluded for Part D. <b>Renewal</b> 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. Exclusion criteria: will not be covered in combination with Nexavar <sup>®</sup> or Sutent <sup>®</sup> and for unapproved or investigational indications.

MEDICATION/ DRUG CLASS	CRITERIA
	Initial and Renewal coverage duration: 12 months.
<b>Amitiza</b> <sup>®</sup> (lubiprostone)	Following criteria are used in reviewing Amitiza: patient must be age 18 or older, AND diagnosed with Chronic Idiopathic Constipation or Constipation-Irritable Bowel Syndrome AND 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.
<b>Angiotensin II Receptor Blockers (ARBs):</b> Avapro <sup>®</sup> (irbesartan)/Avalide <sup>®</sup> , Benicar <sup>®</sup> (olmesartan)/HCT, Cozaar <sup>®</sup> (losartan)/Hyzaar <sup>®</sup> Atacand <sup>®</sup> (candesartan)/HCT, Diovan <sup>®</sup> (valsartan)/HCT, Micardis <sup>®</sup> (telmisartan)/HCT, Teveten <sup>®</sup> (eprosartan)/HCT	Requires documentation that member has experienced failure of or intolerance to an ACE-Inhibitor such as Accupril <sup>®</sup> (g), Capoten <sup>®</sup> (g), Prinivil <sup>®</sup> /Zestril <sup>®</sup> (g), Vasotec <sup>®</sup> (g), etc.
<b>Bisphosphonates 1:</b> Actonel <sup>®</sup> (risedronate)	Actonel <sup>®</sup> requires trial and failure of or intolerance to Fosamax <sup>®</sup> (g).
<b>Bisphosphonates 2:</b> Boniva <sup>®</sup> (ibandronate)	Boniva <sup>®</sup> requires trial and failure of or intolerance to Fosamax <sup>®</sup> (g) <u>AND</u> Actonel <sup>®</sup> .
<b>Byetta</b> <sup>®</sup> (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%. Exclusion criteria = will not be covered for weight loss in patients with or without diabetes. Coverage duration = lifetime.
<b>Bystolic</b> <sup>®</sup> (nebivolol)	Requires documentation that member has tried and failed or is intolerant to at least 2 of the formulary cardioselective beta blockers.
<b>Campral</b> <sup>®</sup> (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 a 12-step facilitation, social skills training or a cognitive-behavioral therapy program. As new FDA approved indications become available plan

MEDICATION/ DRUG CLASS	CRITERIA
	will consider coverage accordingly. Coverage duration = one year.
<b>Cholesterol-Lowering Therapies 1:</b> Crestor® (rosuvastatin)	Crestor® requires documentation that member has experienced failure of or intolerance to at least <b>one</b> high dose (≥ 40mg) generic statin: Mevacor® (g), Pravachol® (g), Zocor® (g).
<b>Cholesterol-Lowering Therapies 2:</b> 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).
<b>Cholesterol-Lowering Therapies 3:</b> Advicor® (niacin/lovastatin), Altoprev® (lovastatin), Lipitor® (atorvastatin), Lescol/XL® (fluvastatin) Vytorin® (ezetimibe/simvastatin)	Requires documentation that member has experienced failure of or intolerance to at least <b>one</b> high dose (≥ 40mg) generic statin: (Mevacor® (g), Pravachol® (g) Zocor® (g)), <u>AND one</u> formulary brand agent (Crestor® or Zetia®).
<b>Cimzia®</b> (certolizumab pegol)	Coverage will be provided for the treatment of acute exacerbation of moderate to severe Crohn's disease when one 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. 2) Patient is experiencing breakthrough disease while stabilized on an immunomodulatory medication for at least two months and 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 with a 3 month trial with two concurrent DMARD's (one must be methotrexate unless contraindicated) <b>and</b> 2) Treatment failure or documented intolerance to infliximab (Remicade) <b>or</b> adalimumab (Humira) and 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
<b>Cinryze®</b> (C1-inhibitor (human))	<b>Initial</b> 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 procedures): I.) History of attacks involving swelling of the face and airway or II.) Inadequate response or has a contraindication or intolerance to

