Blue Cross Blue Shield of Michigan

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Blue Cross Blue Shield of MI
Prior Authorization/Step Therapy Program
August 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/Step Therapy Drug Categories
(CLINICAL 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 (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). • Patient does not have prior treatment and failure with Ampyra. **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. • Renewal will not be authorized if there is failure to demonstrate benefit after the initial 3 month trial period while on medication. Continuation and future coverage of Ampyra will not be authorized for patients who have been identified as non-responders. 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® (cyclobenzaprine) *Nonformulary*	Approval requires previous trial and failure of generic immediate-release cyclobenzaprine.

MEDICATION/ DRUG CLASS	CRITERIA
Anabolic Steroids: *Formulary* **Oxandrin®** [g] (oxandrolone) *Nonformulary* **Anadrol-50®** (oxymetholone)	**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):** 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.
Antidepressants: *Nonformulary* **Aplenzin®** (bupropion hydrobromide) **Cymbalta®** (duloxetine) **Forfivo XL®** (bupropion hydrochloride) **Luvox® CR** (fluvoxamine) **Pexeva®** (paroxetine) **Pristiq®** (desvenlafaxine) **Viibryd™** (vilazodone)	**Nonformulary agents:** **Aplenzin®** and **Forfivo XL®** require 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/failure of at least 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.
Anti-Diabetic Agents: *Formulary* **Byetta®** (exenatide) *Nonformulary* **Bydureon™** (exenatide extended-release) **Cycloset®** (bromocriptine) **Jentadueto™** (linagliptin / metformin) **Tradjenta™** (linagliptin) **Victoza®** (liraglutide)	**Byetta®, Bydureon™, Cycloset® and Victoza®**: 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 documentation that the member failed to achieve desired glucose control evidenced by a Hgb A1c greater than 7%. **Byetta®, Bydureon™, Cycloset®** and **Victoza®** are **NOT** covered for the primary indication of weight loss in patients with or without diabetes. **Jentadueto™**: Requires successful treatment of linagliptin and metformin as individual agents for at least 3 months. **Tradjenta™**: Requires trial and failure of Januvia® **AND** Onglyza®.

MEDICATION/ DRUG CLASS	CRITERIA
Antipsychotics: *Formulary:* **Abilify** (Aripiprazole) *Non-formulary:* **Fanapt®** **(**Iloperidone) **Invega®** (Paliperidone) **Latuda®** (Lurasidone) **Saphris®** (Asenapine) **Seroquel XR®** (quetiapine fumarate)	**Abilify®**: Requires a trial of a generic antipsychotic (clozapine, risperidone, quetiapine, olanzapine, ziprasidone) **Fanapt®, Latuda®, and Saphris®**: Require a trial of a generic antipsychotic (clozapine, risperidone, quetiapine, olanzapine, ziprasidone) AND Abilify® **Invega®**: Requires trial of generic risperidone (Risperdal®) AND Abilify® **Seroquel XR®**: Requires trial of generic quetiapine (Seroquel®) AND Abilify®
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® (donepezil) 23mg *Formulary*	Requires 3 month trial of Aricept® [g] (donepezil) 10 mg tablets within the last year.
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) *Nonformulary* **Atelvia™** (risedronate) **Binosto™** (alendronate sodium) **Fosamax Plus D®** **(alendronate/vitamin D_3)**	**Actonel®** (risedronate) requires documentation that the member has tried and failed/not tolerated treatment with Fosamax® [g]. **Atelvia™** (risedronate) requires documentation that the member has tried and failed/not tolerated treatment with both Fosamax® [g] **AND** Actonel® (risendronate). **Binosto™** requires documentation that the member has experienced treatment failure or intolerance, or has a contraindication to alendronate (Fosamax®), ibandronate (Boniva®) and Actonel®. **Fosamax Plus D®** requires documentation that the member has tried and failed/not tolerated treatment with both Fosamax® [g] AND Actonel® (risedronate).
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).

