BCBSM monitors the use of certain medications to ensure our members receive the most appropriate and cost-effective drug therapy. Prior authorization is the process we use to ensure that members always receive prescription drugs that are most appropriate for treating their conditions. Prior authorization requires that a physician obtains approval from BCBSM before prescribing select prescription drugs.

In the case of drugs that require step therapy, previous treatment with one or more formulary drugs may be necessary. In addition, certain clinical criteria must be met before coverage is provided. For example, members may have to have certain laboratory values or be treated for specific diseases. The criteria for authorization are based on current medical information and the recommendations of the BCBSM 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 authorization. Your physician can contact our Pharmacy Help Desk to request authorization for these drugs.

When your doctor prescribes a brand-name drug that is nonformulary, it requires prior authorization or it will not be covered under your drug plan. BCBSM reviews all physician and member requests to determine if the drug is medically necessary and that there are not equally effective alternative drugs on the formulary. In the chart below, we have identified drug classes that require prior authorization. If the criteria are not met, authorization will not be approved.

Please call the Customer Service telephone 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 classes

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<thead>
<tr>
<th>Medication/Drug Class</th>
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<tbody>
<tr>
<td><strong>Adcirca™</strong> (tadalafil)</td>
<td>Approved for members with a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for Adcirca™ in combination with bosentan (Tracleer®), epoprostenol (Flolan®), treprostinil (Remodulin®) or iloprost (Ventavis®) is provided after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient’s symptoms. Coverage is not provided for Adcirca™ in situations where patients are receiving nitrate therapy.</td>
</tr>
<tr>
<td><strong>Amitiza®</strong> (lubiprostone)</td>
<td>Approval of lubiprostone requires the following: 1. Patient must be age 18 years or older 2. Diagnosis of chronic idiopathic constipation 3. Documented failure within the last 12 months using: a. One fiber laxative AND b. Two stimulant laxative products 4. Drug-induced constipation must be ruled out</td>
</tr>
</tbody>
</table>
| **Anabolic Steroids**  
*Anadrol-50® (oxymetholone)*  
*Deca-Durabolin® (nandrolone decanoate)*  
*Oxandrin®* [g] (oxandrolone) | **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) |
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<tr>
<td><strong>OR for the treatment of HIV-associated wasting OR if prophylactic therapy is needed in patients with hereditary angioedema.</strong></td>
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<tr>
<td><strong>Arcalyst™ (rilonacept)</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>COX-2 Preferential NSAIDs:</strong> <strong>Celebrex® (celecoxib)</strong></td>
<td>Requires prior use of an NSAID. Patients who are on concurrent therapy with an ulcer drug or anticoagulant or patients who are 65 years of age and older are approved outright.</td>
</tr>
</tbody>
</table>
| **Erythropoiesis Stimulating Agents (ESAs)**  
* Aranesp® (darbepoetin alfa)  
* Epogen® (epoetin alfa)  
* Procrit® (epoetin alfa) | Information may need to be submitted describing the use and setting of the drug to make the determination. Approved for use in the following conditions with a hemoglobin less than 12mg/dl: anemia of chronic renal disease (not yet on dialysis), anemia secondary to active chemotherapy of solid tumors, anemia secondary to active zidovudine (AZT) therapy, anemia in myelodysplastic disorders and prophylactic use during some major surgeries. Coverage is not provided in the following conditions:  
A. Anemia due to folate, vitamin B-12, and iron deficiencies, hemolysis, bleeding, or bone marrow fibrosis  
B. Anemia associated with treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers  
C. Anemia due to cancer treatment in patients with uncontrolled hypertension  
D. Anemia not associated with cancer treatment or renal disease under inclusion criteria  
E. Anemia associated only with radiotherapy  
F. Prophylactic use to prevent chemotherapy induced anemia  
G. Prophylactic use to reduce tumor hypoxia  
H. Patients with Erythropoietin type resistance due to neutralizing antibodies.  
Coverage duration = 3 months |
| **Flector® (diclofenac patch)** | Use of this agent will require medical necessity documentation. Alternative is oral diclofenac. Only FDA-approved for short term pain management. |
| **Forteo® (teriparatide)** | Forteo® will be provided for the following guidelines:  
1. For the treatment of postmenopausal women with osteoporosis who are at high risk of fracture or men with primary or hypogonadal osteoporosis who are at high risk for fracture and meet the following criteria (a, b and c):  
   a. Have a bone mineral density (BMD) that is 2.5 standard deviations or more below the mean (T-score at or below -2.5).  
   b. Patient has tried and failed a bisphosphonate (formulary agents include Fosamax® [g] and Actone®) 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)  
      2. Documented intolerance to a bisphosphonate  
   c. Coverage will not be provided in the following situations:  
      1. Concurrent treatment with a bisphosphonate  
      2. Hypercalcemia |

