Blue Cross Blue Shield of MI
Prior Authorization and Step Therapy Program
January 2012

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 and Step Therapy Drug Categories
(CUSTOM FORMULARY)

MEDICATION/DRUG CLASS	CRITERIA
Adcirca® (tadalafil) *Nonformulary*	Approved for members with documentation of a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage is **NOT** provided for Adcirca® in situations where the patient is receiving nitrate therapy.
Amitiza® (lubiprostone) *Nonformulary*	Patient must be 18 years or older and have a diagnosis of constipation predominant Irritable Bowel Syndrome (IBS) (female only) **OR** Chronic idiopathic constipation with documented failure with one fiber laxative and either a stimulant or osmotic laxative. Drug induced constipation must also be ruled out.
Ampyra® (dalfampridine) *Nonformulary*	Coverage may be provided in patients ≥ 18 years of age when the criteria below are met: • Diagnosis of multiple sclerosis. • Prescribing physician is a neurologist. • Patient has documented difficulty walking, resulting in significant limitations of instrumental activities of daily living. • Clinical notes are provided documenting two measurements with variability within 10% demonstrating the patient is able to walk 25 feet in 8-45 seconds. The faster time of the two measurements will serve as the baseline value. Ambulatory function assessed with the timed 25-foot walk (T25FW). • Patient does not have a history of seizure. • Patient does not have moderate to severe renal impairment (CrCl ≤ 50 ml/min). **Initial approval length is for 3 months** Coverage may be renewed for 12 months when the following criteria are met: • Clinical notes are provided documenting improvement in walking speed by at least 10% as assessed by the timed 25-foot walk. • Indication that the significant limitations of instrumental activities of daily living have improved/resolved as a result of increased speed of ambulation. Coverage may be renewed annually thereafter (12 month intervals) when clinical notes document no deterioration in walking speed, compared to the previous walking speed measured for renewal of therapy, as assessed by the timed 25-foot walk.
Amrix® [g] (cyclobenzaprine) *Nonformulary*	Approval requires previous trial and failure of generic immediate-release cyclobenzaprine.
Anabolic Steroids: *Formulary:* **Oxandrin® [g]** (oxandrolone) *Nonformulary:* **Anadrol-50®** (oxymetholone) **Deca-Durabolin®** (nandrolone decanoate)	**Oxandrin® [g]:** 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. **Anadrol-50® (oxymetholone) and Deca-Durabolin® (nandrolone decanoate):** 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.

MEDICATION/DRUG CLASS	CRITERIA
Angiotensin II Receptor Blockers (ARBs): *Formulary:* **Benicar®/HCT** (olmesartan) *Nonformulary:* **Atacand®/HCT** (candesartan) **Avapro®/Avalide®** (irbesartan) **Diovan®/HCT** (valsartan) **Edarbi™** (azilsartan medoxomil) **Micardis®/HCT** (telmisartan) **Teveten®/HCT** (eprosartan)	**Benicar®/HCT** requires documentation that the member has experienced failure of or intolerance to Cozaar® (losartan)/Hyzaar® [g]. Approval of **nonformulary agents** require documentation that the member has experienced failure of or intolerance to Cozaar® (losartan)/Hyzaar® [g] **AND** Benicar®/HCT (olmesartan).
Antidepressants: *Formulary:* **Lexapro®** (escitalopram) *Nonformulary:* **Aplenzin®** (bupropion hydrobromide) **Cymbalta®** (duloxetine) **Luvox® CR** (fluvoxamine) **Pexeva®** (paroxetine) **Pristiq®** (desvenlafaxine) **Viibryd™** (vilazodone)	**Lexapro®** requires step therapy with at least one of the following generic formulary alternatives: Celexa® [g], Effexor®/XR® [g], Luvox® [g], Paxil/CR® [g], Prozac® [g], Remeron® [g], venlafaxine XR, Wellbutrin/SR® [g], Wellbutrin XL® [g] or Zoloft® [g]. **Nonformulary agents:** **Aplenzin®** requires trial/failure of at least two formulary antidepressant agents, one of which must be generic bupropion. **Luvox® CR** requires trial/failure of at least two formulary antidepressant agents, one of which must be generic fluvoxamine. **Pexeva®** requires trial/failure of at least two formulary antidepressant agents, one of which must be generic paroxetine. **Cymbalta®** for diagnosis of major depression requires trial and failure with two formulary antidepressant agents. **Pristiq®** requires trial/failure of at least two formulary antidepressant agents, one of which must be Effexor® [g], Effexor XR® [g] or venlafaxine ER. **Viibryd™** requires trial/failure of at least two formulary antidepressant agents.
Arcalyst® (rilonacept) *Formulary*	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.
Aricept® 23 mg (donepezil) *Nonformulary*	Requires 3 month trial of Aricept® [g] (donepezil) 10 mg tablets within the last year.

