

# Blue Care Network

## Prior Authorization and Step-Therapy Guidelines (Formerly BCN Quality Interchange Program)

### January 2013

Blue Care Network's Prior Authorization and Step-Therapy Guidelines (formerly called the BCN Quality Interchange Program) help ensure that safe, high-quality cost-effective drugs are prescribed prior to the use of more expensive agents that may not have proven value over current formulary medications. Our prior authorization and step-therapy criteria are based on current medical information and have been approved by the BCBSM/BCN Pharmacy and Therapeutics Committee. These guidelines apply to all members with a BCN commercial drug rider.

**PRIOR AUTHORIZATION (PA):** Drugs requiring PA are covered only if the member meets specific criteria.

**STEP THERAPY (ST):** Drugs subject to ST require previous treatment with one or more formulary agents prior to coverage.

#### OTHER UTILIZATION MANAGEMENT TOOLS:

- Quantity Limits (QL) and mandatory generic dispensing are applied to all BCN commercial drug riders.
- Specialty drugs <s> are limited to a maximum 30-day supply per fill and are available through Walgreens Specialty Pharmacy and most retail pharmacies. Some specialty drugs require a 15-day first fill.
- Most BCN members do not have coverage for nonformulary drugs. Requests for coverage of nonformulary drugs are considered when the member meets BCN's criteria and the member has tried and failed to respond to an adequate trial of the available formulary agents from the same drug class, or the available formulary agents would pose unnecessary risk to the member.

Please visit us online at [BCBSM.com/RxInfo](http://BCBSM.com/RxInfo) for more information.

This information applies to members with a BCN commercial drug benefit. Criteria for **BCN Advantage<sup>SM</sup>** and **Blue Cross Complete of Michigan** members can be viewed on our Web site: [MiBCN.com](http://MiBCN.com).

**(g)=generic available**

ANTI-INFECTIVES	
<b>Anti-Fungals</b>	
Approval duration: up to 3 months	
<b>Nonformulary:</b> Lamisil <sup>®</sup> Granules	Requires documentation that the member has experienced treatment failure of or intolerance to at least three months of treatment with griseofulvin (Grifulvin V <b>(g)</b> ) suspension.
<b>Miscellaneous Anti-infectives</b>	
Approval duration: up to 3 months	
<b>Nonformulary:</b> Cayston <sup>®</sup>	Coverage is provided for the treatment of pneumonia in patients with cystic fibrosis.
<b>Quinolones</b>	
Approval duration: up to 1 month	
<b>Formulary:</b> Cipro <sup>®</sup> XR <b>(g)</b> (ciprofloxacin-extended release)	<b>Formulary agents:</b> <b>Cipro XR(g):</b> Approved only for uncomplicated urinary tract infection (cystitis). Alternatives include Cipro <b>(g)</b> 100-250mg BID x 3 days and Bactrim DS <sup>®</sup> <b>(g)</b> BID x 3-5 days.

**ANTI-INFECTIVES (Cont.)**

<b>Tetracyclines</b>		Approval duration: up to 1 year
<p><b>Formulary:</b> Adoxa®(g) (doxycycline), Doryx®(g) (doxycycline), Monodox®(g) (doxycycline), Solodyn®(g) (minocycline),</p> <p><b>Nonformulary:</b> Oracea®, Solodyn, Ximino™</p>	<p><b>Formulary agents*:</b> <b>Adoxa(g):</b> Requires documentation that the member has experienced treatment failure of or intolerance to generic doxycycline monohydrate (Monodox (g)). <b>Doryx(g), Monodox(g):</b> Requires documentation that the member has experienced treatment failure of or intolerance to generic immediate release doxycycline hyclate (Periostat(g), Vibramycin (g), Vibratabs (g))</p> <p><b>Nonformulary agents*:</b> <b>Oracea:</b> Requires documentation that the member has experienced treatment failure of or intolerance to generic doxycycline monohydrate (Monodox (g)). <b>Solodyn, Ximino:</b> Requires documentation that the member has experienced treatment failure of or intolerance to generic minocycline immediate release (Minocin (g), Dynacin (g)).</p> <p>*Approved if above criteria are met, and a copy of the completed MedWatch form (that has been submitted to the FDA) has been submitted to the plan to document treatment failure of or intolerance to a formulary agent.</p>	

**ANTINEOPLASTICS & IMMUNOSUPPRESSANTS**

<b>Hormonal Agents</b>		Approval duration: up to 1 year
<p><b>Formulary:</b> Arimidex® (g) (anastrozole), Aromasin® (g) (exemestane), Femara® (g) (letrozole)</p>	PA required for males: Approved only for ER-positive breast cancer treatment.	
<b>Immunomodulators</b>		Approval duration: up to 1 year
<p><b>Formulary:</b> Arcalyst™ (riloncept)</p> <p><b>Nonformulary:</b> Revlimid® Rayos™</p>	<p><b>Formulary agent:</b> <b>Arcalyst:</b> Approved for the treatment of cryopyrin-associated periodic syndrome in members ≥12 years of age.</p> <p><b>Nonformulary agent:</b> <b>Revlimid:</b> Approved for treatment of transfusion-dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes (MDS) with deletion 5q abnormality; multiple myeloma, or members with documentation of enrollment in a Phase II-IV investigative study approved by an appropriate Investigational Review Board (IRB). MDS must be confirmed by FISH analysis or other genetic testing. <b>Rayos:</b> Member must have a diagnosis of rheumatoid arthritis and documentation of trial or intolerance of two generic oral corticosteroids, one of which must be prednisone and an explanation why delayed release is expected to work if prednisone immediate release has not.</p>	

<b>Kinase Inhibitors &amp; Molecular Target Inhibitors</b>		Approval duration: up to 1 year
<p><b>Formulary:</b> Afinitor, Disperz® (everolimus), Bosulif® (bosutinib), Caprelsa® (vandetanib),</p> <p>Cont. next page...</p>	<p><b>Formulary agents*:</b> <b>Afinitor:</b> Approved for the treatment of advanced renal cell carcinoma in members who have experienced disease progression or recurrence following treatment with Sutent or Nexavar, OR requires documentation. <b>Afinitor Disperz:</b> Approved for adults and pediatric use (&gt; 1 year of age) with a diagnosis of: Tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. <b>Bosulif:</b> Requires documentation that the member has been newly diagnosed with chronic phase Philadelphia chromosome-positive chronic myeloid (Ph+ CML), or accelerated or chronic phase in situations where the member has experienced resistance or intolerance to prior therapy with imatinib mesylate (Gleevec). Member must have also previously tried and failed one other TKI, either dasatinib (Sprycel) or nilotinib (Tasigna), with documentation of failure OR intolerance per patient records. <b>Caprelsa:</b> Approved for the treatment of symptomatic or progressive medullary thyroid cancer (MTC) in patients with unresectable, locally advanced or metastatic disease.</p>	

