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Blue Cross Blue Shield of MI Prior Authorization/Step Therapy Program January 2010

BCBSM monitors the use of certain medications to ensure our members receive the most appropriate and cost-effective drug therapy. **Prior authorization** for these drugs means that certain clinical criteria must be met before coverage is provided. In the case of drugs requiring **step therapy**, for example, previous treatment with one or more formulary drugs may be required. Drugs that must meet clinical criteria are identified in the formulary list with (PA) or (ST). Your physician can contact our pharmacy help desk to request prior authorization for these drugs.

The 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. You may be required to pay the full cost of the drug if your physician does not obtain prior authorization.

When your doctor prescribes a brand-name drug that's nonformulary, requires prior authorization or is not covered under your drug rider, it may not be a covered benefit. BCBSM reviews all physician and member requests to determine if the drug is medically necessary and that there aren't equally effective alternative drugs on the formulary.

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

Prior Authorization/Step Therapy Drug Categories (CLINICAL FORMULARY)

MEDICATION/ DRUG CLASS	CRITERIA
Adcirca™ (tadalafil) <i>Nonformulary</i>	Approved for members with a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for Adcirca™ IN COMBINATION with bosentan (Tracleer®), epoprostenol (Flolan®), treprostinil (Remodulin®) or iloprost (Ventavis®) <u>is provided</u> after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient's symptoms. Coverage is NOT provided for Adcirca™ in situations where patients are receiving nitrate therapy.
Amitiza® (lubiprostone) <i>Nonformulary</i>	Approval of lubiprostone requires the following: <ol style="list-style-type: none"> 1. Patient must be age 18 years or older 2. Diagnosis of chronic idiopathic constipation 3. Documented failure within the last 12 months using <ol style="list-style-type: none"> a. One fiber laxative AND b. Two stimulant laxative products 4. Drug-induced constipation must be ruled out
Anabolic Steroids Oxandrin® [g] (oxandrolone) <i>Nonformulary:</i> Anadrol-50® (oxymetholone) Deca-Durabolin® (nandrolone decanoate)	<u>Oxandrin® [g]:</u> Approved when used as an adjunct therapy to promote weight gain in patients who have had extensive surgery, chronic infection, or severe trauma OR for therapy to offset protein catabolism associated with prolonged use of corticosteroids OR for bone pain associated with osteoporosis OR if prophylactic therapy is needed in patients with hereditary angioedema. <u>Anadrol-50® (oxymetholone) and Deca-Durabolin® (nandrolone decanoate):</u> Approved for the treatment of clinically diagnosed anemia (documentation must support the trial of standard supportive measures for treating anemia including: transfusion, correction of iron, folic acid, vitamin B12, or pyridoxine deficiency, antibacterial therapy, and the appropriate use of corticosteroids) OR for the treatment of HIV-associated wasting OR if prophylactic therapy is needed in patients with hereditary angioedema.
Arcalyst™ (rilonacept)	Only FDA-approved for treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older.