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Aromatase Inhibitors: *Formulary:* **Arimidex® [g]** (anastrazole) **Aromasin® [g]** (exemestane) **Femara® [g]** (letrozole)	Coverage review required for males only. Approved only for ER-positive breast cancer treatment and other literature supported cancer therapies.
Betaseron® (Interferon beta-1b) *Nonformulary*	Requires trial and failure or intolerance of Extavia®.
Bisphosphonates: *Formulary:* **Actonel®** (risedronate) **Actonel® with Calcium** *Nonformulary:* **Atelvia™** (risedronate) **Boniva®** (ibandronate) **Fosamax Plus D®**	**Actonel®** (risedronate) requires documentation that the member has tried and failed/not tolerated treatment with Fosamax® [g]. **Atelvia™** requires documentation that the member has tried and failed/not tolerated treatment with Fosamax® [g]. **Boniva®** (ibandronate) and **Fosamax Plus D®** require documentation that the member has tried and failed/not tolerated treatment with both Fosamax® [g] **AND** Actonel® (risedronate) ***or*** Atelvia™ (risedronate).
Brand Tetracyclines: *Formulary:* **Adoxa®** (doxycycline) **Doryx®** (doxycycline) **Solodyn®** (minocycline) *Nonformulary:* **Dynacin®** (minocycline) **Oracea®** (doxycycline)	**Adoxa®, Doryx® and Oracea®** Requires documentation that the member has experienced treatment failure of generic doxycycline. **Dynacin® and Solodyn®** Requires documentation that the member has experienced treatment failure of generic minocycline.
Butrans® (buprenorphine) *Nonformulary*	Coverage will be provided for the management of moderate to severe chronic pain in patients requiring around the clock opioid analgesia for an extended period of time. Criteria also require trial and failure or intolerance of **two** of the following: extended release morphine, fentanyl patch or methadone. Coverage will not be provided for use as an "as needed" analgesic or for acute pain or postoperative pain.

MEDICATION/DRUG CLASS	CRITERIA
Byetta® (exenatide) *Nonformulary*	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%. Byetta® is **NOT** covered for the primary indication of weight loss in patients with or without diabetes.
Bystolic® (nebivolol) *Nonformulary*	Approval requires documentation that the patient has tried and failed/intolerant to at least TWO of the formulary cardioselective beta blockers: Kerlone® [g], Sectral® [g], Tenormin® [g], Zebeta® [g], Lopressor® [g] OR Toprol XL® [g].
Cambia™ (diclofenac potassium) *Nonformulary*	Approval requires documentation that the patient has tried and failed or is intolerant to generic oral diclofenac **AND** one oral generic NSAID (Non-steroidal anti-inflammatory drug).
Carbaglu® (carglumic acid) *Formulary*	Covered for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS).
Cayston® (aztreonam lysine) *Nonformulary*	Covered for the improvement of respiratory symptoms in cystic fibrosis patients with *Pseudomonas aeruginosa*.
Celebrex® (celecoxib) *Nonformulary*	Requires one of the following: • Age > 60 **OR** • Concomitant use of anticoagulants **OR** • Oral steroids **OR** • Risk of GI bleed (history of PUD, previous GI bleed, alcoholism).
Chenodal™ (chenodeoxycholic acid) *Nonformulary*	Coverage approved for patients with radiolucent stones in well-opacifying gallbladders in whom selective surgery would be undertaken except for the presence of increased surgical risk because of systemic disease or age. Requires: 1. Trial and failure or intolerance of ursodiol 2. Patient is not a candidate for surgery 3. Patient has no history of hepatocellular disease 4. If the patient is a woman, required that they are not pregnant and may not become pregnant. Coverage is limited to 24 months total of ursodiol plus Chenodal™.