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|                       | 3. Paget’s disease  
4. Bone metastases or a history of skeletal malignancies  
5. Metabolic bone disease other than osteoporosis  
6. Pediatric patients or young adults with open epiphyses  
7. Prior radiation therapy involving the skeleton  
2. Forteo will be approved for a maximum of two years. |
| **Growth Hormone** (somatropin) (all) | Coverage will be provided for:  
**Pediatric Growth Hormone Deficiency**  
Children (M < 16 years old, F < 15 years old):  
*Initial Treatment:* Req. ≥ six months of initial height measurements, Ht < 5th percentile for age (based on initial evaluation), abnormal growth velocity based on ≥ six months 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 six months of therapy and documented growth of ≥ 4.5 cm/year for each succeeding six 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. |
| **H.P. Acthar Gel**® (repository corticotropin) | 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 ACTH gel is considered not 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 ACTH gel. |
| **Increlex**® (mecasermin) | Approval will require the following:  
1. Medication to be prescribed by a pediatric endocrinologist **AND**  
2. Diagnosis of one of the following:  
   a. Severe primary IGF-1 deficiency or growth hormone gene deletion or genetic mutation of growth hormone receptor (Laron Syndrome) **AND**  
   b. Current height measurement at less than 3rd percentile for age and sex **AND**  
   c. IGF-1 level greater than or equal to three standard deviations below normal **AND**  
   d. Normal or elevated growth hormone levels based on at least one growth hormone stimulation test **AND**  
   e. 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**
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|                       | 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 |
|                       | Mecasermin is considered investigational for all other indications, including, but not limited to:  
a. Amyotrophic lateral sclerosis (ALS)  
b. Children less than two years of age  
c. Combination treatment with growth hormone  
d. Diabetes  
e. Individuals with closed growth plates  
f. Secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism or chronic treatment with steroids  
g. Idiopathic short stature  
h. Growth failure due to other identifiable causes (including, but not limited to Prader-Willi syndrome, Russell-Silver syndrome, Turner syndrome, Noonan syndrome)  
i. Less severe forms of IGF-1 deficiency |
| **Lotronex** (alosetron hydrochloride) | 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. |
| **Narcotics**  
Actiq® [g] (fentanyl citrate)  
*Fentora™* (fentanyl citrate)  
*Onsolis™* (fentanyl citrate) | Requires appropriate diagnosis for coverage and tolerance to high doses of narcotics. |
| **Promacta®** (eltrombopag) | 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 > two 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. |
| **Relistor™** (methylnaltrexone bromide) injection | 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 two weeks  
3. Duration of methylnaltrexone therapy shall be limited to three 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 five days duration  
5. Maximum initial regimen shall be one box (seven doses). Monthly doses will not exceed 14  
Patients experiencing withdrawal symptoms while taking methylnaltrexone should consider using an alternate form of therapy |
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<td><strong>Remodulin® (treprostinil)</strong></td>
<td>For the treatment of PAH in patients with New York Heart Association (NYHA) class II to IV symptoms OR To diminish the rate of clinical deterioration in patients requiring transition from epoprostenol (Carefully consider the risks and benefits of each drug prior to transition)</td>
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<tr>
<td><strong>Revatio® (sildenafil citrate)</strong></td>
<td>Approved for members with a diagnosis of Pulmonary Arterial Hypertension (PAH). Coverage for sildenafil (Revatio®) in combination with bosentan (Tracleer®), epoprostenol (Flolan®), treprostinil (Remodulin®) or iloprost (Ventavis®) is provided after monotherapy with one of these agents has been found to be inadequate in the treatment of the patient’s symptoms. Coverage is not provided for sildenafil (Revatio®) in situations where patients are receiving nitrate therapy.</td>