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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) *Formulary*	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 female, required that they are not pregnant and may not become pregnant. Coverage is limited to 24 months total of ursodiol plus Chenodal™.
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.
Cymbalta® (duloxetine) *Nonformulary*	Coverage for Cymbalta® will be provided for: <u>Treatment of major depression</u> Approval requires trial and failure of two formulary antidepressants. **OR** <u>Treatment of diabetic neuropathic pain</u> ➢ ***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** <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,

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Cymbalta® continued	cyclobenzaprine, tramadol. **OR** <u>Treatment of Chronic Musculoskeletal Pain</u> 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, tramadol. **OR** <u>Treatment of Generalized Anxiety Disorder</u> 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 <u>NOT</u> provided for weight loss management in patients with HIV infection**.

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Erivedge™ (vismodegib) *Formulary*	Coverage will be provided for the following: 1) Prescriber is an oncologist or dermatologist 2) Diagnosis of metastatic Basal Cell Carcinoma (mBCC) OR 3) Diagnosis of locally advanced Basal Cell Carcinoma (laBCC) a) that has recurred following surgery OR b) who are not candidates for surgery AND who are not candidates for radiation. Coverage will be reviewed to assess disease progression and intolerance. Coverage will NOT be provided for all other conditions. Initial coverage approval = 6 months.
<u>Erythropoiesis Stimulating Agents (ESAs):</u> *Formulary:* **Aranesp®** (darbepoetin alfa) **Procrit®** (epoetin alfa) ***Nonformulary:*** **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 at least one formulary agent. Coverage duration = 3 months
Ferriprox® (deferiprone) *Nonformulary*	**Coverage** for **Ferriprox®** will be provided for patients with a diagnosis of transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate **AND** monitoring Absolute Neutrophilic Count (ANC) and serum ferritin level prior to and during therapy **AND** documented previous trial of both Exjade® and Desferal®. Coverage will not be provided for all other indications. Initial approval = 12 months. Coverage may be renewed for 12 months with documentation of >20% decline in serum ferritin within one year of baseline level.
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.

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Forteo® (teriparatide) *Formulary*	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], Boniva® [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**.
Giazo® (balsalazide disodium) *Nonformulary*	Coverage for Giazo® will be provided for the treatment of mildly to moderately active ulcerative colitis in patients 18 years of age and older who have had trial and failure or intolerance of generic Colazal® and generic Azulfidine®.
Gilenya™ (fingolimod) *Nonformulary*	Approval for Gilenya™ requires (1,2,3,4 **AND** 5): 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. 5. Patient does not have contraindication to Gilenya™ Renewal Requests Only: Coverage will be provided at 12 month intervals. Authorization will be reviewed annually to confirm that current medical necessity criteria are met and that the medication is effective based on relapse events or MRI data.
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.

MEDICATION/ DRUG CLASS	CRITERIA
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 Inhibitors *Formulary:* **Incivek**™ (telaprevir) **Victrelis**™ (boceprevir)	**Incivek**™ (telaprevir) 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™** (boceprevir) 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) ****Renewal criteria for both Incivek™ and Victrelis™ require updated viral load****

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Horizant™ (gabapentin ER) *Nonformulary*	*Treatment of moderate to severe Restless Leg Syndrome (RLS) in adults*: Approval requires treatment failure of or intolerance to all three of the formulary alternatives: generic Mirapex®, generic Neurontin® AND generic Requip®. OR *Treatment of Postherpetic Neuralgia (PHN):* Approval requires treatment failure of or intolerance to formulary alternatives: -If the patient is equal to or greater than 65 years of age: After a 30 day trial of gabapentin at a dose of 1200mg per day. -If the patient is less than 65 years of age: After a 30 day trial of gabapentin at a dose of 1200mg per day and a tricyclic antidepressant such as amitriptyline, despiramine, or imipramine
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
Inlyta® (Axitinib) *Formulary*	Coverage for Inlyta® will be provided for patients with a documented diagnosis of Advanced Renal Cell Carcinoma (RCC) AND documented trial of one prior systemic treatment showing ineffective, not tolerated or contraindicated. Coverage will not be provided for all other conditions.
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.
Jakafi™ **(**ruxolitinib) *Formulary*	Coverage for Jakafi™ requires chart notes documenting **ALL** of the following: 1) Diagnosis of intermediate or high risk myelofibrosis 2) Refractory or not a candidate to hydroxyurea 3) Prescribing physician is an oncologist/hematologist 4) Imaging tests documenting spleen enlargement and measurement 5) Bone marrow testing documenting fibrosis 6) Documentation of disease symptoms (for example: abdominal discomfort, pain under left rib, night sweats, itching, bone/ muscle pain, and early satiety)7) CBC and platelet count prior to initiation of therapy 8) Requested dose appropriate for platelet count and renal or hepatic impairment Initial approval = 6 months Renewal of therapy requires documentation of at least a 35% reduction in spleen volume **OR** a 50% reduction in palpable spleen length **AND** at least a 50% improvement of symptoms compared to score assessed prior to treatment measured by the MFSAF diary. Coverage may be renewed for 6 months based on response.