ANTINEOPLASTICS & IMMUNOSUPPRESSANTS (Cont.)	
Kinase Inhibitors & Molecular Target Inhibitors (cont.)	Approval duration: up to 1 year
<p><b>Formulary:</b>  Hycamtin® (topotecan),  Iressa® (gefitinib),  Inlyta® (axitinib),  Nexavar® (sorafenib),  Sprycel® (dasatinib),  Sutent® (sunitinib),  Tarceva® (erlotinib),  Tasigna® (nilotinib),  Tykerb® (lapatinib),  Votrient® (pazopanib),  Xalkori® (crizotinib),  Zelboraf® (vemurafenib)</p> <p><b>Nonformulary:</b>  Xtandi®,  Zytiga®</p>	<p><b>Formulary agents*:</b>  <b>Hycamtin:</b> Approved for treatment of relapsed small cell lung cancer.  <b>Iressa:</b> Approved only for members continuing existing therapy prior to the 09/2005 FDA label revisions.  <b>Inlyta:</b> Approved for treatment of advanced recurrent renal cell carcinoma in members who has experienced treatment failure of or intolerance to one systemic treatment.  <b>Nexavar:</b> Approved for treatment of advanced or recurrent renal cell carcinoma or hepatocellular carcinoma.  <b>Sprycel:</b> Approved for treatment of chronic myelogenous leukemia in members who have experienced resistance or intolerance to Gleevec; treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia in members who have experienced resistance or intolerance to Gleevec or cytotoxic chemotherapy.  <b>Sutent:</b> Approved for treatment of advanced renal cell carcinoma or gastrointestinal stromal tumor. Evidence of disease progression or intolerance to Gleevec must be provided for members with gastrointestinal stromal tumor.  <b>Tarceva:</b> Approved for treatment of non-small cell lung cancer in members who have experienced treatment failure with at least one chemotherapy regimen or treatment of pancreatic cancer in members who will be receiving Tarceva in combination with gemcitabine.  <b>Tasigna:</b> Requires documentation that the member has been newly diagnosed with chronic phase Philadelphia chromosome-positive chronic myeloid (Ph+ CML), or accelerated or chronic phase in situations where the member has experienced resistance or intolerance to prior therapy with imatinib mesylate (Gleevec).  <b>Tykerb:</b> Approved only for treatment of HER2 or HER2/neu positive advanced or metastatic breast cancer. Evidence of disease progression following treatment with an anthracycline, a taxane, and trastuzumab (Herceptin) must be provided. The member must be receiving Tykerb in combination with Xeloda.  <b>Xalkori:</b> Approved for treatment of advanced or metastatic non-small cell lung cancer that is anaplastic lymphoma kinase positive.  <b>Votrient:</b> Approved for treatment of advanced renal cell carcinoma.  <b>Zelboraf:</b> Approved for the treatment of unresectable or metastatic melanoma with a BRAF V600E mutation.</p> <p><b>Nonformulary agent*:</b>  <b>Xtandi, Zytiga:</b> Requires a diagnosis of metastatic castration-resistant prostate cancer (CRPC) in patients who have previously received chemotherapy treatment with docetaxel. Also requires members to receive concurrent therapy with oral prednisone.</p> <p><i>*Approved for FDA indication, or requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB.</i></p>
Miscellaneous Antineoplastic Agents	Approval duration: up to 1 year
<p><b>Formulary:</b>  Erivedge™ (vismodegib),  Jakafi® (ruxolitinib),  Zolinza® (vorinostat)</p>	<p><b>Formulary:</b>  <b>Erivedge:</b> Approved for the treatment of metastatic basal cell carcinoma.  <b>Jakafi:</b> Approved for the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, postpolycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Requires documentation that the member has experienced treatment failure of or intolerance to hydroxyurea.  Approval duration: up to 6 months  <b>Zolinza:</b> Approved for treatment of cutaneous manifestation of cutaneous T-cell lymphoma and requires documentation of persistent progressive or recurrent disease after trial with two systemic therapies, such as oral bexarotene (Targetin), α-interferon (Intron-A, Pegasys, PEG-Intron), denileukin diftitox (Ontak), photochemotherapy (Psoralen plus ultraviolet A (PUVA)), or systemic chemotherapy, OR requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB.</p>

<b>CARDIOVASCULAR, HYPERTENSION, CHOLESTEROL</b>	
<b>Alpha-adrenergic Agents</b> Approval duration: up to 10 years	
<b>Nonformulary:</b> Nexiclon™ XR	Requires documentation that member has experienced failure of or intolerance to Catapres(g) or Catapres-TTS(g).
<b>Angiotensin Converting Enzyme Inhibitors (ACE-Inhibitor)</b> Approval duration: up to 10 years	
<b>Nonformulary:</b> Altace® Tablets	Requires documentation that member has experienced failure of or intolerance to Altace(g) capsules.
<b>Angiotensin II Receptor Blockers (ARBS)</b> Approval duration: up to 10 years	
<b>Formulary:</b> Atacand® HCT (g) (candesartan/hctz), Avapro® (g) (irbesartan), Avalide® (g) (irbesartan/HCTZ); Benicar® (olmesartan medoxomil), HCT, Diovan® HCT(g) (valsartan/hctz)	<b>Formulary agent:</b> <b>Atacand HCT(g), Avapro (g), Avalide (g); Benicar, HCT; Diovan HCT(g):</b> Requires documentation that the member has experienced intolerance to a generic ARB (Cozaar(g), Hyzaar(g), Teveten 600mg(g)).
<b>Nonformulary:</b> Atacand, Azor®, Diovan, Edarbi®, Edarbyclor®, Exforge®, HCT; Micardis®, HCT; Teveten® HCT; Tribenzor™, Twynsta®	<b>Nonformulary agents:</b> <b>Atacand, Diovan, Edarbi, Edarbyclor, Micardis, HCT; Teveten HCT:</b> Requires documentation that the member has experienced intolerance to an ACE inhibitor and experienced treatment failure of or intolerance to a formulary ARB (Atacand HCT (g), Avapro (g), Avalide (g), Cozaar(g), Diovan HCT (g), Benicar, HCT; Hyzaar(g)) <b>Azor, Exforge, HCT; Tribenzor, Twynsta:</b> Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage.
<b>Beta Blockers</b> Approval duration: up to 10 years	
<b>Nonformulary:</b> Bystolic®, Coreg CR™	<b>Bystolic:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least two unique formulary beta blockers, such as betaxolol, atenolol, acebutolol, metoprolol, or bisoprolol. <b>Coreg CR:</b> Requires documentation that the member experienced treatment failure of or intolerance to both carvedilol immediate-release (Coreg(g)) AND metoprolol succinate (Toprol XL(g)).
<b>Cardiovascular Treatment</b> Approval duration: up to 10 years	
<b>Nonformulary:</b> Ranexa®	<b>Ranexa:</b> Requires documentation that the member has experienced treatment failure of or intolerance to both a beta-blocker and a nitrate. The member must have no history of or high risk for cancer.
<b>Cholesterol-Lowering Agents</b> Approval duration: up to 10 years	
<b>Formulary:</b> Crestor® (rosuvastatin)	<b>Formulary agents:</b> <b>Crestor:</b> Requires documentation that member has experienced failure of or intolerance to at least <u>one</u> high dose (>=40mg) generic statin.
<b>Nonformulary:</b> Advicor®, Altoprev®, Juvissync™, Livalo®, Simcor®, TriLipix®, Vytorin®	<b>Nonformulary agents:</b> <b>Altoprev, Livalo, Vytorin:</b> Requires documentation that member has experienced treatment failure of or intolerance to at least one high dose (>=40mg) generic statin AND at least one formulary brand agent (Crestor or Zetia). <b>Advicor, Juvissync, Simcor:</b> Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage. <b>TriLipix:</b> Requires documentation that the member has experienced treatment failure of or intolerance to ALL generic fenofibrates, such as Lofibra(g) and Lopid(g), and Tricor(g) AND supporting evidence for the use of this agent. Concomitant use of a statin does not satisfy criteria.
<b>Miscellaneous Antihypertensives</b> Approval duration: up to 10 years	
<b>Nonformulary:</b> Amturnide®, Tekamlo™, Tekturma®, HCT	<b>Amturnide, Tekamlo:</b> Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage. <b>Tekturma, HCT:</b> Approved for the treatment of hypertension AND requires documentation that the member has experienced treatment failure of or intolerance to ALL of the following drug classes: diuretics, beta-blockers, ACE inhibitors, and angiotensin II receptor blockers (ARBS).