</tr>
<tr>
<td><strong>Sancuso® (granisetron)</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Sandostatin® (octreotide) [g]</strong> Sandostatin LAR®</td>
<td>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 AND 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)</td>
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<tr>
<td><strong>Savella™ (milnacipran)</strong></td>
<td>Treatment of Fibromyalgia Fibromyalgia characterized by pain in all four body quadrants, for at least three months, with or without fatigue and sleep disturbance AND 1. The patient has tried and experienced intolerance to gabapentin OR a. Had inadequate pain relief at doses of 1200 mg or above AND b. Has tried and experienced intolerance or inadequate pain relief to three of the following: Tricyclic antidepressant SSRI SNRI Cyclobenzaprine Tramadol</td>
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| **TNF-alpha agents and related products:**    | **Enbrel® and Humira®:**  
| *Cimzia*<sup>®</sup> (certolizumab pegol injection) | *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  
| *Enbrel*<sup>®</sup> (etanercept)            | *Ankylosing spondylitis:* Requires therapy is being supervised by a Rheumatologist  
| *Humira*<sup>®</sup> (adalimumab)            | *Moderate to severe psoriasis:* Requires three months of previous treatment with topical corticosteroids **AND** three months treatment with PUVA (unless PUVA is contraindicated) **AND** therapy must be supervised by a Dermatologist  
| *Kineret*<sup>®</sup> (anakinra)              | *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.**  
| *Simponi™* (golimumab)                       |                                                                                                                                                                                                             |
| **Enbrel® and Humira®:**                     |                                                                                                                                                                                                             |
| **Cimzia®:**                                 | The following criteria are used in reviewing medical exceptions for Cimzia®:  
| A. Age 18 or older and for the treatment 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 two months **AND**  
| 2) Previous trial/failure/contraindication of Remicade® or 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 (a **OR** b) |  
| a. Infliximab (Remicade®) **OR** |  
| b. Adalimumab (Humira®) **and** Etanercept (Enbrel®) **OR** |  
| **Kineret®:**                                | Rheumatoid arthritis in adults: Requires three-month trial with two concurrent DMARDs, (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine **AND** Treatment failure or intolerance to Enbrel® and Humira®  
<p>| <strong>Simponi™:</strong>                                |<br />
| 18 years of age or older and A <strong>OR</strong> B |<br />
| A. Rheumatoid arthritis and psoriatic arthritis: Requires a three-month trial on two concurrent Disease Modifying Anti-Rheumatic Drugs (DMARDs), one of which must be methotrexate unless contraindicated <strong>AND</strong> treatment failure or contraindication to Remicade® <strong>OR</strong> both Enbrel® <strong>AND</strong> Humira® <strong>OR</strong> |<br />
| B. Ankylosing spondylitis: Requires a treatment failure or contraindication to Remicade® <strong>OR</strong> treatment failure or contraindication to both Enbrel® <strong>AND</strong> Humira®. |</p>
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<td><strong>Tracleer™</strong> (bosentan)</td>
<td>Requires a diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class II to IV symptoms.</td>
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<tr>
<td><strong>Uloric®</strong> (febuxostat)</td>
<td>Requires treatment failure, intolerance or contraindication with formulary alternative allopurinol.</td>
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</tbody>
</table>
| **Xenazine®** (tetrabenazine) | 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 |

[g] = generic available