MEDICATION/DRUG CLASS	CRITERIA
Cholesterol lowering Agents: *Formulary:* **Crestor**® (rosuvastatin) *Nonformulary:* **Altoprev**® (lovastatin ER) **Lescol**®**/XL**® (fluvastatin) **Livalo**® (pitavastatin) **Vytorin**® (simvastatin/ezetimibe) **Advicor**® (lovastatin/niacin ER) **Simcor**® (simvastatin/niacin ER)	**Crestor**® requires documentation that member has experienced failure of or intolerance to at least one generic statin (Mevacor [g], Zocor [g], Pravachol [g] or Lipitor [g]). **Nonformulary agents:** **Altoprev**®**, Lescol**®**, Lescol XL**®**, Livalo**®**, Vytorin**®**:** Requires documentation that member has experienced failure of or intolerance to at least **one** generic statin (Mevacor [g], Zocor [g], Pravachol [g] or Lipitor [g]) **AND one** formulary brand agent (Crestor® or Zetia®). **Advicor**®**:** Requires documentation that member has had at least 3 months of treatment with lovastatin and niacin extended release as individual agents when used concomitantly. **Simcor**®**:** Requires documentation that member has had at least 3 months of treatment with simvastatin and niacin extended release as individual agents when used concomitantly.
Cialis® (tadalafil) *Formulary*	Requires diagnosis of Benign Prostatic Hyperplasia (**BPH**) **AND** trial and failure or intolerance of an alpha-blocker **AND** a 5-alpha reductase inhibitor. May be covered for the diagnosis of erectile dysfunction dependent on the plan's benefit with quantity limit restrictions.
Clarinex/-D® (desloratadine/ pseudoephedrine) *Nonformulary*	Coverage for **Clarinex/Clarinex-D**® requires failure of or intolerance to loratadine/loratadine-D **AND** cetirizine/cetirizine-D **AND** fexofenadine/fexofenadine-D **AND** Xyzal® [g] (levocetirizine).
Cycloset® (bromocriptine) *Nonformulary*	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%. Cycloset® is **NOT** covered for the primary indication of weight loss in patients with or without diabetes.
Cymbalta® (duloxetine) *Nonformulary*	Coverage for Cymbalta® will be provided for: Treatment of major depression Approval requires trial and failure with two formulary antidepressants. **OR** Treatment of diabetic neuropathic pain ➢ ***If patient equal to or greater than 65 years of age:*** After a 30-day trial of gabapentin. ➢ ***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**

MEDICATION/DRUG CLASS	CRITERIA
	Treatment of Fibromyalgia 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 and tramadol. **OR** Treatment of Chronic Musculoskeletal Pain Approval requires failure or intolerance of two generic formulary alternatives from any of the following three drug classes: antidepressants, NSAIDs and centrally acting analgesics. Examples of centrally acting analgesics include: codeine, hydrocodone, morphine, meperidine, oxycodone and tramadol. **OR** Treatment of Generalized Anxiety Disorder Approval requires trial and failure of two formulary antidepressants.
Daliresp® (roflumilast) *Nonformulary*	Coverage for Daliresp® will be approved for use in patients with severe COPD associated with chronic bronchitis AND a history of exacerbations despite maximal therapy with a LABA (long-acting beta agonist), an anticholinergic and an inhaled corticosteroid. Supporting documentation will be required for processing.
Duexis® (ibuprofen/famotidine) *Nonformulary*	Coverage for Duexis® requires trial and failure of individual generic agents ibuprofen and famotidine taken concurrently **AND** explanation of why the combination product is expected to work if the individual agents have not.
Egrifta® (tesamorelin) *Nonformulary*	Coverage for Egrifta® will be provided for the FDA approved indication only. The reduction of excess abdominal fat in HIV-infected patients with lipodystrophy **AND** supporting documentation will be required for the following criteria: A. Patient is infected with human immunodeficiency virus (HIV). B. Patient is receiving antiretroviral therapy (ART). C. Weight loss efforts (dietary modification and exercise) have been ineffective in reducing the excess abdominal fat due to lipodystrophy. D. Documentation of the medical complication(s) caused by excess abdominal fat. E. The medical complication(s) due to excess abdominal fat are unresponsive to conventional therapy. Initial approval is for 6 months. Coverage may be renewed for 12 months when the following criteria are met: A. Clinical documentation indicating a decrease in waist circumference (decrease in lipodystrophy). B. Reduction of complication(s) provided in the initial request caused by excess abdominal fat. **Coverage is NOT provided for weight loss management in patients with HIV infection.**