**CENTRAL NERVOUS SYSTEM**

**Anticonvulsants**

Approval duration: up to 10 years

**Nonformulary:**

Gralise™  
Lyrica®  
Onfi™

**Nonformulary:**

**Gralise:** Requires documentation that the member has:

- Diagnosis of neuropathic pain associated with post-herpetic neuralgia AND the member has experienced treatment failure of or intolerance to:
  - o Members ≥ 65 years of age: gabapentin 1200 mg per day
  - o Members < 65 years: gabapentin 1200 mg per day AND a tricyclic antidepressant.
- An explanation why gabapentin extended release is expected to work if gabapentin immediate release has not.

**Lyrica:** Requires documentation that the member has at least one of the three listed diagnoses:

- Seizure disorder that is being treated concurrently with other anticonvulsants
- Neuropathic pain associated with either diabetic peripheral neuropathy or post-herpetic neuralgia AND the member has experienced treatment failure of or intolerance to:
  - o Members ≥ 65 years of age: gabapentin 1200 mg per day
  - o Members < 65 years: gabapentin 1200 mg per day, AND a tricyclic antidepressant.
- Fibromyalgia and documentation that the member has experienced intolerance to gabapentin or inadequate relief from gabapentin 1200 mg per day, AND treatment failure of or intolerance to at least three of the following: a tricyclic antidepressant, an SSRI, an SNRI, cyclobenzaprine, or tramadol.

Additional criteria:

- Approvals are granted only at the specific strength requested.
- Approved dosage is limited to < 300 mg per day for initial treatment and will not exceed 600 mg per day if 300 mg/day is tolerated.
- Any previous authorizations are discontinued when a new strength is approved.

**Onfi:** Requires diagnosis of Lennox-Gastaut Syndrome (LGS) in patients 2 years old or older.

**Antidepressants**

Approval duration: up to 10 years

**Formulary:**

Serzone® (g) (nefazodone)

**Formulary agents:**

**Serzone(g):** Requires documentation that member has experienced treatment failure of or intolerance to at least three of the following antidepressants (Prozac(g), Celexa(g), Paxil/CR(g), Luvox(g), Zoloft(g), Effexor, XR(g), or Wellbutrin SR, XL(g)).

Approval Duration: Up to 1 year

**Nonformulary:**

Aplenzin™, Cymbalta®

**Nonformulary agents:**

**Aplenzin:** Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants AND documentation that continued use of Wellbutrin SR/XL(g) will adversely affect the member's mental health.

**Cymbalta:**

- **Depression and/or anxiety:** Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants, once of which is a generic SNRI.
- **Post-herpetic neuralgia or diabetic peripheral neuropathy:** If older than 65 years, requires treatment failure of or intolerance to gabapentin 1200 mg per day. If under 65 years, requires treatment failure of or intolerance to gabapentin 1200 mg per day and a tricyclic antidepressant.
- **Fibromyalgia:** Documentation is required to show that the member has experienced intolerance to gabapentin OR inadequate relief from gabapentin 1200 mg per day AND treatment failure of or intolerance to at least three of the following: a tricyclic antidepressant, an SSRI, an SNRI, cyclobenzaprine, or tramadol.
- **Chronic musculoskeletal pain:** Requires documentation of treatment failure or intolerance of two generic formulary medications from any three drug classes (NSAID, centrally acting analgesics, or antidepressants).

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CENTRAL NERVOUS SYSTEM	
Approval duration: up to 10 years	
<b>Antidepressants</b>	
<p><b>Nonformulary:</b> Cymbalta®, Forvifo XL®, Luvox CR®, Oleptro™, Pexeva®, Pristiq®, Savella®, Viibryd™</p>	<p><b>Nonformulary agents:</b>  <b>Forvifo XL:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants one of which is high dose Wellbutrin XL(g) AND documentation that continued use of Wellbutrin XL(g) will adversely affect the member's mental health.  <b>Luvox CR:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants AND documentation that continued use of Luvox(g) will adversely affect the member's mental health.  <b>Oleptro:</b> Approved for major depressive disorder in members who have experienced treatment failure of or intolerance to at least three formulary antidepressants one of which is Desyrel®(g) AND documentation that continued use of Desyrel(g) will adversely affect the member's mental health.  <b>Pexeva:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants AND documentation that continued use of Paxil(g) will adversely affect the member's mental health.  <b>Pristiq:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants, one of which is a generic SNRI, AND documentation that continued use of Effexor(g) or Effexor XR(g) will adversely affect the member's mental health.  <b>Savella:</b> Approved for treatment of fibromyalgia AND requires documentation that the member has experienced intolerance to gabapentin or inadequate relief from gabapentin 1200 mg per day and treatment failure of or intolerance to at least three of the following: a tricyclic antidepressant, an SSRI, an SNRI, cyclobenzaprine, or tramadol.  <b>Viibryd:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least three generic antidepressants.</p>
Approval duration: up to 10 years	
<b>Antipsychotics</b>	
<p><b>Formulary:</b> Abilify® (aripiprazole),</p> <p><b>Nonformulary:</b> Fanapt®, Fazaclo, Invega®, Latuda®, Saphris®, Seroquel XR®</p>	<p><b>Formulary agents:</b>  <b>Abilify:</b> Requires treatment failure of or intolerance to one of the following 2nd generation formulary antipsychotics: Geodon(g), Risperdal(g), Seroquel(g), Zyprexa(g).</p> <p><b>Nonformulary agents:</b>  <b>Fanapt, Fazaclo, Latuda, Saphris:</b> Requires treatment failure of or intolerance to one of the following 2nd generation antipsychotics: Geodon(g), Risperdal(g), Seroquel(g), Zyprexa(g) AND Abilify.  <b>Invega:</b> Requires documentation that the member has experienced treatment failure of or intolerance Risperdal(g). Maximum dose of Invega is limited to 12 mg per day.  <b>Seroquel XR:</b> Requires documentation that the member has experienced treatment failure of or intolerance to Seroquel(g).</p>
Approval duration: up to 5 years	
<b>CNS Stimulants</b>	
<p><b>Formulary:</b> Adderall XR® (amphet asp/ amphet/d-amphet)(g), Procentra™ (dextroamphetamine), Provigil® (modafinil) (g)</p> <p><b>Nonformulary:</b> Nuvigil®</p> <p>Cont. next page...</p>	<p><b>Formulary agents:</b>  <b>Adderall XR(g):</b> Requires documentation that member has experienced treatment failure of or intolerance to brand name Adderall XR.  <b>Procentra:</b> Requires documentation that member has experienced treatment failure of or intolerance to both Metadate CD and Adderall XR; both of which may be sprinkled on food.  <b>Provigil(g):</b> Approved only for members with narcolepsy, or obstructive sleep apnea. Dosage limited to a maximum of 400mg per day. Shift-work sleep disorder is not covered since treatment is not medically necessary.  Approval duration: up to 1 year</p> <p><b>Nonformulary agents:</b>  <b>Nuvigil:</b> Approved for treatment of narcolepsy or obstructive sleep apnea and requires documentation that member has experienced treatment failure of or intolerance to Provigil (g).  Approval duration: up to 1 year</p>