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Kalydeco™ (ivacaftor) *Formulary*	Coverage will be provided for patients with a documented diagnosis of cystic fibrosis (CF) with the specific G551D mutation confirmed by a genetic test. Coverage will NOT be provided for all other conditions such as but not limited to: other mutations aside from G551D mutation, heterozygous F508-del CFTR mutation. Initial approval = 12 months. Authorization may be reviewed at least annually to assess treatment response.
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.
Korlym™ (mifepristone) *Formulary*	Coverage for Korlym requires documentation of **ALL** the following: 1) Diagnosis of hypercortisolism as a result of endogenous Cushing's syndrome 2) Diagnosis of type II diabetes mellitus or glucose intolerance 3) Surgical treatment has been ineffective or not a candidate for surgery 4) Treatment failure to ketoconazole or mitotane, unless contraindicated or not tolerated Initial approval = 6 months. Renewal of coverage requires documentation of ≥ 25% reduction in HbA1c from baseline. Coverage may be renewed for 6 months based on response. Coverage will NOT be provided for all other conditions.
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.
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 , post-herpetic neuralgia or neuralgia or neuropathic pain associated with spinal cord injury ➢ ***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.

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Mirapex® ER (pramipexole ER) *Nonformulary*	Coverage approved for the treatment of Parkinson's. Requires trial and failure of Mirapex® [g].
Myrbetriq™ (mirabegron extended release) *Nonformulary*	Coverage will be provided when the following are met: 1. Treatment failure or intolerance to at least two generic formulary preferred OAB (Overactive Bladder) therapies **AND** 2. Documentation of no hypertension, or documentation of controlled hypertension via treatment, based on 3 most recent blood pressure readings.
Narcotics: Fentanyl Products *Formulary:* **Actiq® [g]** (fentanyl citrate) *Nonformulary:* **Abstral®** (fentanyl citrate) **Fentora®** (fentanyl citrate) **Onsolis®** (fentanyl citrate) **Lazanda®** (fentanyl citrate) **Subsys™** (fentanyl citrate) Other Narcotic Agents *Formulary:* **Oxycontin** (oxycodone HCl) **Nucynta® Immediate Release** (tapentadol) *Nonformulary:* **Butrans®** (buprenorphine) **Exalgo®** (hydromorphone ER) **Opana ER** (oxymorphone HCl) **Nucynta® ER** (tapentadol)	**Actiq®** requires a diagnosis for the treatment of breakthrough cancer pain in members that are tolerant to high dose narcotics and who are currently receiving a long-acting narcotic. **Abstral®, Fentora® and Onsolis®** require a diagnosis for the treatment of breakthrough cancer pain in members that are tolerant to high dose narcotics and who are currently receiving a long-acting narcotic. Also the member must have experienced treatment failure of or intolerance to generic short acting fentanyl products. **Lazanda®** and **Subsys™** require a diagnosis for the treatment of breakthrough cancer pain in members that are tolerant to high dose narcotics and who are currently receiving a long-acting narcotic. Also the member must have experienced treatment failure of or intolerance to fentanyl citrate buccal lollipop and buccal tablet. **Butrans®** 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. Butrans® also requires trial and failure or intolerance of **TWO** of the following: extended release morphine, fentanyl patch, tramadol extended release, or methadone. Coverage will not be provided for use as an "as needed" analgesic or for acute pain or postoperative pain. **Exalgo®** 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. **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. **Nucynta® Immediate Release** requires documentation that the patient has experienced treatment failure of or intolerance to generic immediate-release tramadol or tramadol/acetaminophen *AND* **TWO** formulary immediate-release narcotics: MS-IR(g), Opana IR(g), or oxycodone IR(g). **If use is to exceed 30 days**, Nucynta must be used in combination with a long-acting narcotic, such as methadone, morphine sulfate extended-release (Oramorph(g), MS Contin(g)), or fentanyl transdermal patch (Duragesic(g)).