MEDICATION/DRUG CLASS	CRITERIA
Erythropoiesis Stimulating Agents (ESAs): *Formulary:* **Procrit®** (epoetin alfa) *Nonformulary:* **Aranesp®** (darbepoetin alfa) **Epogen®** (epoetin alfa)	Information may need to be submitted describing the use and setting of the drug to make the determination. Approved for use in members with hemoglobin less than 12 g/dL and one of the following conditions: anemia secondary to chronic renal failure, chronic renal insufficiency, HIV infection, HIV therapy, chemotherapy, myelodysplasia or chronic hepatitis C therapy OR prophylaxis prior to major surgery. Duration of approval is dependent on the indication. **Nonformulary agent(s):** Coverage for nonformulary agents also requires documentation that the member has experienced failure of or intolerance to formulary epoetin alfa (Procrit®). Coverage duration = 3 months
Exalgo® (hydromorphone ER) *Nonformulary*	Coverage will be provided for management of moderate to severe pain in opioid tolerant patients requiring continuous, around the clock opioid analgesia for an extended period of time. Criteria also require trial and failure or intolerance of **two** of the following: extended release morphine, fentanyl patch or methadone. Coverage will not be provided for use as an "as needed" analgesic or for acute pain or postoperative pain.
Firazyr® (icatibant) *Nonformulary*	Coverage for Firazyr® will be provided for a diagnosis of hereditary angioedema (HAE) established by an immunologist or hematologist. Supporting documentation will be required for processing.
Flector® (diclofenac patch) *Nonformulary*	For FDA approved indications only. Member must have tried and failed or demonstrated intolerance to oral diclofenac **AND** at least two other oral, traditional NSAIDs unless the patient is unable to take any oral medications. **AND** Coverage will **NOT** be provided in the presence of concurrent therapy with oral NSAIDs or a COX II inhibitor.
Forte® (teriparatide) *Nonformulary*	Forteo® will be provided for the following guidelines: 1. For patients with a history of fracture. **OR** 2. 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 and b**): 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 **Forteo will be approved for a maximum of two years**.

MEDICATION/DRUG CLASS	CRITERIA
Gilenya™ (fingolimod) *Nonformulary*	Approval for Gilenya™ requires (1,2,3 **and** 4): 1. That the patient is 18 years of age or older with a relapsing form of multiple sclerosis 2. The prescribing physician must be a neurologist 3. Trial of at least one interferon beta product (e.g. Avonex®, Betaseron®, Extavia®, Rebif®) **OR** Copaxone® has demonstrated clinical failure or intolerance, unless all products are contraindicated based on clinical documentation. • **Treatment failure is demonstrated by the following**: - Documented clinical relapse - The presence of new and/or newly enlarged MRI lesions in the previous year. 4. Will not be used in combination with other disease-modifying treatments of multiple sclerosis.
Gralise™ (gabapentin CR) *Nonformulary*	Covered for the treatment of post-herpetic neuralgia with the following criteria: ➢ ***If patient equal to or greater than 65 years of age:*** After a 30-day trial of gabapentin. ➢ ***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.
Growth Hormone: *Formulary:* **Genotropin®** (somatropin) **Nutropin®** (somatropin) *Nonformulary:* **Humatrope®** **Norditropin®** **Omnitrope®** **Saizen®** **Serostim®** **Tev-Tropin®** **Zorbtive™**	Coverage will be provided for: **Pediatric Growth Hormone Deficiency** *Children (M < 16 years old, F < 15 years old):* *Initial Treatment*: Req. ≥ 6 months of initial height measurements, Ht < 5th percentile for age (based on initial evaluation), abnormal growth velocity based on ≥ 6 mo. of measurement, < 50th percentile for age with growth hormone therapy, initial subnormal blood test for growth hormone. *To continue treatment:* must have a documented growth velocity of ≥ 2.5 cm/year during the first 6 mo. 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). **Adults:** 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. **Nonformulary agents require that the member has experienced treatment failure of or intolerance to formulary agents.**
Hepatitis C Protease	**Incivek™** (telaprevir)