MEDICATION/ DRUG CLASS	CRITERIA
<p>Bisphosphonates: Fosamax[®] [g] (alendronate) Fosamax[®] [g] weekly Fosamax Plus D[™] Actonel[®] (risedronate)</p> <p><i>Nonformulary:</i> Boniva[®] (ibandronate)</p>	<p>Approval of Actonel[®] (risedronate) requires documentation that the member has tried and failed/not tolerated treatment with Fosamax[®] [g].</p> <p>Approval of Boniva[®] (ibandronate) requires documentation that the member has tried and failed/not tolerated treatment with both Fosamax[®] [g] and Actonel[®] (risedronate).</p>
<p>Byetta[®] (exenatide)</p>	<p>Approved as adjunctive therapy in combination with at least one of the following medications: metformin, sulfonylurea or a thiazolidinedione AND being used to improve glycemic control in patients who have a diagnosis of type II diabetes mellitus AND have tried at least 2 of the following: metformin, a sulfonylurea or a thiazolidinedione (unless contraindicated) AND the patient must have documentation of an A1c greater than 7%.</p> <p>Byetta[®] IS NOT covered for the primary indication of weight loss in patients with or without diabetes.</p>
<p>Bystolic[®] (nebivolol) <i>Nonformulary</i></p>	<p>Approval requires documentation that the patient has tried and failed/intolerant to at least 2 of the formulary cardioselective beta blockers: Kerlone[®] [g], Sectral[®] [g], Tenormin[®] [g], Zebeta[®] [g], Lopressor[®] [g] OR Toprol XL[®] [g].</p>
<p>COX-2 Preferential NSAIDs: Celebrex[®] (celecoxib)</p>	<p>Requires age > 60 OR concomitant use of anticoagulants OR oral steroids OR risk of GI bleed (history of PUD, previous GI bleed, alcoholism).</p>
<p>Cymbalta[®] (duloxetine) <i>Nonformulary</i></p>	<p>Coverage for Cymbalta[®] will be provided for:</p> <p><u>Treatment of major depression</u> Approval requires trial and failure with two formulary antidepressants including one generic SSRI/SNRI.</p> <p>OR</p> <p><u>Treatment of diabetic neuropathic pain</u> <i>If patient equal to or greater than 65 years of age:</i> After a 30-day trial of gabapentin.</p> <p><i>If patient less than 65 years of age:</i> After a 30-day trial of gabapentin AND a tricyclic antidepressant, such as amitriptyline, desipramine, or imipramine.</p> <p>OR</p> <p><u>Treatment of Fibromyalgia</u> Fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance AND the patient has tried and experienced intolerance to gabapentin OR had inadequate pain relief at doses of 1200 mg or above AND has tried and experienced intolerance or inadequate pain relief to three of the following: tricyclic antidepressant, SSRI, SNRI, cyclobenzaprine, tramadol.</p>
<p>Erythropoiesis Stimulating Agents (ESA's): Aranesp[®] (darbepoetin alfa) Procrit[®] (epoetin alfa)</p> <p><i>Nonformulary:</i> Epoen[®] (epoetin alfa)</p>	<p>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, H. Patients with Erythropoietin type resistance due to neutralizing antibodies.</p> <p>Coverage duration = 3 months</p>

MEDICATION/ DRUG CLASS	CRITERIA
Flector® (diclofenac patch) <i>Nonformulary</i>	Use of this agent will require medical necessity documentation. Alternative is oral diclofenac. Only FDA-approved for short term pain management.
Forteo® (teriparatide)	Forteo® coverage will be provided for the following guidelines: 1. For the treatment of postmenopausal women with osteoporosis who are at high risk of fracture or men with primary or hypogonadal osteoporosis who are at high risk for fracture and meet the following criteria (a, b and c): a. Have a bone mineral density (BMD) that is 2.5 standard deviations or more below the mean (T-score at or below -2.5). b. Patient has tried and failed a bisphosphonate (formulary agents include Fosamax® [g] and Actonel®) for a 24 month period except when: 1. contraindication to a bisphosphonate (such as a stricture or achalasia, inability to stand or sit upright for at least 30 minutes and increased risk of aspiration). OR 2. documented intolerance to a bisphosphonate c. Coverage will NOT be provided in the following situations: 1. Concurrent treatment with a bisphosphonate 2. Hypercalcemia 3. Paget's disease 4. Bone metastases or a history of skeletal malignancies 5. Metabolic bone disease other than osteoporosis 6. Pediatric patients or young adults with open epiphyses 7. Prior radiation therapy involving the skeleton 2. Forteo will be approved for a maximum of two years.
Growth Hormone Nutropin® (somatropin) (all) Saizen® (somatropin) <i>Nonformulary:</i> Genotropin® Humatrope® Norditropin® Omnitrope® Serostim® Tev-Tropin® Zorbitive™	Coverage will be provided for: <u>Pediatric Growth Hormone Deficiency</u> <u>Children (M < 16 years old, F < 15 years old):</u> <i>Initial Treatment:</i> Req. ≥ 6 months of initial height measurements, Ht < 5 th percentile for age (based on initial evaluation), abnormal growth velocity based on ≥ 6 months of measurement, < 50 th percentile for age with growth hormone therapy, initial subnormal blood test for growth hormone. <i>To continue treatment:</i> must have a documented growth velocity of ≥ 2.5 cm/year during the first 6 months. of therapy & documented growth of ≥ 4.5 cm/year for each succeeding 6 month review period. Treatment may continue until final height or epiphyseal closure has been documented or patient has reached age 16 years (M) or 15 years (F). <u>Adults:</u> Diagnosis of growth hormone deficiency confirmed by laboratory testing (e.g. provocative stimulation), known indication for pituitary disease and multiple pituitary hormone deficiencies. Multiple stimulation tests may be required in certain clinical circumstances. May be approved for AIDS-wasting cachexia and Turner's Syndrome. Growth hormone therapy is NOT covered for anti-aging, obesity or athletic enhancement.
H.P. Acthar Gel® (repository corticotropin) <i>Nonformulary</i>	Coverage will be provided for the treatment of infantile spasms, OR for the diagnostic testing of adrenocortical function only if use of cosyntropin is contraindicated. Use of H.P. Acthar Gel® is NOT considered medically necessary as treatment of steroid-responsive conditions, unless there are medical contraindications or intolerance to corticosteroids that are not also expected to occur with use of H.P. Acthar Gel® .