CENTRAL NERVOUS SYSTEM (Cont.)	
Approval duration: up to 5 years	
<p><b>Nonformulary:</b> Strattera™, Vyvanse™, Xyrem®</p>	<p><b>Nonformulary agents:</b>  <b>Xyrem:</b> Approved members with a diagnosis of narcolepsy with cataplexy. For members with a diagnosis of narcolepsy with excessive day time sleepiness, requires documentation that member has experienced treatment failure of or intolerance to either Ritalin(g) or Procenta(g), AND Provigil(g).            Approval duration: up to 1 year  <b>Strattera:</b> Approvable when stimulants are contraindicated by medical history OR the following criteria by age:  <ul style="list-style-type: none"> <li>• <b>For BCN members age 5 to 20:</b> Requires documentation that the member has experienced treatment failure of or intolerance to both a methylphenidate (such as Ritalin(g) or Concerta(g)) AND an amphetamine (such as Adderall(g)).</li> <li>• <b>For BCN members age 21 and older:</b> Requires documentation that the member has experienced treatment failure of or intolerance to either a methylphenidate OR an amphetamine.</li> <li>• <b>Note:</b> The use of Strattera in members ≤ 4 years of age is not recommended or supported by literature.</li> </ul> <b>Vyvanse:</b> Requires documentation that the member has experienced treatment failure of or intolerance to both a methylphenidate (such as Ritalin(g) or Concerta(g)) AND an amphetamine (such as Adderall(g)).</p>
Approval duration: up to 10 years	
<p><b>Formulary:</b> Amerge® (g) (naratriptan), Maxalt®, MLT® (rizatriptan)</p> <p><b>Nonformulary:</b> Alsuma®, Axert®, Cambia™, Frova®, Relpax®, Sumavel™ DosePro™, Treximet®, Zomig®, nasal spray, ZMT®;</p>	<p><b>Formulary agents:</b>  <b>Amerge(g), Maxalt, MLT:</b> Requires documentation that member has experienced treatment failure of or intolerance to sumatriptan (Imitrex(g)).</p> <p><b>Nonformulary agents:</b>  <b>Alsuma, Axert, Frova, Relpax, Sumavel DosePro; Zomig, ZMT, nasal spray:</b> Requires documentation that member has experienced failure of or intolerance to both sumatriptan (Imitrex(g)) and Maxalt.  <b>Cambia:</b> Requires documentation that member has experienced failure of or intolerance to diclofenac (oral) and one oral generic NSAID.            Approval duration: up to 1 year  <b>Treximet:</b> Requires documentation that the member has experienced treatment failure of or intolerance to a combination of sumatriptan (Imitrex(g)) or Maxalt AND naproxen. Documentation as to why sumatriptan (Imitrex(g)) or Maxalt and naproxen as individual agents do not work for and/or may be harmful to the member must be provided.</p>
Approval duration: up to 1 year	
<p><b>Formulary:</b> Nuedexta® (Dextromethorphan/ Quinidine), Zanaflex®, capsules (tizanadine) (g)</p> <p><b>Nonformulary:</b> Aricept® 23mg, Intuniv™, Kapvay™,</p>	<p><b>Formulary Agents:</b>  <b>Nuedexta:</b> Requires documentation that member has a diagnosis of pseudobulbar affect.  <b>Zanaflex(g):</b> Requires patient has had trial failure of or intolerance to baclofen and Flexeril(g).  <b>Zanaflex capsules(g):</b> Requires patient has had trial failure of or intolerance to both baclofen and Flexeril(g), and documentation must be provided as to why continued use of generic Zanaflex tablets will adversely affect the member's health.</p> <p><b>Nonformulary Agents:</b>  <b>Aricept 23mg:</b> Requires documentation for a progressive-type dementia AND requires successful treatment with Aricept 10mg for three months.  <b>Intuniv, Kapvay:</b> Approved for treatment of ADHD and requires documentation that the member has experienced treatment failure of or intolerance to both a methylphenidate (such as Ritalin(g) or Concerta(g)), an amphetamine (such as Adderall(g)), generic guanfacine immediate-release, and clonidine.</p>

**CENTRAL NERVOUS SYSTEM (Cont.)**

**Narcotics**

Approval duration: up to 1 year

**Formulary:**

Actiq® (fentanyl citrate) (g),  
 Opana® (oxymorphone) (g),  
 Opana ER (oxymorphone) 7.5,  
 15mg (g)

**Nonformulary:**

Abstral™, Butrans™, Exalgo™,  
 Fentora®, Lazanda®, Nucynta®, ER,  
 Soln; Onsolis, Subsys™

**Formulary agents:**

**Actiq(g):** Approved for the treatment of breakthrough cancer pain in members that are tolerant of high dose narcotics and is currently receiving a long-acting narcotic. The member must also have experienced treatment failure of or intolerance to the use of other oral immediate-release narcotics for the management of breakthrough pain.

**Opana(g):** Requires documentation that the member has experienced treatment failure of or intolerance to morphine sulfate 20mg/mL (Roxanol(g)) or morphine sulfate immediate-release (MSIR(g)).

**Opana ER 7.5, 15mg(g):** Requires documentation that the member has experienced treatment failure of or intolerance to ALL of the following long-acting formulary agents: methadone, morphine sulfate extended-release (Oramorph(g), MS Contin(g)), and fentanyl transdermal patch (Duragesic(g)).

**Nonformulary agents:**

**Abstral, Fentora, Lazanda, Onsolis Subsys:** Approved for the treatment of breakthrough cancer pain in members that are tolerant of high dose narcotics and who are currently receiving a long-acting narcotic. The member must also have experienced treatment failure of or intolerance to the use of Actiq(g) and other oral immediate-release narcotics for the management of breakthrough pain. Lazanda and Subsys also require treatment failure of or intolerance to a buccal fentanyl product.

**Butrans:** Coverage is provided for a diagnosis of moderate to severe chronic pain AND documentation that the member has experienced treatment failure of or intolerance to methadone, Duragesic(g) AND morphine sulfate (MS Contin(g) or Oramorph SR(g)).

**Exalgo:** Coverage is provided for the management of moderate to severe pain in opioid tolerant patients requiring continuous around the clock analgesia for an extended period of time AND requires documentation that the member has experienced treatment failure of or intolerance to ALL of the following long-acting formulary agents: methadone, morphine sulfate extended-release (Oramorph(g), MS Contin(g)), and fentanyl transdermal patch (Duragesic(g)).

**Nucynta:** Requires documentation that member has experienced treatment failure of or intolerance to a generic immediate-release tramadol or tramadol/acetaminophen AND three formulary immediate-release narcotics. 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)), and fentanyl transdermal patch (Duragesic(g)).

**Nucynta ER:** Requires documentation that member has experienced treatment failure of or intolerance to Ultram ER(g) AND two of the following formulary alternatives: morphine sulfate extended-release (Oramorph(g), MS Contin(g)), fentanyl transdermal patch (Duragesic(g)) OR methadone.

- For Post-herpetic neuralgia or diabetic peripheral neuropathy: If older than 65 years, requires treatment failure of or intolerance to gabapentin 1200 mg per day. If under 65 years, requires treatment failure of or intolerance to gabapentin 1200 mg per day and a tricyclic antidepressant.

**Opana ER, Oxycontin:** Requires documentation that the member has experienced treatment failure of or intolerance to ALL of the following long-acting formulary agents: methadone, morphine sulfate extended-release (Oramorph(g), MS Contin(g)), and fentanyl transdermal patch (Duragesic(g)).

**Oxecta:** Requires documentation that the member has experienced treatment failure of or intolerance to at least three of the following immediate-release narcotics MS-IR(g), Opana IR(g), oxycodone IR. 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)), and fentanyl transdermal patch (Duragesic(g)).