MEDICATION/DRUG CLASS	CRITERIA
Inhibitors *Formulary:* **Incivek™** (telaprevir) **Victrelis™** (boceprevir)	Coverage will be provided for adult patients (18 years or older) with Chronic hepatitis C genotype 1 infection **AND** 1. Compensated liver disease (including cirrhosis) **AND** with recent HCV-RNA level. 2. Used in combination with peg interferon alfa (PegIntron or Pegasys) and ribavirin (Rebetol, Copegus). **Victrelis™** Coverage will be provided for adult patients (18yo or older) with Chronic hepatitis C genotype 1 infection **AND** 1. Compensated liver disease (including cirrhosis) **AND** with recent HCV-RNA level. 2. Used in combination with peg interferon alfa (PegIntron or Pegasys) and ribavirin (Rebetol, Copegus) **AND** 3. Therapy must be initiated for 4 weeks with peg interferon alfa and ribavirin (Victrelis therapy starts at treatment week 5) **AND** 4. Treatment with telaprevir (Incivek™) is contraindicated or not recommended: a. History of severe skin reactions or dermatologic conditions b. Moderate to severe hepatic impairment (Child-Pugh B or C) c. Drug-drug interactions not also associated with boceprevir ****Renewal criteria for both Incivek™ and Victrelis™ require updated viral load****
Horizant™ (gabapentin ER) *Nonformulary*	Approval of Horizant™ requires trial and failure of Mirapex® [g], Neurontin® [g] and Requip® [g].
H.P. Acthar Gel® (repository corticotropin) *Nonformulary*	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®.
Human Chorionic Gonadotropin: *Formulary:* **Novarel®** **Pregnyl®**	Coverage for Novarel® or Pregnyl® will be provided in accordance with infertility benefit and policy for both males and females and for FDA approved indications.
Immune Globulin: *Nonformulary:* **Gammagard™** **Gammaked™** **Gamunex-C®** **Hizentra®**	Requires appropriate diagnosis for coverage and other criteria may apply depending on diagnosis.

MEDICATION/DRUG CLASS	CRITERIA
Increlex® (mecasermin) *Nonformulary*	Approval will require all of the following (1, 2, 3, 4, 5 and 6.): 1. Medication to be prescribed by a pediatric endocrinologist 2. Diagnosis of one of the following: o Severe primary IGF-1 deficiency or growth hormone gene deletion **or** o genetic mutation of growth hormone receptor (Laron Syndrome) 3. Current height measurement at less than 3rd percentile for age and sex 4. IGF-1 level greater than or equal to 3 standard deviations below normal 5. Normal or elevated growth hormone levels based on at least one growth hormone stimulation test 6. Open growth plates Authorizations shall be reviewed at least annually 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: 1. Growth velocity is less than 2.5 cm/year **OR** 2. Bone age in males exceeds 16 0/12 years of age **OR** 3. Bone age in females exceeds 14 0/12 years of age
Intranasal Steroids: *Formulary:* **Nasacort AQ® [g]** (triamcinolone) *Nonformulary:* **Beconase® AQ** (beclomethasone) **Nasonex®** (mometasone) **Omnaris®** (ciclesonide) **Rhinocort AQ®** (budesonide) **Veramyst®** (fluticasone)	Approval of triamcinolone (Nasacort AQ®) requires trial and failure/intolerance to (Flonase®) **OR** generic flunisolide (Nasarel®). Approval of **nonformulary agents** requires trial and failure/intolerance of 2 of the following intranasal steroids: generic fluticasone (Flonase®), generic flunisolide (Nasarel®) or generic triamcinolone (Nasacort AQ®).
Intuniv® (guanfacine extended-release) *Nonformulary*	Covered for the members 6 years of age and older with the appropriate diagnosis who have experienced therapeutic failure or intolerance to **BOTH** an amphetamine-type product **AND** a methylphenidate product.
Kapvay™ (clonidine ER) *Nonformulary*	Covered for the members 6 years of age and older with the appropriate diagnosis who have experienced therapeutic failure or intolerance to **BOTH** an amphetamine-type product **AND** a methylphenidate product.
Lotronex® (alosetron hydrochloride) *Nonformulary*	Approved for treatment of women ≥ 18 years old with severe, diarrhea-predominant Irritable Bowel Syndrome (IBS) who have failed to respond to conventional IBS therapy.