MEDICATION/ DRUG CLASS	CRITERIA
<p>Increlex[®] (mecasermin) <i>Nonformulary</i></p>	<p>Approval will require the following:</p> <ol style="list-style-type: none"> 1. Medication to be prescribed by a pediatric endocrinologist AND 2. Diagnosis of one of the following: Severe primary IGF-1 deficiency or growth hormone gene deletion or genetic mutation of growth hormone receptor (Laron Syndrome) AND 3. Current height measurement at less than 3rd percentile for age and sex AND 4. IGF-1 level greater than or equal to 3 standard deviations below normal AND 5. Normal or elevated growth hormone levels based on at least one growth hormone stimulation test AND 6. Open growth plates <p>Authorizations shall be reviewed <u>at least annually</u> to confirm that current medical necessity criteria are met and that the medication is effective. Continued authorization in children may be given for up to 12 months until any one of the following conditions occurs:</p> <ol style="list-style-type: none"> 1. Growth velocity is less than 2.5 cm/year <p>OR</p> <ol style="list-style-type: none"> 2. Bone age in males exceeds 16^{0/12} years of age <p>OR</p> <ol style="list-style-type: none"> 3. Bone age in females exceeds 14^{0/12} years of age <p>Increlex[®] is considered investigational for all other indications, including, but not limited to:</p> <ol style="list-style-type: none"> a. Amyotrophic lateral sclerosis (ALS) b. Children less than two years of age c. Combination treatment with growth hormone d. Diabetes e. Individuals with closed growth plates f. Secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism or chronic treatment with steroids g. Idiopathic short stature h. Growth failure due to other identifiable causes (including, but not limited to Prader-Willi syndrome, Russell-Silver syndrome, Turner syndrome, Noonan syndrome) i. Less severe forms of IGF-1 deficiency
<p>Intranasal Steroids Flonase[®] [g] (fluticasone) Nasalide[®] [g] (flunisolide) Nasarel[®] [g] (flunisolide) Nasacort AQ[®] (triamcinolone) Nasonex[®] (mometasone) Rhinocort AQ[®] (budesonide)</p> <p><i>Nonformulary:</i> Beconase[®] AQ (beclomethasone) Omnaris[®] (ciclesonide) Veramyst[®] (fluticasone)</p>	<p>Approval of Nasacort AQ[®], Nasonex[®], Rhinocort AQ[®] requires trial and failure/intolerance to Flonase[®] [g] OR Nasarel[®] [g].</p> <p>Approval of nonformulary agents requires trial and failure/intolerance to generic fluticasone (Flonase[®]) OR generic flunisolide (Nasarel[®], Nasalide[®]) AND trial and failure/intolerance to Nasacort AQ[®] OR Nasonex[®] OR Rhinocort AQ[®].</p>
<p>Intuniv[™] (guanfacine extended-release) <i>Nonformulary</i></p>	<p>Requires diagnosis of ADHD AND therapeutic failure, intolerance or contraindication to BOTH an amphetamine-type product AND a methylphenidate product.</p>
<p>Lotronex[®] (alosectron hydrochloride) <i>Nonformulary</i></p>	<p>Approved for treatment of women \geq 18 years old with severe, diarrhea-predominant Irritable Bowel Syndrome (IBS) who have failed to respond to conventional IBS therapy.</p>