MEDICATION/ DRUG CLASS	CRITERIA
	<p>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). <b>Renewal</b> 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) <b>AND</b> dose is ≤ 1000 units every 3-4 days.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Age restriction = patients ≥ 9 years of age.</p> <p>Coverage duration = initial request approve for one month; renewal of therapy approve for one month.</p>
<p><b>COX-2 Preferential NSAIDs:</b> Celebrex<sup>®</sup> (celecoxib)</p>	<p>Requires age &gt; 60 <u>OR</u> trial and failure or intolerance to two NSAID's <u>OR</u> concomitant use of anticoagulants <u>OR</u> oral steroids <u>OR</u> risk of GI bleed (history of PUD, previous GI bleed, alcoholism).</p>
<p><b>Cymbalta<sup>®</sup></b> (duloxetine)</p>	<p>For treatment of major depression after trial and failure with two formulary antidepressants including a generic SSRI/SNRI. For generalized anxiety disorder after trial and failure with two formulary anxiolytics or antidepressants. For neuropathic pain associated with diabetic peripheral neuropathy after a 30 day treatment course with gabapentin. For 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.</p> <p>Coverage duration = requested duration or lifetime.</p>
<p><b>Durable Medical Equipment (DME) Supply Drugs</b> <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><b>Exforge HCT<sup>®</sup></b> (amlodipine/valsartan/hydrochlorothiazide)</p>	<p>Requires documentation that the patient has experienced treatment success for at least 3 months with Exforge<sup>®</sup>.</p> <p>Coverage duration = lifetime.</p>
<p><b>Edluar</b> (zolpidem)</p>	<p>Requires trial and failure, or intolerance, to Ambien<sup>®</sup> (g) <b>AND</b> Sonata<sup>®</sup> (g). Documentation that continued use of generic zolpidem will adversely affect the member's health. All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = lifetime.</p>