MEDICATION/DRUG CLASS	CRITERIA
Lyrica® (pregabalin) *Nonformulary*	Coverage of Lyrica® will be provided for: Adjunctive treatment for adult patients with partial onset of seizures **OR** Treatment of diabetic neuropathic pain or post-herpetic neuralgia ➢ ***If patient equal to or greater than 65 years of age:*** After a 30-day trial of gabapentin. ➢ ***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** Treatment of Fibromyalgia 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.
Mirapex® ER (pramipexole ER) *Nonformulary*	Coverage approved for the treatment of Parkinson's. Requires trial and failure of Mirapex® [g].
Narcotics: *Formulary:* **Actiq® [g]** (fentanyl citrate) *Nonformulary:* **Abstral®** (fentanyl citrate) **Fentora®** (fentanyl citrate) **Onsolis®** (fentanyl citrate) **Lazanda®** (fentanyl citrate)	Requires appropriate diagnosis for coverage and tolerance to high doses of narcotics and current use of long-acting narcotic. Approved for breakthrough pain only. **Nonformulary agents:** **(Abstral®, Fentora® and Onsolis®)** require that the member has experienced treatment failure of or intolerance to formulary agents. Coverage for **Lazanda®** will only be provided when members have meet **ALL** of the following criteria: 1. Diagnosis of breakthrough cancer pain **OR** treatment for breakthrough cancer pain 2. Patient is opioid tolerant and is currently being treated with a long acting opioid analgesic 3. Previous trial and failure of generic short acting fentanyl products (fentanyl citrate buccal lollipop and buccal tablet)
Nexiclon™ XR (clonidine ER) *Nonformulary*	Requires appropriate diagnosis for coverage and trial and failure of generic clonidine tablet or generic clonidine patch.
Nucynta® ER (tapentadol) *Nonformulary*	Coverage for Nucynta ER requires documented trial and failure or intolerance to Ultram® ER [g] **AND** trial and failure of **TWO** of the following generic formulary alternatives: extended-release morphine, fentanyl patch or methadone.
Nuedexta® (dextromethorphan/ quinidine) *Nonformulary*	Requires appropriate diagnosis for coverage. Coverage approved for the treatment of PBA (pseudobulbar affect) secondary to ALS and/or MS.
Oleptro™ (trazodone ER) *Nonformulary*	Coverage approved for the treatment of major depressive disorder. Requires trial and failure of Desyrel [g] and documentation why the long acting would be more efficacious.

MEDICATION/DRUG CLASS	CRITERIA
Pennsaid® (diclofenac sodium) *Nonformulary*	For FDA approved indications only. Member must have tried and failed or demonstrated intolerance to oral diclofenac **AND** at least two other oral, traditional NSAIDs unless the patient is unable to take any oral medications. **AND** Coverage will **NOT** be provided in the presence of concurrent therapy with oral NSAIDs or a COX II inhibitor.
Promacta® (eltrombopag) *Formulary*	Initial approval for coverage requires all of the following: 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 ≤ 75 mg/day Renewal approval for Promacta® requires recent platelet count of 30,000-150, 000 mcL **AND** dose is ≤ 75 mg/day.
Proton Pump Inhibitors (PPI's): *Nonformulary:* **Aciphex®** (rabeprazole) **Dexilant™** (dexlansoprazole) **Nexium®** (esomeprazole) **Zegerid® powder for oral suspension** (omeprazole/sodium bicarbonate)	Approval of nonformulary medications requires failure of or intolerance to all formulary alternatives: Prilosec® [g] **OR** Prilosec OTC® [g] **AND** Protonix® [g] **AND** Prevacid®/Prevacid® SoluTab™ [g]
Relistor® (methylnaltrexone bromide) *Formulary*	Coverage of Relistor® will be provided for: 1. The treatment of opioid-induced constipation in patients with advanced illnesses 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). 6. Monthly doses shall not exceed 14. Patients experiencing withdrawal symptoms while taking methylnaltrexone should consider using an alternate form of therapy.
Revatio® (sildenafil citrate) *Formulary*	Approved for members with documentation of a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage is **NOT** provided for sildenafil (Revatio®) in situations where patients are receiving nitrate therapy.