CENTRAL NERVOUS SYSTEM (Cont.)	
<b>Narcotic Mixed Agonist/Antagonist</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<b>Nonformulary:</b> Rybix® ODT	<b>Nonformulary agent:</b> <b>Rybix ODT:</b> Requires documentation that the member cannot swallow ANY oral tramadol tablets OR the member has exhibited intolerance to at least two different manufacturer's brands of generic tramadol.
<b>Non-Steroidal Anti-Inflammatory Drugs</b>	
<b>Formulary:</b> Arthrotec® (g)	<b>Formulary agent:</b> <b>Arthrotec(g):</b> Approved for members >60 years of age, receiving anticoagulant or antiplatelet therapy, receiving chronic treatment with oral corticosteroids (≥ 60 days duration), or a history of or current diagnosis of peptic ulcer disease, clinically significant gastrointestinal bleeding, and/or alcoholism. Approval duration: up to 10 years
<b>Nonformulary:</b> Arthrotec®, Celebrex®, Flector® Patch, Pennsaid™, Voltaren® Gel, Vimovo™	<b>Nonformulary agents:</b> <b>Celebrex: <i>Approved for members &gt;60 years of age</i></b> who are not at high risk for cardiovascular events, and do not have a previous history of stroke, myocardial infarction (MI), coronary heart disease, or blood clots. The member must not be receiving concomitant anticoagulant or an antiplatelet therapy. <b><i>Approved for members ≤ 60 years of age</i></b> who are receiving chronic treatment with oral corticosteroids (≥ 60 days duration) or have a history of or current diagnosis of peptic ulcer disease, clinically significant gastrointestinal bleeding, and/or alcoholism. The member must not be receiving concomitant anticoagulant or antiplatelet therapy AND have no previous history or evidence of cardiovascular and thromboembolic disease. <b>Note:</b> Lodine®(g) is more selective than Celebrex for the COX-2 enzyme. Approval duration: up to 10 years <b>Flector Patch:</b> Approved only for the treatment of acute sprains AND requires treatment failure of or intolerance to Voltaren(g)/XR(g) tablets AND an OTC topical analgesic (Myoflex OR Aspercreme). Approval duration: up to 1 month <b>Pennsaid, Voltaren Gel:</b> Requires documentation of treatment failure of or intolerance to Voltaren(g)/XR(g) tablets AND an OTC topical analgesic (Myoflex OR Aspercreme). Approval duration: up to 3 months <b>Vimovo:</b> Requires documentation that member has had treatment failure of or intolerance to Prilosec(g), Protonix(g) and Prevacid(g) AND meets any one of the following criteria: •Greater than 60 years of age •Receiving anticoagulant or antiplatelet therapy •Receiving chronic treatment with oral corticosteroids (≥ 60 days duration) •A history of peptic ulcer disease, clinically significant gastrointestinal bleeding, and/or alcoholism. Approval duration: up to 10 years
<b>Parkinson's Disease and Related Disorders</b> <span style="float: right;">Approval duration: up to 10 years</span>	
<b>Nonformulary:</b> Horizant™, Mirapex ER®, Neupro®	<b>Horizant:</b> Requires a diagnosis of restless legs syndrome and treatment failure or intolerance to Requip(g), XL(g); Mirapex(g), and Neurontin(g), and an explanation why gabapentin extended release is expected to work if gabapentin immediate release has not. <b>Mirapex ER:</b> Requires a diagnosis of Parkinson's Disease and treatment failure or intolerance to Mirapex IR(g) AND documentation that the continued use will adversely affect the member's condition. <b>Neupro:</b> Requires a diagnosis of Parkinson's Disease or restless leg syndrome, and treatment failure of or intolerance to pramipexole (Mirapex(g), ER) AND ropinirole (Requip(g), XL(g)). <b>RLS:</b> also requires treatment failure of or intolerance to Neurontin(g).
<b>Sedatives/Hypnotics</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<b>Formulary:</b> Ambien CR® (g) (zolpidem)	Requires documentation that member has experienced treatment failure of or intolerance to an adequate trial of both zolpidem (Ambien®(g)) and zaleplon (Sonata®(g)).
Cont. next page...	

CENTRAL NERVOUS SYSTEM (Cont.)	
<b>Sedatives/Hypnotics (cont.)</b>	
<b>Nonformulary:</b> Edluar™, Intermezzo®, Lunesta®, Rozerem®, Silenor™, ZolpiMist™	<b>Nonformulary agents:</b> <b>Edluar, Intermezzo, Lunesta, Rozerem, ZolpiMist:</b> Requires documentation that member has been diagnosed with middle of the night waking and experienced treatment failure of or intolerance to Ambien CR(g), AND Sonata(g), coverage is not provided in combination with other sedatives. <b>Silenor:</b> Requires documentation that member has experienced treatment failure of or intolerance to Sinequan®(g), Ambien(g), Sonata(g) AND Desyre®(g).
DERMATOLOGY	
<b>Acne Treatment</b>	
<b>Nonformulary:</b> Veltin™ gel, Ziana® gel	Requires documentation of medical necessity to identify why individual agents [Cleocin-T®(g) plus Retin-A®(g)] cannot be used.
<b>Antipsoriatic/Antiseborrheic</b>	
<b>Formulary:</b> Enbrel® (etanercept), Humira® (adalimumab)	<b>Formulary agents:</b> <b>Enbrel, Humira:</b> <b>Moderate to Severe Psoriasis:</b> Requires 3 months of previous treatment with topical corticosteroids and 3 months treatment with PUVA.
<b>Antipsoriatic/Antiseborrheic</b>	
<b>Nonformulary:</b> Taclonex, Scalp®	<b>Nonformulary agent:</b> <b>Taclonex:</b> Requires documentation that the member has experienced treatment failure of or intolerance to at least 30 days of treatment with the combination of a very high potency corticosteroid [Diprolene ointment(g), Temovate(g), Psorcon(g)] AND Dovonex(g).
<b>Miscellaneous Dermatologicals</b>	
<b>Nonformulary:</b> Protopic®, Solaraze®	<b>Nonformulary agents:</b> <b>Protopic:</b> Approved for members ≥2 years of age with a diagnosis of atopic dermatitis or eczema and documentation that the member has experienced treatment failure of or intolerance to Elidel®. For members ages 2 to 15, only the 0.03% strength may be used. <b>Solaraze:</b> Approved for members with a diagnosis of actinic keratosis how have experience treatment failure with cryotherapy or phototherapy and TWO other medications such as Efudex(g), Aldara(g), or Retin-A(g).
DERMATOLOGY	
<b>Wound &amp; Burn Therapy</b>	
<b>Nonformulary:</b> Regranex®	Requires documentation that the member has a diagnosis of lower extremity diabetic neuropathic ulcers that have an adequate blood supply and extend into the subcutaneous tissue or beyond (must be a full thickness – for example, Stage III to the muscle or Stage IV to the bone). Members must be participating in a comprehensive wound care program which includes treatment such as surgical removal of tissue, pressure relief (for example, non-weight bearing), and infection control.
DIAGNOSTICS & OTHER MISCELLANEOUS	
<b>Diagnostic &amp; Other Miscellaneous</b>	
<b>Formulary:</b> Kalydeco™ (ivacaftor), Kuvan® (sapropterin dihydrochloride), Xenazine® (tetrabenazine)  Cont. next page...	<b>Formulary agents:</b> <b>Kalydeco:</b> Requires documentation that the member has a confirmed diagnosis of cystic fibrosis with the G551D mutation confirmed by genetic test <b>Kalydeco:</b> Requires documentation that the member has a confirmed diagnosis of cystic fibrosis with the G551D mutation confirmed by genetic test <b>Kuvan:</b> Requires documentation that member has a diagnosis of phenylketonuria (PKU) and will be following a phenylalanine-restricted diet in conjunction with Kuvan. Approval duration: up to 1 year <b>Xenazine:</b> Requires documentation that member has a diagnosis of chorea associated with Huntington's disease. Approval duration: up to 10 years

## DIAGNOSTICS & OTHER MISCELLANEOUS (Cont.)

### Diagnostic & Other Miscellaneous (cont.)

#### Nonformulary:

Campral<sup>®</sup>, Exjade<sup>®</sup>, Ferriprox<sup>®</sup>, Firazyr<sup>®</sup>, Kalydeco<sup>™</sup>, Korlym<sup>™</sup>

#### Nonformulary agents:

**Campral:** Approved for the treatment of alcohol dependence, to maintain abstinence from alcohol in members who have been abstinent at treatment initiation for at least 5 days post-detoxification. Members must be enrolled in a comprehensive alcohol management program that includes psychosocial support.