MEDICATION/ DRUG CLASS	CRITERIA
<b>Fibricor<sup>®</sup></b> (fenofibric acid)	Requires documentation of trial and failure to gemfibrozil (g) and fenofibrate (g). Coverage duration = lifetime
<b>Growth Hormone</b> (somatropin)  Genotropin <sup>®</sup> , Humatrope <sup>®</sup> , Norditropin <sup>®</sup> , Nutropin <sup>®</sup> (all), Saizen <sup>®</sup> , Serostim <sup>®</sup> , Tev-Tropin <sup>®</sup> , Zorbtive <sup>™</sup> ,	<p><b><u>INITIAL requests for human growth hormone in pediatric patients:</u></b> 1. For all indications, growth hormone must be prescribed by a pediatric endocrinologist, or pediatric nephrologist. <b><u>AND</u></b> 2. One of the following indications: Growth Hormone Deficiency (GHD), Prader-Willi Syndrome (PWS), Turner's Syndrome, Chronic Renal Insufficiency (CRI). <b><u>AND</u></b> 3. Initiating therapy in <u>children</u> (male less than 16, female less than 15): Initial height measurements less than 5<sup>th</sup> percentile for age (based on initial evaluation), abnormal growth velocity for at least 6 months, initial subnormal growth hormone test.</p> <p><b><u>RENEWING</u></b> 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.</p> <p><b><u>Requests in Adult patients:</u></b></p> <p>1. The diagnosis of growth hormone deficiency with hypopituitarism when one of the following criteria (a or b) are met:</p> <p>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:</p> <p>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. <b><u>AND</u></b></p> <p>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. <b><u>OR</u></b></p> <p>b. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement <b><u>AND</u></b> an IGF-1 level below 80 ng/ml.</p> <p>2. Coverage for <b>Serostim<sup>®</sup></b> for the treatment of AIDS-related cachexia.            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.            Coverage duration = pediatrics-one year; adults-lifetime.</p>
<b>Hepatitis Vaccine</b> Comvax <sup>®</sup> , Engerix-B <sup>®</sup> , Recombivax HB <sup>®</sup> , Pediarix <sup>®</sup> , Twinrix <sup>®</sup>	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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<b>Immunosuppressive Therapy for an Organ Transplant</b> <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.
<b>Inhaled Nasal Steroids 1:</b> Nasocort AQ <sup>®</sup> (triamcinolone)	Nasocort AQ <sup>®</sup> requires trial and failure of or intolerance to Flonase <sup>®</sup> (g), Nasalide <sup>®</sup> (g) <u>OR</u> Nasarel <sup>®</sup> (g).
<b>Inhaled Nasal Steroids 2:</b> Beconase AQ <sup>®</sup> (beclomethasone), Nasonex <sup>®</sup> (mometasone), Omnaris <sup>®</sup> (ciclesonide), Rhinocort Aqua <sup>®</sup> (budesonide), Veramyst <sup>®</sup> (fluticasone)	Beconase AQ <sup>®</sup> , Nasonex <sup>®</sup> , Omnaris <sup>®</sup> , Rhinocort Aqua <sup>®</sup> , Veramyst <sup>®</sup> requires trial and failure of or intolerance to Flonase <sup>®</sup> (g) or Nasalide <sup>®</sup> (g) / Nasarel <sup>®</sup> (g) <u>AND</u> Nasacort AQ <sup>®</sup> .
<b>Intravenous Immune Globulin (IVIG)</b> <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.
<b>Janumet<sup>®</sup></b> (sitagliptin/metformin)	Requires documentation that the patient has experienced treatment success for at least 3 months with Januvia <sup>®</sup> (sitagliptin) <u>AND</u> Glucophage <sup>®</sup> (metformin) as individual agents when taken concurrently as evidenced by improvement in HbA1c and lack of adverse effects. Coverage duration = lifetime.
<b>Januvia<sup>®</sup></b> (sitagliptin)	Approved in patients who have a diagnosis of type II diabetes mellitus <u>AND</u> documentation that patient has tried 2 of the 4 therapies recommended by the ADA/EASD consensus treatment guidelines. The therapeutic classes recommended include metformin, basal insulin, sulfonylurea and TZD's.
<b>Letairis<sup>®</sup></b> (ambrisentan)	Diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class II or III symptoms. As new FDA approved indications become available plan will consider coverage accordingly. Coverage duration = Lifetime.
<b>Lotronex<sup>®</sup></b> (alosetron hydrochloride)	Patient must be a female at least 18 years of age, and diagnosed with severe diarrhea-predominant Irritable Bowel Syndrome (IBS), and unresponsive to conventional IBS therapy, and patient-physician agreement for Lotronex and physician attestation of qualifications and acceptance of responsibilities signatures have been attained as recommended in product labeling. As new FDA approved indications become available plan will consider coverage accordingly. Age restrictions = greater than or equal to 18 years of age. Coverage duration = one year.
<b>Lyrica<sup>®</sup></b> (pregabalin)	Treatment of seizures/epilepsy. <u>OR</u> For neuropathic pain associated with diabetic peripheral neuropathy or post-herpetic