MEDICATION/ DRUG CLASS	CRITERIA
<p>Lyrica[®] (pregabalin) Nonformulary</p>	<p>Coverage for Lyrica[®] will be provided for: <u>Adjunctive treatment for adult patients with partial onset of seizures</u> OR <u>Treatment of diabetic neuropathic pain or post-herpetic neuralgia</u> If patient equal to or greater than 65 years of age: After a 30-day trial of gabapentin.</p> <p>If patient less than 65 years of age: After a 30-day trial of gabapentin AND a tricyclic antidepressant, such as amitriptyline, desipramine, or imipramine. OR <u>Treatment of Fibromyalgia</u> Fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance AND the patient has tried and experienced intolerance to gabapentin OR had inadequate pain relief at doses of 1200 mg or above AND has tried and experienced intolerance or inadequate pain relief to three of the following: tricyclic antidepressant, SSRI, SNRI, cyclobenzaprine, tramadol.</p>
<p>Narcotics Actiq[®] [g] (fentanyl citrate)</p> <p>Nonformulary: Fentora[™] (fentanyl citrate) Onsolis[™] (fentanyl citrate)</p>	<p>Requires appropriate diagnosis for coverage and tolerance to high doses of narcotics.</p>
<p>Non-Sedating Antihistamines (NSA's): Claritin/-D[™] OTC (loratadine/pseudoephedrine) Zyrtec/-D[™] OTC (cetirizine/pseudoephedrine) Allegra/-D[®] [g] (fexofenadine/pseudoephedrine)</p> <p>Nonformulary: Allegra[®] Suspension (fexofenadine) Allegra[®] ODT (fexofenadine) Clarinet/-D[®] (desloratadine/pseudoephedrine) Xyza[®] (levocetirizine)</p>	<p><u>Clarinet/Clarinet-D[®] and Xyza[®]</u> Requires failure of or intolerance to OTC loratadine/loratadine-D AND OTC cetirizine/cetirizine-D, AND generic fexofenadine/Allegra-D[®].</p> <p><u>Allegra[®] Suspension and Allegra[®] ODT</u> Requires failure or intolerance to loratadine AND cetirizine.</p>
<p>Promacta[®] (eltrombopag)</p>	<p>Initial approval for coverage requires all of the following:</p> <ol style="list-style-type: none"> 1. Age greater than 18 years old AND 2. Diagnosis of chronic immune thrombocytopenia (ITP) and persistent thrombocytopenia (platelet count < 150,000 mcL) for ≥ 2 months AND 3. Prescribed by a hematologist or in consultation with a hematologist AND 4. Inadequate response or patient must not be a candidate for corticosteroids, immunoglobulins, or splenectomy AND 5. Current platelet count is < 50,000 mcL AND 6. Dose is ≤ 75mg/day <p>Renewal approval for Promacta[®] requires recent platelet count of 30,000-150, 000 mcL AND dose is ≤ 75mg/day.</p>
<p>Proton Pump Inhibitors (PPI's): Prilosec OTC[™] [g] (omeprazole) Prilosec[®] [g] (omeprazole) Protonix[®] [g] (pantoprazole) Prevacid[®] [g] (lansoprazole)</p> <p>Prevacid[®] SoluTab[™] (lansoprazole)</p> <p>Nonformulary: Aciphex[®] (rabeprazole) Kapidex[™] (dexlansoprazole) Nexium[®] (esomeprazole) Zegerid[®] (omeprazole)</p>	<p>Approval of nonformulary medications requires failure of or intolerance to all formulary alternatives: Prilosec[®] [g] OR Prilosec OTC[™] [g] AND Protonix[®] [g] AND Prevacid[®] [g]/Prevacid[®] SoluTab[™]</p>

