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Blue Cross Blue Shield of Michigan - Medicare Part D, PPO Prior Authorization / Step Therapy Program January 1, 2010

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
Adcirca TM (tadalafil)	Diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for tadalafil (Adcirca TM) 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 TM) in situations where patients are receiving Nitrate therapy . Coverage duration = lifetime.
Advicor [®] (lovastatin/extended release niacin)	Criteria pending CMS review.
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

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	<p>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..</p>
<p>Alpha-1 Proteinase Inhibitors Aralast NP[®] Prolastin[®] Zemaira[®]</p>	<p>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.</p>
<p>Amitiza[®] (lubiprostone)</p>	<p>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.</p>
<p>Angiotensin II Receptor Blockers (ARBs): Avapro[®](irbesartan)/Avalide[®], Benicar[®] (olmesartan)/HCT, Cozaar[®](losartan)/Hyzaar[®] 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. Age restrictions = patients 12 years of age and older. Coverage duration = One year.</p>

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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)	Criteria pending CMS review.
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 = one year.
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)	Criteria pending CMS review.
Cimzia[®] (certolizumab pegol)	Criteria pending CMS review.
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

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	<p>14mg/L, II.) C1 inhA (antigenic) level less than 150 mg, III.) C1 inhF (functional) level less than or equal to 84 percent.</p> <p>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 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)</p> <p>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.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Age restrictions = patients ≥ 9 years of age.</p> <p>Coverage duration = initial request approve for one month; renewal of therapy approve for one month.</p>
<p>COX-2 Preferential NSAIDs: Celebrex[®] (celecoxib)</p>	<p>Criteria pending CMS review.</p>
<p>Cymbalta[®] (duloxetine)</p>	<p>Criteria pending CMS review.</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.</p> <p>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[®].</p> <p>Coverage duration = lifetime.</p>
<p>Flector[®] (diclofenac)</p>	<p>Requires the diagnosis of treatment in acute pain due to minor strains, sprains and contusions.</p> <p>All FDA-approved indications not otherwise excluded for Part D.</p> <p>Coverage duration = One month</p>

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Forteo® (teriparatide, rDNA origin)	Criteria pending CMS review.
Growth Hormone (somatotropin), Genotropin®, Humatrope®, Norditropin®, Norditropin Nordiflex®, Nutropin® (all), Omnitrope®, Saizen®, Serostim®, Tev-Tropin®, Zorbtive™	<p>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. AND 2. One of the following indications: Growth Hormone Deficiency (GHD), Prader-Willi Syndrome (PWS), Turner’s Syndrome, Chronic Renal Insufficiency (CRI). AND 3. Initiating therapy in <u>children</u> (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.</p> <p>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.</p> <p>Requests in Adult patients:</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: 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</p> <p>b. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement AND 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>
Hepatitis Vaccine Comvax®, Engerix-B®, Recombivax HB®, Pediarix®, Twinrix®	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 = 1 year
HP Acthar Gel[®] (repository corticotropin)	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). All FDA-approved indications not otherwise excluded for Part D. Coverage duration for diagnostic testing = one month Coverage duration for FDA approved indications = 6 months
Immunosuppressive Therapy for an Organ Transplant <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.
Increlex[®] (mecasermin)	Criteria pending CMS review.
Inhaled Nasal Steroids 1: Nasocort AQ [®] (triamcinolone)	Nasocort AQ [®] requires trial and failure of or intolerance to Flonase [®] (g), Nasalide [®] (g) OR Nasarel [®] (g). Coverage duration = Lifetime
Inhaled Nasal Steroids 2: Beconase AQ [®] (beclomethasone), Nasonex [®] (mometasone), Omnaris [®] (ciclesonide), Rhinocort Aqua [®] (budesonide), Veramyst [®] (fluticasone)	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
Innohep[®] (tinzaparin)	Criteria pending CMS review.
Intravenous Immune Globulin (IVIG) <i>Various products</i>	Criteria pending CMS review.
Janumet[®] (sitagliptin/metformin)	Criteria pending CMS review.
Letairis[®] (ambisentan)	Diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class II or III symptoms. All FDA-approved indications not otherwise excluded for Part D.