Approval duration: up to 1 year

**Exjade:** Approved for members  $\geq 2$  years of age with a diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) and documentation that the member has experienced treatment failure of or intolerance to Desferal<sup>®</sup>(g) OR requires documentation that the member is enrolled in a Phase II-IV investigative study approved by an appropriate IRB.

Approval duration: up to 1 year

**Ferriprox:** Requires treatment failure of or intolerance to Desferal(g) and Exjade for members with transfusional iron overload.

Approval duration: up to 1 year

**Firazyr:** Approved for members  $\geq 18$  years of for the treatment of acute attacks of hereditary angioedema (HAE).

Approval duration: up to 1 year

**Korlym:** Requires documentation that the member has a diagnosis of:

- Hypercortisolism as a result of endogenous Cushing's syndrome
- Diagnosis of type II diabetes mellitus or glucose intolerance
- Surgical treatment has been ineffective or are not candidates for surgery

Approval duration: up to 1 year

## ENDOCRINOLOGY

### Growth Hormone & Related Products

#### Formulary:

Genotropin<sup>®</sup> (somatropin),  
Nutropin<sup>®</sup>, AQ (somatropin)

#### Formulary agents:

**Children (<18 years of age):** Requires a diagnosis of growth hormone deficiency, growth failure secondary to chronic renal failure/insufficiency in children who have not received a renal transplant, growth failure in children small for gestational age or with intrauterine growth retardation, Turner's Syndrome, Noonan's Syndrome, Prader-Willi Syndrome, SHOX deficiency, or for treatment of severe burns covering >40% of the total body surface area. The member's current height and weight must be provided. The member must also have open epiphyses.

**Initial treatment:** For growth hormone deficiency, two growth hormone stimulation tests OR one GH stimulation test along with a subnormal IGF-1 level and IGFBP-3 level must be provided. The member's height must be below the 5th percentile.

**To continue:** The member must achieve a growth velocity of > 4.5 cm/year while receiving therapy over the past year. Treatment may continue until final height or epiphyseal closure has been documented.

Approval duration: up to 1 year

**Adults ( $\geq 18$  years of age):** Approved for treatment of growth hormone deficiency, AIDS wasting cachexia, Turner's Syndrome, and Short Bowel Syndrome (SBS). The diagnosis must be made by an endocrinologist or a nephrologist. Initial diagnosis must be based on two growth hormone stimulation tests, three or more pituitary hormone deficiencies with an IGF-1 below 80ng/ml OR one growth hormone and at least one pituitary hormone deficiency

Approval duration: up to 10 years (exception SBS 1 month)

#### Nonformulary:

Humatrope<sup>®</sup>, Norditropin<sup>®</sup>,  
Omnitrope<sup>®</sup>, Saizen<sup>®</sup>, Serostim<sup>®</sup>,  
Tev-Tropin<sup>®</sup>, Valtropin<sup>®</sup>, Zorbitive<sup>™</sup>,  
Increlex<sup>™</sup>

**Nonformulary agents:** Also requires documentation that the member has experienced treatment failure of or intolerance to formulary agents.

**Increlex:** Approved for treatment of severe IGF-1 deficiency, growth hormone gene deletion, and Laron's syndrome in members <18 years of age, with open epiphyses, and height below the 3rd percentile. Member must have a normal or elevated growth hormone level with an IGF-1 level 3 or more standard deviations below normal. The prescriber must be a pediatric endocrinologist.

Approval duration: Initial approval is granted for 1 year and renewal can be obtained if member has clinical response with therapy, as demonstrated by an annual growth velocity of  $\geq 2.5$  cm

ENDOCRINOLOGY (Cont.)	
<b>Non-Insulin Hypoglycemic Agents</b> <span style="float: right;">Approval duration: up to 10 years</span>	
<p><b>Nonformulary:</b> Actoplus MET<sup>®</sup> XR, Avandamet<sup>®</sup>, Avandaryl<sup>®</sup>, Avandia<sup>®</sup>, Byetta<sup>®</sup>, Bydureon<sup>™</sup>, Cycloset<sup>®</sup>, Janumet<sup>®</sup>, XR; Januvia<sup>®</sup>, Jentadueto<sup>™</sup>, Juvisync<sup>®</sup>, Kombiglyze<sup>™</sup> XR, Onglyza<sup>™</sup>, Prandimet<sup>®</sup>, Tradjenta<sup>™</sup>, Symlin<sup>®</sup>, Victoza<sup>®</sup></p>	<p><b>Nonformulary agents:</b> <b>Actoplus MET XR, Avandamet, Avandaryl, Janumet, XR; Jentadueto, Juvisync, Kombiglyze XR, Prandimet:</b> Requires documentation that the member has experienced successful treatment with at least three months of therapy with the individual agents that are in the combination product. Avandamet, Avandaryl coverage subject to enrollment in REMS.</p> <p><b>Avandia:</b> Requires documentation that the member has had treatment failure of or intolerance to both Glucophage(<b>g</b>) and Actos. Coverage is subject to enrollment in REMS.</p> <p><b>Byetta, Bydureon, Victoza:</b> Approved for treatment of type 2 diabetes in members with a contraindication to or have experienced treatment failure of or intolerance to metformin. The member must currently be taking either metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione. The member must also have tried and failed to achieve desired glucose control with at least TWO types of oral agents and insulin.</p> <p><b>Cyclocet, Januvia, Onglyza, Tradjenta:</b> Requires documentation that member has experienced treatment failure of or intolerance to the use of three of the following: metformin, basal insulin, sulfonylurea, and a TZD.</p> <p><b>Symlin:</b> Approved for members ≥18 years of age for the treatment of type 1 or 2 diabetes who are receiving insulin therapy and has not achieved desired glucose control (Hgb A1C &gt;7%) despite good compliance with optimal insulin therapy.</p>
<b>Miscellaneous</b>	
<p><b>Nonformulary:</b> Egrifta<sup>®</sup></p>	<p>Approved for members ≥ 18 years of age for the reduction of excess abdominal fat in HIV-associated lipodystrophy, receiving antiretroviral therapy, with gender-specific measures when other weight loss efforts have been ineffective and there is functional impairment in activities of daily living. Renewal coverage is provided for the reduction of excess abdominal fat in HIV-associated lipodystrophy when clinical documentation is provided indicating a decrease in waist circumference and continuation of functional impairment in activities of daily living.</p> <p>Approval duration: Initial approval length up to 6 months, renewal up to 1 year.</p>
GASTROINTESTINAL AGENTS	
<b>Antiemetics</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<p><b>Nonformulary:</b> Sancuso<sup>®</sup>, Zuplenz<sup>®</sup></p>	<p>Requires documentation that the member has experienced treatment failure of or intolerance to oral granisetron (Kytril(<b>g</b>)) AND ondansetron (Zofran(<b>g</b>)).</p>
<b>Hematopoietic Agents</b>	
<p><b>Formulary:</b> Procrit<sup>®</sup> (epoetin alfa), Promacta<sup>®</sup> (eltrombopag)</p>	<p><b>Procrit:</b> Requires documentation that the member has 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 surgery to reduce need for allogenic blood transfusions. A Hgb level of less than 10 g/dL is required for initial therapy. For continued coverage dose adjustments are required to maintain Hgb between 10 to 12 g/dL. Duration of approval is dependent on the indication.</p> <p>Approval duration: Initial approval up to 6 months to 1 year</p> <p><b>Promacta:</b> Approved for treatment of thrombocytopenia with chronic immune thrombocytopenic purpura, has a platelet count of &lt;400 x 10<sup>9</sup>/L if continuing therapy, and inadequate response to, intolerance to, or is not a candidate for standard first-line treatments, such as corticosteroids, immunoglobulins, or splenectomy.</p> <p>Approval duration: up to 6 months</p>
<p><b>Nonformulary:</b> Aranesp<sup>®</sup>, Epopgen<sup>®</sup></p>	<p><b>Nonformulary agents:</b> Also requires documentation that member has experienced failure of or intolerance to formulary epoetin alfa (Procrit).</p> <p>Approval duration: up to 6 months to 1 year</p>