MEDICATION/ DRUG CLASS	CRITERIA
Relistor™ (methylnaltrexone bromide) injection	Coverage of Relistor™ will be provided for: <ol style="list-style-type: none"> 1. The treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. 2. Patients shall be on stable doses of opioids for greater than 2 weeks. 3. Duration of methylnaltrexone therapy shall be limited to 3 months. 4. Previous history of treatment for constipation shall include fluids, stool softeners, bulk laxatives, saline laxatives and osmotic laxatives. Laxatives trials shall be of at least 5 days duration. 5. Maximum initial regimen shall be 1 box (7 doses). Monthly doses shall not exceed 14. 6. Patients experiencing withdrawal symptoms while taking methylnaltrexone should consider using an alternate form of therapy.
Revatio® (sildenafil citrate)	Approved for members with a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for sildenafil (Revatio®) IN COMBINATION with bosentan (Tracleer®), epoprostenol (Flolan®), treprostinil (Remodulin®) or iloprost (Ventavis®) <u>is provided</u> after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient's symptoms. Coverage is NOT provided for sildenafil (Revatio®) in situations where patients are receiving nitrate therapy.
Sancuso® (granisetron) <i>Nonformulary</i>	Coverage of Sancuso® will be provided for: <ol style="list-style-type: none"> 1. Indication for prevention and/or treatment of nausea/vomiting associated with chemotherapy and/or radiation therapy AND 2. Documented treatment/failure with generic ondansetron (Zofran®) AND generic granisetron (Kytril®) AND 3. Not a candidate for IV granisetron therapy
Sandostatin® (octreotide) [g] Sandostatin LAR®	<u>Sandostatin® [g]</u> Approval requires one of the following (1, 2 or 3): <ol style="list-style-type: none"> 1. Clinically diagnosed acromegaly AND one of the following (a, b, or c) <ol style="list-style-type: none"> a. failure to respond to surgery or radiation OR b. not a candidate for surgery or radiation OR c. use to shrink tumor prior to surgery 2. Diagnosis of metastatic carcinoid tumor 3. Diagnosis of vasoactive intestinal peptide tumors (VIPomas) <u>Sandostatin LAR®</u> Approval requires member to have previously tried, responded and tolerated immediate-release octreotide injection AND one of the following (1,2 or 3): <ol style="list-style-type: none"> 1. Clinically diagnosed acromegaly AND one of the following (a,b or c) <ol style="list-style-type: none"> a. failure to respond to surgery or radiation OR b. not a candidate for surgery or radiation OR c. use to shrink tumor prior to surgery 2. Diagnosis of metastatic carcinoid tumor 3. Diagnosis of vasoactive intestinal peptide tumors (VIPomas)
Savella™ (milnacipran) <i>Nonformulary</i>	<u>Treatment of Fibromyalgia</u> Fibromyalgia characterized by pain in all 4 body quadrants, for at least 3 months, with or without fatigue and sleep disturbance AND the patient has tried and experienced intolerance to gabapentin OR had inadequate pain relief at doses of 1200 mg or above AND has tried and experienced intolerance or inadequate pain relief to three of the following: tricyclic antidepressant, SSRI, SNRI, cyclobenzaprine, tramadol.
Sedative/Hypnotics Ambien® [g] (zolpidem) Sonata® [g] (zaleplon) <i>Nonformulary:</i> Ambien CR™ (zolpidem) Lunesta™ (eszopiclone) Edluar® (zolpidem sublingual) Rozerem™ (ramelteon) Zolpimist® (zolpidem tartrate oral spray)	Requires documentation that member has experienced failure of or intolerance to Ambien® [g] OR Sonata® [g]. Edluar® and Zolpimist® require trial and failure, or intolerance, to Ambien® (zolpidem) AND Sonata® (zaleplon) AND documentation of medical necessity.