[g]= generic available

MEDICATION/DRUG CLASS	CRITERIA
Sancuso® (granisetron) *Nonformulary*	Coverage of Sancuso® will be provided for: 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® [g] (octreotide) **Sandostatin LAR®** *Formulary*	**Sandostatin® [g]** Approval requires one of the following (1, 2 or 3): 1. Clinically diagnosed acromegaly **AND** one of the following (a, b **or** c) 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) **Sandostatin LAR** - Approval requires member to have previously tried, responded and tolerated immediate-release octreotide injection in addition to the diagnosis requirement listed under Sandostatin [g].
Savella® (milnacipran) *Nonformulary*	Requires diagnosis of 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: *Nonformulary:* **Edluar™** (zolpidem tartrate SL) **Zolpimist®** (zolpidem tartrate)	**Edluar™** and **Zolpimist®** require trial and failure, or intolerance, to the formulary alternatives Ambien® (zolpidem) **AND** Sonata® (zaleplon) **AND** documentation of medical necessity.
Silenor® (doxepin) *Nonformulary*	Requires trial and failure of the formulary alternatives Ambien [g] **AND** Sonata [g].
Somavert® (pegvisomant) *Formulary*	For the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies or for whom these therapies are not appropriate.
Suprenza™ (phentermine HCl) *Nonformulary*	Coverage for Suprenza™ requires trial and failure of generic phentermine **AND** explanation of why Suprenza™ is expected to work if generic phentermine has not.
Tekturna® (aliskiren) *Nonformulary*	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: 1. Diuretic 2. Beta-blocker 3. ACE-Inhibitor 4. Angiotension II Receptor Blocker (ARB)

MEDICATION/DRUG CLASS	CRITERIA
TNF-alpha agents and related products: *Formulary:* **Enbrel®** (etanercept) **Humira®** (adalimumab) *Nonformulary:* **Cimzia®** (certolizumab pegol) **Kineret®** (anakinra) **Simponi®** (golimumab) **Orencia® SC** (abatacept)	**Enbrel® and Humira®:** • *Rheumatoid arthritis, juvenile RA or psoriatic arthritis*: Requires three-month trial with two concurrent DMARDs (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azothioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine. • *Ankylosing spondylitis*: requires therapy is being supervised by a Rheumatologist. • *Moderate to severe psoriasis*: 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. • *Crohn's Disease*: 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.*** **Orencia® SC:** Coverage will be provided for adults with Rheumatoid Arthritis after a three-month trial with two concurrent DMARDs (one must be methotrexate unless contraindicated) **AND** treatment failure or intolerance to Enbrel® and Humira®. **Cimzia®:** The following criteria are used in reviewing medical exceptions for **Cimzia®** A. ***OR*** B. 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): 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. **AND** 2) Previous trial/failure/contraindication of Humira®. **OR** B. Age 18 or older and for the treatment of rheumatoid arthritis when the following criteria are met (1 **AND** 2) 1) Treatment failure with a three month trial with two concurrent DMARDs (one must be methotrexate unless contraindicated) **AND** 2) Treatment failure or documented intolerance to Adalimumab (Humira®) **and** Etanercept (Enbrel®) **Kineret®:** Rheumatoid arthritis in adults: Requires three-month trial with two concurrent DMARDs (one must be methotrexate unless contraindicated) **AND** treatment failure or intolerance to Enbrel® and Humira®. Examples of DMARDs include: methotrexate, sulfasalazine, azothioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine. **Simponi®:** 18 years of age or older and A ***OR*** B A. Rheumatoid arthritis and psoriatic arthritis: 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 both Enbrel® **AND** Humira®. **OR** B. Ankylosing spondylitis: Requires a treatment failure or contraindication to both Enbrel® **AND** Humira®