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	<p>neuralgia: (a) if patient equal to or greater than 65 years of age – after a 30-day trial of gabapentin or carbamazepine, OR (b) if patient less than 65 years of age – after a 30-day trial of gabapentin, or carbamazepine or a tricyclic antidepressant such as amitriptyline, desipramine or imipramine (note: 2 of the 3 options must be attempted – one must be gabapentin) <u>OR</u></p> <p>For fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance AND patient must try/fail gabapentin (doses greater than 1200mg) AND experience intolerance or inadequate pain relief to 3 of the following: tricyclic antidepressant, SSRI, SNRI, cyclobenzaprine, tramadol.</p> <p>Off-label uses: 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>As new FDA approved indications become available plan will consider coverage accordingly.</p> <p>Coverage duration = One year or lifetime.</p>
<p><b>Miscellaneous Vaccine: BCG Live Vaccine, Hepatitis A Vaccine, Measles Virus Vaccine, Rabies Vaccine, Tetanus Toxoid Vaccine</b> <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><b>Mozobil®</b> (plerixafor)</p>	<p>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.</p> <p>Coverage duration = one month.</p>
<p><b>Non-Sedating Antihistamines (NSA's):</b> Allegra (fexofenadine)/D<sup>®</sup>, Clarinet (desloratadine)/D<sup>®</sup></p>	<p>Requires failure of or intolerance to over-the-counter (OTC) loratadine or loratadine-D <u>OR</u> cetirizine or cetirizine-D.</p>
<p><b>Non-Sedating Antihistamines 2 (NSA's):</b> Xyzal<sup>®</sup> (levocetirizine)</p>	<p>Requires step therapy with OTC loratadine or loratadine-D <u>OR</u> cetirizine or cetirizine-D <u>AND</u> Allegra<sup>®</sup> (fexofenadine).</p>
<p><b>Nplate<sup>®</sup></b> (romiplostim)</p>	<p>Patient 18 years of age or older, requires a diagnosis of chronic immune thrombocytopenia (ITP) and persistent thrombocytopenia. Documentation of platelet</p>

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	<p>count less than 150,000mcL for greater than or equal to 2 months and a current platelet count less than 30,000mcL.            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.            All FDA-approved indications not otherwise excluded for Part D.            Age restrictions = patients 18 years of age or older.            Coverage duration = 3 months.</p>
<p><b>Oral Anti-emetics Agents</b>  <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><b>Oral Chemotherapeutic Agents</b>  <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><b>Parenteral Nutrition</b>  <i>(Numerous ingredients may be reflected in 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><b>Prandimet<sup>®</sup></b>            (repaglinide/metformin)</p>	<p>Prandimet requires documentation that the patient has experienced treatment succues (documented improvement in HbA1c and lack of adverse events) for at least 3 months with metformin and Prandin as individual agents when taken concurrently. All FDA-approved indications not otherwise excluded for Part D.            Coverage duration = lifetime.</p>
<p><b>Promacta<sup>®</sup></b>            (eltrombopag)</p>	<p>Patient 18 years of age or older, requires a diagnosis of chronic immune thrombocytopenia (ITP) and persistent thrombocytopenia. Documentation of platelet count less than 150,000mcL for greater than or equal to 2 months and a current platelet count less than 30,000mcL.            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.</p>

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<p><b>Proton Pump Inhibitors (PPI's):</b>            Aciphex<sup>®</sup> (rabeprazole),            Kapidex<sup>®</sup> (dexlansoprazole)            Nexium<sup>®</sup> (esomeprazole)</p>	<p>Requires trial and failure of or intolerance to 2 of the following formulary preferred alternatives; Prilosec OTC or Prilosec<sup>®</sup> (g) <u>AND</u> Prevacid<sup>®</sup> or Protonix<sup>®</sup>.</p>
<p><b>Recombinant Human Erythropoietin</b>            Epogen<sup>®</sup>, Procrit<sup>®</sup>, Aranesp<sup>®</sup></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. Approved for use in the following conditions with a hemoglobin less than 12mg/dl: anemia of chronic renal disease (not yet on dialysis), anemia secondary to active chemotherapy of solid tumors, anemia secondary to active zidovudine (AZT) therapy, anemia in myelodysplastic disorders and prophylactic use during some major surgeries. 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), 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.            Coverage duration = 3 months.</p>
<p><b>Relistor<sup>®</sup></b>            (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 has any contraindication to methylnaltrexone (this includes GI motility), patients who are not receiving palliative care, pediatric patients or co-morbid conditions that affect GI motility. Age restrictions = patients 18 years of age or older.            Coverage duration = 3 months.</p>
<p><b>Revatio<sup>®</sup></b>            (sildenafil citrate)</p>	<p>Diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for sildenafil (Revatio<sup>®</sup>) <b>in combination</b> with bosentan (Tracleer<sup>®</sup>), epoprostenol (Flolan<sup>®</sup>), treprostinil (Remodulin<sup>®</sup>) or iloprost (Ventavis<sup>®</sup>) <b>is provided</b> after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient's symptoms. As new FDA approved indications become available plan will consider coverage accordingly. Exclusion criteria = coverage is <b>not provided</b> for sildenafil (Revatio<sup>®</sup>) in situations where patients are receiving <b>Nitrate therapy</b>. Coverage duration = lifetime.</p>