MEDICATION/ DRUG CLASS	CRITERIA
Narcotics continued	**Opana® ER and Oxycontin®**: Requires documentation that the member has experienced treatment failure of or intolerance to two of the following long-acting formulary agents: methadone, morphine sulfate extended-release, fentanyl transdermal patch.
Nasal Steroids and Combination Products: *Formulary:* **Nasonex®** (mometasone) **Rhinocort AQ®** (budesonide) *Nonformulary:* **Beconase® AQ** (beclomethasone) **Dymista®** (azelastine and fluticasone) **Omnaris®** (ciclesonide) **Qnasl™ (**beclomethasone) **Veramyst®** (fluticasone) **Zetonna™** (ciclesonide)	Approval **o**f **Beconase AQ, Nasonex, Omnaris, Qnasl, Rhinocort AQ, Veramyst,** or **Zetonna** require trial and failure/intolerance of 2 of the following intranasal steroids: generic fluticasone (Flonase®), generic flunisolide (Nasarel®) or generic triamcinolone (Nasacort AQ®). **Dymista®** requires documentation that the member has experienced treatment failure of or intolerance to 2 generic intranasal steroid products one of which must be intranasal fluticasone used in combination with intranasal azelastine for a 3 month trial.
Neupro® (rotigotine transdermal system) *Nonformulary*	1. For the treatment of the signs and symptoms of Parkinson's disease and documented treatment failure, intolerance or contraindication of Mirapex® (g) and Requip® (g) unless the member is unable to take an oral formulation. **OR** 2. For the treatment of moderate-to-severe primary restless legs syndrome (RLS) and documented treatment failure, intolerance or contraindication of Mirapex® (g), Requip® (g) and Neurontin® (g) unless the member is unable to take an oral formulation.
Nexiclon™ XR (clonidine ER) *Nonformulary*	Requires appropriate diagnosis for coverage and trial and failure of generic clonidine tablet or generic clonidine patch.
Nuedexta™ (dextromethorphan-quinidine) *Formulary*	Requires appropriate diagnosis for coverage. Coverage approved for the treatment of PBA (pseudobulbar affect) secondary to ALS and/or MS.
Nuvigil® (armodafinil) *Nonformulary*	Coverage for Nuvigil requires treatment failure or intolerance to generic Provigil.
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.
Onfi™ (clobazam) *Nonformulary*	For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years and older.

MEDICATION/ DRUG CLASS	CRITERIA
Oral Tetracyclines: *Formulary* **Adoxa®** [g] (doxycycline) **Doryx®** [g] (doxycycline) **Solodyn®** [g] (minocycline) *Nonformulary* **Oracea®** (doxycycline)	**Adoxa®, Doryx® and Oracea®** Requires documentation that the member has experienced treatment failure of a preferred generic doxycycline product. **Solodyn®** Requires documentation that the member has experienced treatment failure of a preferred generic minocycline product.
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.
Picato® (ingenol mebutate) *Nonformulary*	Coverage for **Picato®** will be provided after **ALL** the following criteria have been met: 1. Chart notes showing diagnosis of actinic keratosis 2. Member has not responded to, or has been intolerant to 3 different treatment courses using cryotherapy or phototherapy 3. Trial of two formulary agents, which may include Efudex(g), Aldara(g) or Retin-A(g)
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 ≤ 75mg/day Renewal approval for Promacta® requires recent platelet count of 30,000-150, 000 mcL **AND** dose is ≤ 75mg/day.
Proton Pump Inhibitors (PPI's): *Nonformulary:* **Aciphex®** (rabeprazole) **Dexilant™** (dexlansoprazole) **Nexium®** (esomeprazole)	Approval of nonformulary medications requires failure of or intolerance to all formulary alternatives: Prilosec® [g] **AND** Protonix® [g] **AND** Prevacid® / Prevacid® SoluTab™ [g].