GASTROINTESTINAL AGENTS (Cont.)	
<b>Miscellaneous Gastrointestinal Agents</b> Approval duration: up to 1 year	
<p><b>Formulary:</b> Relistor® (methylnaltrexone)</p> <p><b>Nonformulary:</b> Amitiza®, Chenodal™, Giazo™, Cimzia®, Lizness™, Lotronex®, Xifaxan 550®</p>	<p><b>Formulary agent:</b> <b>Relistor:</b> Approved for the treatment of opioid-induced constipation in members with advanced illness whom are receiving palliative care and requires documentation that the member has experienced inadequate response to at least 3 of the following laxatives: bulk laxatives (polycarbophil, psyllium, methylcellulose), saline laxatives (milk of magnesia/magnesium hydroxide), osmotic laxatives (Miralax(g)), or stimulant (Dulcolax(g), Senna(g)).</p> <p><b>Nonformulary agents:</b> <b>Amitiza:</b> Approved for the treatment of chronic idiopathic constipation (fewer than 3 bowel movements/week) or constipation predominant IBS (females only) in members 18 to 65 years of age whom have tried and failed ALL of the following: dietary advice, trials of bulk laxatives, stool softeners, and a short course of stimulant laxatives and are NOT taking medications causing constipation. A total of 12 weeks can be approved, with renewal, only if improvement in bowel frequency is seen with initial trial. <b>Chenodal:</b> Approved for dissolution of gallstones only in patients where surgery is not appropriate. In addition, member must have experience treatment failure of or have an intolerance to Actigall(g). Member cannot have history of hepatocellular disease. Approval duration: up to 2 years <b>Cimzia:</b> Approved for the treatment of Crohn's disease in members ≥18 years of age whom have experienced treatment failure of or intolerance to both Enbrel, and Humira. <b>Gaizo:</b> Approved for the treatment of mild to moderate active ulcerative colitis in male pts ≥18 who have experienced treatment failure of or intolerance to Colazal(g) AND Azulfidine(g). <b>Linzess:</b> Approved for female members, requires treatment failure of or intolerance to Amitiza. <b>Lotronex:</b> Approved for the treatment of severe, diarrhea-predominant irritable bowel syndrome in women at least 18 years of age who have failed to respond to conventional diarrhea therapy including one OTC product (loperamide, bismuth subsalicylate) and one prescription agent (diphenoxylate/atropine (Lomotil(g))). <b>Xifaxan 550:</b> Requires diagnosis of hepatic encephalopathy AND documentation that the member has had treatment failure of or intolerance to lactulose.</p>
<b>Proton Pump Inhibitors</b> Approval duration: up to 5 year	
<p><b>Formulary:</b> Prevacid®(g) capsule (lansoprazole), Prevacid Solutab™, Zegerid®(g) capsule (omeprazole/sodium bicarbonate)</p> <p><b>Nonformulary:</b> Aciphex®, Dexilant™, Nexium®, Prilosec suspension, Protonix suspension, Vimovo™, Zegerid Packet</p>	<p><b>Formulary agents:</b> <b>Prevacid(g), Solutab:</b> Requires documentation that the member has experienced failure of or intolerance to Prilosec OTC(g) or Prilosec(g), AND Protonix(g). <b>Zegerid(g):</b> Requires documentation that member has experienced failure of or intolerance to Prilosec OTC(g) or Prilosec(g) AND Protonix(g), AND Prevacid(g) or Prevacid Solutab.</p> <p><b>Nonformulary agents:</b> <b>Aciphex, Zegerid Packet:</b> Requires documentation that the member has experienced treatment failure of or intolerance to Prilosec OTC or Prilosec(g) AND Protonix(g), AND Prevacid(g) or Prevacid Solutab. <b>Dexilant, Nexium:</b> Requires documentation that the member has experienced treatment failure of or intolerance to all BCN formulary alternatives [either Prilosec OTC or Prilosec(g), Protonix(g), AND Prevacid(g)], one of which is at a twice daily, high dose regimen. <b>Prilosec suspension, Protonix suspension:</b> Requires documentation that member has experienced treatment failure of or intolerance to Prevacid Solutab. <b>Vimovo:</b> Requires documentation that member has had treatment failure of or intolerance to Prilosec(g), Protonix(g) and Prevacid(g) AND meets any one of the following criteria: •Greater than 60 years of age •Receiving anticoagulant or antiplatelet therapy •Receiving chronic treatment with oral corticosteroids (&gt;= 60 days duration) •A history or peptic ulcer disease, clinically significant gastrointestinal bleeding, and/or alcoholism. Approval duration: up to 10 years</p>

## IMMUNOLOGY & HEMATOLOGY

### Hepatitis B & C Therapy

#### Formulary:

Incivek™ (telaprevir),  
Infergen (interferon alfacon-1),  
Intron-A (interferon alfa-2B),  
Pegasys (peginterferon alfa 2-A),  
Peg-Intron (peginterferon alfa-2B),  
Ribavirin,  
Victrelis™ (boceprevir)

#### Formulary agents:

**Incivek:** Requires a diagnosis of Hepatitis C genotype 1. Patients taking Incivek must be receiving triple therapy along with a peg interferon and ribavirin for the appropriate duration of the treatment.

Approval duration: Initial approval: up to 6 weeks. Renewal: up to 6 weeks if viral load is 1000 IU/mL or less at treatment week 4.

**Infergen:** Approved for the treatment of Hepatitis B.

Approval duration: up to 1 year

**Intron-A:** Approved for the treatment of Hepatitis B, condyloma acuminata, essential thrombocythemia, hairy cell leukemia, Kaposi's sarcoma, malignant melanoma, multiple myeloma, non-Hodgkin's lymphoma, Philadelphia chromosome (Ph) positive chronic phase myelogenous leukemia (CML), and renal cell carcinoma.

Approval duration: up to 1 year

**Peg-Intron, Pegasys:** Approved for the treatment of Hepatitis B and Hepatitis C. For hepatitis C, approved for members naïve to pegylated interferon therapy only. Genotype, HIV status, previous therapy and duration must also be provided. The member must receive pegylated interferon in combination with ribavirin unless contraindicated.