MEDICATION/ DRUG CLASS	CRITERIA
<p>Selective Reuptake Inhibitor – antidepressants: Celexa® [g] (citalopram) Effexor® [g] (venlafaxine) Luvox® [g] (fluvoxamine) Paxil® [g] (paroxetine) Paxil CR® [g] (paroxetine) Prozac® [g] (fluoxetine) Remeron® [g] (mirtazapine) Wellbutrin SR® [g] (bupropion) Wellbutrin XL® [g] (bupropion) Zoloft® [g] (sertraline) Lexapro® (escitalopram) Effexor XR® (venlafaxine) Venlafaxine ER</p> <p><i>Nonformulary:</i> Aplenzin® (bupropion hydrobromide) Luvox® CR (fluvoxamine) Pexeva® (paroxetine) Pristiq® (desvenlafaxine) Prozac Weekly® (fluoxetine)</p>	<p>Lexapro®, Effexor XR® and Venlafaxine ER require step therapy with at least one of the following generic formulary alternatives; <i>Celexa® [g], Effexor® [g], Luvox® [g], Paxil/CR® [g], Prozac® [g], Remeron® [g], Wellbutrin/SR® [g], Wellbutrin XL® [g], or Zoloft® [g].</i></p> <p>Aplenzin®; requires trial/failure of at least 2 formulary agents plus documentation that continued use of Wellbutrin® [g] will adversely affect the member's mental health.</p> <p>Luvox® CR; requires trial/failure of at least 2 formulary agents plus documentation that continued use of Luvox® [g] will adversely affect the member's mental health.</p> <p>Pexeva®; requires trial/failure of at least two of the above formulary agents PLUS documentation that continued use of Paxil® [g] will adversely affect the member's health.</p> <p>Pristiq®; requires trial/failure of at least 2 formulary agents.</p> <p>Prozac Weekly®; requires trial/failure of at least two of the above formulary agents PLUS documentation that continued use of Prozac® [g] will adversely affect the member's health.</p>
<p>Strattera® (atomoxetine)</p>	<p><i>For members age 5-21:</i> Requires documentation that member has experienced failure of or intolerance to BOTH a methylphenidate product (such as Ritalin® [g] or Concerta®) AND an amphetamine (such as Adderall® [g]).</p> <p><i>For members age >21:</i> Requires documentation that the member has experienced failure of or intolerance to EITHER a methylphenidate product OR an amphetamine.</p> <p>Approvable when stimulants are contra-indicated by medical history.</p>
<p>Tekturna® (aliskiren) <i>Nonformulary</i></p>	<p>Requires documentation that the member has tried standard effective doses and not reached therapeutic goals or could not tolerate therapy with ALL of the following drug classes:</p> <ol style="list-style-type: none"> 1. Diuretic 2. Beta-blocker 3. ACE-Inhibitor 4. Angiotension II Receptor Blocker (ARB)

MEDICATION/ DRUG CLASS	CRITERIA
<p>TNF-alpha agents and related products: Enbrel® (etanercept) Humira® (adalimumab)</p> <p><i>Nonformulary:</i> Cimzia® (certolizumab pegol injection) Kineret® (anakinra) Simponi™ (golimumab)</p>	<p>Enbrel® and Humira®: <u>Rheumatoid arthritis, juvenile RA, or psoriatic arthritis:</u> Requires three-month trial with two concurrent DMARDs, (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine.</p> <p><u>Ankylosing spondylitis:</u> requires therapy is being supervised by a Rheumatologist.</p> <p><u>Moderate to severe psoriasis:</u> Requires 3 months of previous treatment with topical corticosteroids AND 3 months treatment with PUVA (unless PUVA is contraindicated) AND therapy must be supervised by a Dermatologist.</p> <p><u>Crohn's Disease:</u> Coverage for patients age 18 years and older, with a diagnosis of moderately to severely active Crohn's disease with a history of inadequate response to conventional therapy. Applies to Humira® only.</p> <p>Cimzia®: The following criteria are used in reviewing medical exceptions for Cimzia® A. OR B.</p> <p>A. Age 18 or older AND for the treatment of acute exacerbation of moderate to severe Crohn's disease when the following criteria are met (1 AND 2):</p> <ol style="list-style-type: none"> 1) Treatment with an adequate course of systemic corticosteroids has been ineffective or is contraindicated or patient has been unable to taper or patient is experiencing breakthrough disease while stabilized on an immunomodulatory medication for at least 2 months. <p style="text-align: center;">AND</p> <ol style="list-style-type: none"> 2) Previous trial/failure/contraindication of Remicade® or Humira®. <p>OR</p> <p>B. Age 18 or older AND for the treatment of rheumatoid arthritis when the following criteria are met (1 AND 2)</p> <ol style="list-style-type: none"> 1) Treatment failure with a three month trial with two concurrent DMARDs (one must be methotrexate unless contraindicated) <p style="text-align: center;">AND</p> <ol style="list-style-type: none"> 2) Treatment failure or documented intolerance to (a OR b) <ol style="list-style-type: none"> a. Infliximab (Remicade®) OR b. Adalimumab (Humira®) and Etanercept (Enbrel®) <p>Kineret®: <u>Rheumatoid arthritis in adults:</u> Requires three-month trial with two concurrent DMARDs, (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine AND treatment failure or intolerance to Enbrel® and Humira®</p> <p>Simponi™: 18 years of age or older AND A OR B</p> <p>A. <u>Rheumatoid arthritis and psoriatic arthritis:</u> Requires a 3-month trial on two concurrent Disease Modifying Anti-Rheumatic Drugs (DMARDs), one of which must be methotrexate unless contraindicated AND treatment failure or contraindication to Remicade® OR both Enbrel® AND Humira® .</p> <p>OR</p> <p>B. <u>Ankylosing spondylitis:</u> Requires a treatment failure or contraindication to Remicade® OR treatment failure or contraindication to both Enbrel® AND Humira® .</p>