MEDICATION/ DRUG CLASS	CRITERIA
<b>Sancuso<sup>®</sup></b> (granisetron)	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.
<b>Savella<sup>®</sup></b> (milnacipran)	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.
<b>Sedative Hypnotics:</b> Ambien CR <sup>®</sup> (zolpidem), Lunesta <sup>®</sup> (eszopiclone), Rozerem <sup>®</sup> (ramelteon)	Ambien CR <sup>®</sup> , Lunesta <sup>®</sup> , Rozerem <sup>®</sup> requires trial and failure of or intolerance to Ambien <sup>®</sup> (g) <u>OR</u> Sonata <sup>®</sup> .
<b>Select Cholesterol Combination Products:</b> Simcor <sup>®</sup> (simvastatin + niacin extended release)	Requires documentation that the member has had at least 3 months of treatment with simvastatin <u>AND</u> niacin extended release as individual agents when used concomitantly.
<b>Selective Reuptake Inhibitor – antidepressants (SRI 1):</b> Effexor XR <sup>®</sup> , Lexapro <sup>®</sup> , Venlafaxine OSM <sup>®</sup>	Effexor XR <sup>®</sup> , Lexapro <sup>®</sup> and Venlafaxine OSM <sup>®</sup> require step therapy with at least one of the following <b>generic</b> formulary alternatives; <i>Celexa<sup>®</sup> (g), Effexor<sup>®</sup> (g), Luvox<sup>®</sup> (g), Paxil<sup>®</sup>/CR (g), Prozac<sup>®</sup> (g), Remeron<sup>®</sup> (g), Wellbutrin/SR/XL<sup>®</sup> (g), or Zoloft<sup>®</sup> (g).</i>
<b>Selective Reuptake Inhibitor – antidepressants (SRI 2):</b> Luvox CR <sup>®</sup> (fluvoxamine), Pexeva <sup>®</sup> (paroxetine), Pristiq <sup>®</sup> (desvenlafaxine), Prozac Weekly <sup>®</sup> (fluoxetine)	<u>Luvox CR<sup>®</sup></u> ; Requires prior authorization/step therapy with at least two formulary agents PLUS documentation that continued use of Luvox (g) will adversely affect the member's health <u>Pexeva<sup>®</sup></u> ; Requires prior authorization/step therapy with at least two formulary agents PLUS documentation that continued use of Paxil (g) will adversely affect the member's health. <u>Pristiq<sup>®</sup></u> ; Requires prior authorization/step therapy with at least two formulary agents. <u>Prozac Weekly<sup>®</sup></u> ; Requires prior authorization/step therapy with at least two formulary agents PLUS documentation that continued use of Prozac (g) will adversely affect the member's health.
<b>ST B VS D Methotrexate:</b> Rheumatrex <sup>®</sup> (oral), Trexall <sup>®</sup> (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.
<b>Strattera<sup>®</sup></b> (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 <sup>®</sup> or Ritalin <sup>®</sup> (g)