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	Coverage duration = Lifetime.
Lotronex[®] (alosetron hydrochloride)	Criteria pending CMS review.
Lyrica[®] (pregabalin)	Criteria pending CMS review.
Miscellaneous Vaccine: BCG Live Vaccine, Hepatitis A Vaccine, Measles Virus Vaccine, Rabies Vaccine, Tetanus Toxoid Vaccine <i>Various products</i>	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 = One 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 = one month.
Non-Sedating Antihistamines (NSA's): Allegra (fexofenadine)/D [®] (12hr and 24hr)	Requires step therapy with loratadine-d or cetirizine-d. Coverage duration is lifetime.
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.
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.

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	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. 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.
Promacta[®] (eltrombopag)	Criteria pending CMS review.
Proton Pump Inhibitors (PPI's): Aciphex [®] (rabeprazole)	Requires trial 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 [®]	Criteria pending CMS review.
Relistor[®] (methylnaltrexone)	Criteria pending CMS review.
Revatio[®] (sildenafil citrate)	Criteria pending CMS review.
Sancuso[®] (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.
Sandostatin[®] (G) (octreotide acetate)	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

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	<p>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 = One 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>
<p>Select Cholesterol Combination Products: Simcor[®] (simvastatin + niacin extended release)</p>	<p>Criteria pending CMS review.</p>
<p>Selective Reuptake Inhibitor – antidepressants (SRI 1): Effexor XR[®], Lexapro[®], Venlafaxine OSM[®]</p>	<p>Criteria pending CMS review.</p>
<p>Selective Reuptake Inhibitor – antidepressants (SRI 2): Pristiq[®] (desvenlafaxine)</p>	<p>Requires prior authorization/step therapy with at least two formulary agents. Coverage duration is lifetime.</p>
<p>Selective Reuptake Inhibitor – antidepressants (SRI 3): Aplenzin[®] (bupropion), Luvox CR[®] (fluvoxamine), Pexeva[®] (paroxetine), Prozac Weekly[®] (fluoxetine)</p>	<p>Criteria pending CMS review.</p>

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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)	<p>For members age 5-21: 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)).</p> <p>For members age >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. Age restrictions = 5 -21 years old and greater than 21 years old. Coverage duration = lifetime.</p>
Tekturna[®] (aliskiren): Tekturna [®] , Tekturna 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.
Thiazolidinediones (TZDS) combo: 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 <u>AND</u> 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 <u>AND</u> 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[®] <u>AND</u> glimepiride 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[®] <u>AND</u> glimepiride 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>
TNF-alpha agents: Enbrel [®] (etanercept), Humira [®] (adalimumab) Kineret [®] (anakinra)	Criteria pending CMS review.

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Tracleer [®] (bosentan)	<i>Criteria pending CMS review.</i>
Treximet [®] (Sumatriptan/naproxen sodium)	<i>Criteria pending CMS review.</i>
Trilipix [®] (fenofibric acid)	Requires documentation of trial and failure to gemfibrozil (g) <u>and</u> fenofibrate (g).
Triptans 1 (Maxalt [®] , Maxalt MLT [®])	Requires trial and failure with sumatriptan. Coverage duration is lifetime
Triptans 2 (Amerge [®] , Axert [®] , Frova [®] , Relpax [®] , Zomig [®] , Zomig ZMT [®])	Requires trial and failure with sumatriptan and Maxalt [®] . Coverage duration is lifetime.
Uloric [®] (febuxostat)	Requires treatment failure, intolerance or contraindication with allopurinol. Coverage duration = lifetime.
Vytorin [®] (simvastatin/ezetimibe)	<i>Criteria pending CMS review.</i>
Vyvanse [®] (lisdexamfetamine)	<i>Criteria pending CMS review.</i>
Xenazine [®] (tetrabenazine)	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. 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. Coverage duration = one year.

(g) = generic available