MEDICATION/DRUG CLASS	CRITERIA
Tradjenta™ (linagliptin) *Nonformulary*	Approval for Tradjenta™ requires trial and failure of Januvia®.
Treximet® (sumatriptan/naproxen sodium) *Nonformulary*	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) *Nonformulary*	Requires trial and failure of gemfibrozil [g] **AND** fenofibrate [g].
Triptans: *Formulary:* **Maxalt®/MLT** (rizatriptan) *Nonformulary:* **Alsuma™** (sumatriptan) **Axert®** (almotriptan) **Frova®** (frovatriptan) **Relpax®** (eletriptan) **Sumavel® DosePro®** (sumatriptan injection) **Zomig®** (zolmitriptan)	**Maxalt®/MLT** requires trial and failure of the generic formulary alternative Imitrex® [g]. **Axert®, Frova®, Relpax® and Zomig®** will require trial and failure of both the formulary options Imitrex® [g] **AND** Maxalt®. **Alsuma™ and Sumavel® DosePro®** will require trial and failure of both formulary options Imitrex [g] injection **AND** Maxalt MLT®.
Uloric® (febuxostat) *Formulary*	Requires treatment failure, intolerance or contraindication with formulary alternative generic allopurinol.
Victoza® (liraglutide) *Nonformulary*	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%. Victoza® is **NOT** covered for the primary indication of weight loss in patients with or without diabetes.
Vimovo® (naproxen/ esomeprazole) *Nonformulary*	Approval requires trial and failure of Prilosec [g] **AND** Protonix [g] **AND** Prevacid [g] **AND** one of the following criteria: Member is > 60 years of age or Receiving anticoagulant or antiplatelet therapy or Receiving chronic treatment with oral corticosteroids (>60 days duration) or Has a history of or current diagnosis of peptic ulcer disease, clinically significant gastrointestinal bleeding and/or alcoholism.

MEDICATION/DRUG CLASS	CRITERIA
Voltaren Gel® (diclofenac) *Nonformulary*	For FDA approved indications only. Member must have tried and failed or demonstrated intolerance to oral diclofenac **AND** at least two other oral, traditional NSAIDs unless the patient is unable to take any oral medications. **AND** Coverage will **NOT** be provided in the presence of concurrent therapy with oral NSAIDs or a COX II inhibitor.
Vyvanse® (lisdexamfetamine) *Nonformulary*	Covered for members 6 years of age and older with the appropriate diagnosis 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.
Xalkori® (crizotinib) *Formulary*	Coverage for Xalkori® will be provided for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by a FDA approved test.
Xenazine® (tetrabenazine) *Formulary*	Approval will require diagnosis of chorea associated with Huntington's disease **AND**, for doses above 50 mg 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: 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
Xyrem® (sodium oxybate) *Nonformulary*	Requires a diagnosis of narcolepsy and A **OR** B: A. Cataplexy demonstrated by supporting chart documentation or sleep studies **OR** B. Excessive daytime sleepiness demonstrated by supporting chart documentation or sleep studies when (1 **AND** 2): 1. Modafinil in doses up to 400 mg daily has been ineffective, not tolerated or contraindicated. **AND** 2. At least one other formulary/preferred treatment, such as methylphenidate or dextroamphetamine, has been ineffective, not tolerated or is contraindicated. Xyrem® will **NOT** be approved if: 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 Xyrem® is **NOT** considered medically necessary for the following condition(s): 1. Alcohol dependence and withdrawal 2. Fibromyalgia Xyrem® is considered investigational for all other conditions or applications, including, but not limited to, the treatment of: 1. Opioid dependence and withdrawal 2. Parkinsonism 3. Night eating syndrome 4. Myoclonus and essential tremor

MEDICATION/DRUG CLASS	CRITERIA
Zelboraf® **(vemurafenib)** *Formulary*	Coverage for Zelboraf® will be provided for patients with unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation as detected by an FDA-approved test.
Zuplenz® oral soluble film (ondansetron) *Nonformulary*	Requires documentation that the member has experienced treatment failure or intolerance to Zofran ODT [g] **AND** oral Kyrtril [g]. Documentation must be provided as to why continued use of Zofran ODT will harm the patient.