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	<p><u>AND</u> an amphetamine (such as Adderall® (g)).  For members age &gt;21: 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.</p>
<b>Tektuna®</b> (aliskiren): Tektuna®, Tektuna HCT®	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.
<b>Thiazolidinediones (TZDS) combo:</b> Avandamet® (rosiglitazone/metformin) ActoPlus Met® (pioglitazone/metformin) Avandaryl® (rosiglitazone/glimepiride) Duetact® (pioglitazone/glimepiride)	<p><u>Avandamet®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with metformin AND Avandia® as individual agents when taken concurrently.</p> <p><u>ActoPlus Met®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with metformin AND Actos® as individual agents when taken concurrently.</p> <p><u>Avandaryl®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with Avandia® AND Amaryl® as individual agents when taken concurrently.</p> <p><u>Duetact®</u>: Requires documentation that the patient has experienced treatment success for at least 3 months with Actos® and Amaryl® as individual agents when taken concurrently.</p> <p>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>
<b>TNF-alpha agents:</b> Enbrel® (etanercept), Humira® (adalimumab) Kineret® (anakinra)	<p><u>Following criteria are used in reviewing Enbrel®:</u></p> <ol style="list-style-type: none"> <li>1. For <u>rheumatoid arthritis, juvenile RA or psoriatic arthritis</u>, Enbrel® requires a three month trial on two <b>concurrent</b> Disease Modifying Anti-Rheumatic Drugs (DMARDs), one of which must be methotrexate unless contraindicated.</li> <li>2. For <u>moderate to severe psoriasis</u>, a minimum of 3 months of previous treatment with a topical steroid AND 3 months treatment with PUVA (unless PUVA contraindicated).</li> <li>3. For <u>ankylosing spondylitis</u>, requires therapy is being supervised by a Rheumatologist.</li> </ol> <p><u>Following criteria are used in reviewing Humira®:</u></p> <ol style="list-style-type: none"> <li>1. For <u>rheumatoid arthritis, juvenile RA or psoriatic arthritis</u>, Humira® requires a three month trial on two <b>concurrent</b> Disease Modifying Anti-Rheumatic Drugs (DMARDs), one of which must be methotrexate unless contraindicated.</li> <li>2. For <u>Crohn's Disease</u>, for patients age 18 years or older, with a diagnosis of moderately to severely active Crohn's disease with a history of inadequate response to conventional therapy -- <b>Applies to Humira® only.</b></li> </ol>

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	<p>3. For <u>alkylosing spondylitis</u>, requires therapy is being supervised by a Rheumatologist.</p> <p>4. For <u>moderate to severe psoriasis</u>, a minimum of 3 months of previous treatment with a topical steroid AND 3 months treatment with PUVA (unless PUVA contraindicated).</p> <p><u>Following criteria are used in reviewing Kineret®:</u></p> <p>1. For <u>rheumatoid arthritis</u>, Kineret® requires a three month trial on two <b>concurrent</b> Disease Modifying Anti-Rheumatic Drugs (DMARDs), one of which must be methotrexate unless contraindicated <u>AND</u> treatment failure or contraindication to Enbrel®, the formulary alternative.</p> <p>As new FDA approved indications become available plan will consider coverage accordingly.</p> <p>Age restrictions = patients 18 years of age or older for Crohn's disease.</p> <p>Prescriber restrictions = for alkylosing spondylitis, requires therapy is being supervised by Rheumatologist.</p> <p>Coverage duration = lifetime.</p>
<p><b>Tracleer®</b> (bosentan)</p>	<p>Diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class III or IV symptoms. As new FDA approved indications become available plan will consider coverage accordingly. Coverage duration = lifetime.</p>
<p><b>Trilipix®</b> (fenofibric acid)</p>	<p>Requires documentation of trial and failure to gemfibrozil (g) <u>and</u> fenofibrate (g).</p>
<p><b>Uloric®</b> (febuxostat)</p>	<p>Requires treatment failure, intolerance or contraindication with allopurinol. Coverage duration = lifetime.</p>
<p><b>Vyvanse®</b> (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 = one year.</p>
<p><b>Xenazine®</b> (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. Coverage duration = one year.</p>

(g) = generic available