[g]= generic available

MEDICATION/ DRUG CLASS	CRITERIA
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.
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®)
Sandostatin® (octreotide) [g] **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.

MEDICATION/ DRUG CLASS	CRITERIA
Sedative/Hypnotics: *Nonformulary:* **Edluar**™ (zolpidem tartrate SL) **Intermezzo**® (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. **Intermezzo**® requires trial and failure, or intolerance, to the formulary alternatives Ambien CR® (zolpidem extended release) **AND** Sonata® (zaleplon). Also, coverage will not be approved for combination therapy with other sedative hypnotics.
Silenor™ (doxepin) *Nonformulary*	Requires trial and failure of the formulary alternatives Ambien [g] **AND** Sonata [g].
Solaraze® (diclofenac) *Formulary*	Requires documentation of diagnosis of actinic keratosis and that the member has not responded to, or has been intolerant of 3 different treatment courses using cryotherapy or phototherapy, plus 2 formulary agents, which may include Efudex(g), Aldara(g) and Retin-A(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.
Targretin® capsules(bexarotene) *Nonformulary*	Coverage will be provided for the FDA approved indication **only**: Targretin (bexarotene) capsules are indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients who are refractory to at least one prior systemic therapy. Initial approval = 12 months. Coverage may be renewed for 12 months based on response. Coverage will NOT be provided for Alzheimer's disease.
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)
TNF-alpha agents and related products: *Formulary:* **Enbrel**® (etanercept) **Humira**® (adalimumab) *Nonformulary:* **Cimzia**® (certolizumab pegol) **Kineret**® (anakinra)	**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, azathioprine, 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.

[g]= generic available

MEDICATION/ DRUG CLASS	CRITERIA
Simponi™ (golimumab) **Orencia® SC** (abatacept)	• <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.*** **Orcenia® 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®:** <u>Rheumatoid arthritis in adults</u>: 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, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine. **Simponi™:** 18 years of age or older and A ***OR*** B 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 both Enbrel® **AND** Humira®. **OR** B. <u>Ankylosing spondylitis</u>: Requires a treatment failure or contraindication to both Enbrel® **AND** Humira®.

MEDICATION/ DRUG CLASS	CRITERIA
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;* **Axert®** (almotriptan) **Frova®** (frovatriptan) **Relpax®** (eletriptan) **Sumavel™ DosePro™** (sumatriptan injection) **Zomig®/ZMT®** (zolmitriptan)	**Maxalt®/MLT** requires trial and failure of the generic formulary alternative Imitrex® [g]. **Axert®, Frova®, Relpax®, Zomig®**/ZMT® will require trial and failure of both the formulary options Imitrex® [g] **AND** Maxalt®. **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.
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.
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.

MEDICATION/ DRUG CLASS	CRITERIA
Weight Loss Medications: **Belviq** ® (lorcaserin) **Qsymia™** (phentermine and topiramate) ***Nonformulary***	**Belviq and Qsymia™**: Initial coverage (up to 3 months) may be authorized for members who meet one of the following criteria: 1. Documentation is provided that the member's BMI is ≥ 30 kg/m^2 2. Documentation is provided that the member's BMI is ≥ 27 kg/m^2 AND has at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes) AND all of the following: • Documentation of a concurrent lifestyle modification program • The member is ≥ 18 years • Trial and failure of generic phentermine for Qsymia™ **Belviq**®: Continued coverage (up to 12 months) may be authorized for members who provide documentation of weight loss of at least 5% during the first 12 weeks of treatment. **Qsymia™**: Continued coverage may be authorized for members who provide documentation of weight loss of at least 3% during the first 12 weeks of treatment on 7.5mg/46mg dose. Continued coverage (up to 12 months) for Qsymia™ may be authorized for members who provide documentation of a weight loss of at least 5% during 12 weeks on the maximum daily dose of 15mg/92mg.
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 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: 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 400mg daily has been ineffective, not tolerated, or

MEDICATION/ DRUG CLASS	CRITERIA
Xyrem® continued	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
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™ (ondansetron) oral soluble film *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.