MEDICATION/ DRUG CLASS	CRITERIA
Tracleer™ (bosentan)	Requires a diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class II - IV symptoms.
Treximet™ (sumatriptan/naproxen sodium) <i>Nonformulary</i>	Requires prior use of Imitrex® [g] and Naprosyn® [g] in combination AND documentation indicating why use of the individual agents is harmful to the member AND documentation of trial and failure of formulary option Maxalt®.
TriLipix™ (fenofibric acid) <i>Nonformulary</i>	Requires trial and failure of gemfibrozil [g] AND fenofibrate [g].
Triptans: Imitrex® [g] (sumatriptan) Maxalt/MLT® (rizatriptan) <i>Nonformulary</i> Amerge® (natriptan) Axert® (almotriptan) Frova® (frovatriptan) Relpax® (eletriptan) Sumavel™ DosePro™ (sumatriptan needle-free injection) Zomig® (zolmitriptan)	The formulary option Maxalt/MLT® will require trial and failure of the generic formulary alternative Imitrex® [g]. Approval of the nonformulary triptans, Amerge®, Axert®, Frova®, Relpax®, Zomig/ZMT®, will require trial and failure of both the formulary options Imitrex® [g] AND Maxalt/MLT®. Approval of the nonformulary triptan Sumavel™ DosePro™ will require trial and failure of both formulary options Imitrex (g) injection AND Maxalt MLT®.
Uloric® (febuxostat)	Requires treatment failure, intolerance or contraindication with formulary alternative allopurinol.
Vyvance™ (lisdexamfetamine) <i>Nonformulary</i>	Covered for the treatment of ADHD in children and adults 6 years of age and older who have experienced therapeutic failure or intolerance to BOTH an amphetamine-type product AND a methylphenidate product. Maximum dose approved per day will be 70 mg.
Xenazine® (tetrabenazine)	Approval will require diagnosis of chorea associated with Huntington's disease AND for doses above 50mg per day, documentation of the CYP2D6 genotype of the patient will be required. Tetrabenazine is considered investigational when used for all other conditions, including, but not limited to: <ul style="list-style-type: none"> A. Chorea not associated with Huntington's disease B. Tardive dyskinesia C. Dystonia, tics and other dyskinesias D. Hyperkinetic or involuntary movement disorders E. Tourette's syndrome F. Athetoid cerebral palsy

MEDICATION/ DRUG CLASS	CRITERIA
<p>Xyrem[®] (sodium oxybate) <i>Nonformulary</i></p>	<p>Requires a diagnosis of narcolepsy and A OR B:</p> <p>A. Cataplexy demonstrated by supporting chart documentation or sleep studies</p> <p>OR</p> <p>B. Excessive daytime sleepiness demonstrated by supporting chart documentation or sleep studies when (1 AND 2):</p> <ol style="list-style-type: none"> 1. Modafinil in doses up to 400mg daily has been ineffective, not tolerated, or contraindicated. <p>AND</p> <ol style="list-style-type: none"> 2. At least one other formulary/preferred treatment, such as methylphenidate or dextroamphetamine, has been ineffective, not tolerated, or contraindicated. <p>Xyrem[®] will NOT be approved if:</p> <ol style="list-style-type: none"> 1. Patient is being treated with sedative hypnotic agents, other CNS depressants, or using alcohol 2. Patient has a history of drug abuse 3. Patient has succinic semialdehyde dehydrogenase deficiency <p>Xyrem[®] is NOT considered medically necessary for the following condition(s):</p> <ol style="list-style-type: none"> 1. Alcohol dependence and withdrawal 2. Fibromyalgia <p>Xyrem[®] is considered investigational for all other conditions or applications, including, but not limited to, the treatment of:</p> <ol style="list-style-type: none"> 1. Opioid dependence and withdrawal 2. Parkinsonism 3. Night eating syndrome 4. Myoclonus and essential tremor

[g] = generic available