Approval duration:

- **For genotypes 2, 3:** Approval is for a total of 24 weeks duration.
- **For non-genotypes 2,3 receiving dual therapy with ribavirin:** Initial approval is 16 weeks, renewal is 32 weeks if the members achieves >\_ 2 log decrease in viral load after 12 weeks of treatment.
- **For genotype 1 receiving triple therapy:** Initial and renewal approval durations depend on patient's viral loads at all futility points and treatment duration as indicated in the prescribing information.

**Ribavirin:** Approved for the treatment of Hepatitis C. Genotype, HIV status, previous therapy and duration must also be provided.

**Victrelis:** Requires a diagnosis of Hepatitis C genotype 1, and treatment failure of or intolerance to Incivek. Patients taking Victrelis must be receiving triple therapy along with a peg interferon and ribavirin for the appropriate duration of the treatment.

Approval duration: Initial and renewal approval durations depend on patient's viral loads at all futility points and treatment duration as indicated in the prescribing information.

### Interferons and MS Therapy

#### Nonformulary:

Ampyra™, Aubagio™, Betaseron®

**Ampyra: Initial treatment:** Requires a diagnosis of multiple sclerosis and documentation of difficulty walking resulting in significant limitations of instrumental activities of daily living. Also requires two timed 25-foot walk (T25FW) measurements that must be within 10% variability and demonstrates that the patient is able to walk 25 feet in 8-45 seconds. **To continue:** Requires documentation of improvement in walking speed by at least 10% as assessed by the T25FW AND that limitations of instrumental activities of daily living has improved as a result of increased walking speed within the first 2 months of therapy. Coverage thereafter will be provided there is documentation that the member has maintained or experienced improved walking speed from the previous measurement.

Approval duration: initial approval is 2 months, renewal up to 12 months

**Aubagio:** Approved for members 18 and older who have a diagnosis of a relapsing form of multiple sclerosis, where member has experienced treatment failure of or intolerance to an interferon beta product (for example, Avonex®, Extavia® or Rebif®) AND Copaxone®. Treatment failure is defined as documented relapse or the presence of new and/or newly enlarged MRI lesions in the previous year.

**Betaseron:** Requires documentation that member has experienced failure of or intolerance to Extavia®.

Approval duration: up to 10 years

IMMUNOLOGY & HEMATOLOGY (Cont.)	
<b>Interferons and MS Therapy (cont.)</b>	
<b>Nonformulary:</b> Gilenya™	<b>Gilenya:</b> Requires diagnosis of relapsing-remitting, secondary-progressive, and progressive-relapsing types of multiple sclerosis, where the member has experienced failure or intolerance to an interferon beta product (for example, Avonex®, Extavia® or Rebif®) AND Copaxone®. Treatment failure is defined by a documented relapse or the presence of new and/or newly enlarged MRI lesions in the previous year. Approval duration: up to 1 year
LIFESTYLE MODIFICATION PRODUCTS	
<b>Impotence</b> Approval duration: up to 1 year	
<b>Formulary:</b> Caverject® (alprostadil), Cialis® (tadalafil), Muse® (alprostadil), Viagra® (sildenafil citrate)	For men under the age of 18, and for women, not covered For men 18 to 34 years old: requires a diagnosis of erectile dysfunction (ED) secondary to a medical cause such as multiple sclerosis, spinal cord injury, Parkinson's disease, radiation for prostate or bladder cancer, and other indications deemed appropriate. The member must not be using nitrates concomitantly and avoid use of alpha blockers with oral ED agents. Maximum of 6 doses per 28 days.
<b>Nonformulary:</b> Edex®, Levitra®, Staxyn®, Stendra™	For men over the age of 34: requires a diagnosis of ED.
<b>Weight Loss Products</b> Approval duration: up to 1 year	
<b>Formulary:</b> phentermine and related products	<b>Formulary agents:</b> Requires verification that member's Body Mass Index (BMI) is $\geq 30$ kg/m <sup>2</sup> or $>27$ kg/m <sup>2</sup> with comorbidities, and concurrent lifestyle modification plan. Coverage for all anorexiant and related drugs is limited to 3 months. Additional coverage requires documentation of weight loss of at least 2 pounds per month. Maximum benefit is 12 months of treatment per lifetime; 24 months of treatment per lifetime for Xenical.
<b>Nonformulary:</b> Belviq®, Qsymia™, Suprenza™ ODT, Xenical®	<b>Nonformulary agents:</b> Requires verification that member's Body Mass Index (BMI) is $\geq 30$ kg/m <sup>2</sup> or $>27$ kg/m <sup>2</sup> with comorbidities, and concurrent lifestyle modification plan. Coverage for all anorexiant and related drugs is initially limited to 3 months. Additional coverage requires documentation of weight loss of at least 2 pounds per month. Maximum benefit is 12 months of treatment per lifetime. <b>Belviq, Qsymia:</b> Additional coverage requires documentation of at least 5% weight loss in the first 3 months of treatment. <b>Suprenza ODT:</b> also requires documentation as to why continued use of generic phenteramine will adversely affect the member's health.
MISCELLANEOUS	
<b>Compounds</b>	Coverage criteria include all the below: <ul style="list-style-type: none"> <li>• The compound is medically necessary for the member's condition</li> <li>• The compound contains only FDA-approved drugs.</li> <li>• There are no appropriate FDA-approved commercial formulations of the compound available. U6W's (bulk powders) are not covered.</li> </ul> Approval duration: up to 6 months
OBSTETRICS AND GYNECOLOGY	
<b>Infertility treatment</b> Approval duration: up to 1 year	
<b>Formulary:</b> Bravelle® (urofollitropin), Cetrotide® (cetrotirelix acetate), Fertinex™ (urofollitropin), Ganirelix acetate® (ganirelix acetate), Gonal-F®, RFF (follitropin alfa, recomb), Ovidrel® (HCG alfa, recomb), Novarel®/Pregnyl®/Profasi® (gonadotropin, chorionic, human), Repronex® (menotropins)	Coverage is provided for most BCN female members with an infertility benefit and also in accordance with generally accepted medical practice. BCN does not provide coverage for infertility drugs to be used as part of assisted reproductive technology treatment, such as in vitro fertilization (IVF), zygote in vitro fertilization transfer (ZIFT), gamete in vitro fertilization transfer (GIFT). Authorization will be provided for one year. Additional coverage will be based on documentation that the member is being treated according to accepted medical practice. Requests are not considered for men.
<b>Nonformulary:</b> Follistim® AQ, Luveris®, Menopur®	<b>Nonformulary:</b> Also Requires treatment failure of or intolerance to formulary agents.

OTIC & NASAL PREPARATIONS	
<b>Intranasal Steroids</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<p><b>Formulary:</b> Nasacort AQ® (g) (triamcinolone acetonide)</p> <p><b>Nonformulary:</b> Beconase AQ®, Dymista™, Nasonex®, Omnaris™, Qnasl®, Rhinocort Aqua®, Veramyst™, Zetonna™</p>	<p><b>Formulary agent:</b> <b>Nasacort AQ(g):</b> Requires documentation that member has experienced treatment failure of or intolerance to fluticasone (Flonase(g)) or flunisolide (Nasalide(g)/Nasarel(g)).</p> <p><b>Nonformulary agents:</b> Requires documentation that member has experienced treatment failure of or intolerance to fluticasone (Flonase(g)) or flunisolide (Nasalide(g)/Nasarel(g)) AND Nasacort AQ (g).</p>
RESPIRATORY COUGH & COLD	
<b>Antihistamines and Combinations</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<p><b>Formulary:</b> Clarinet® (g) (desloratadine), Xyzal® (g) (levocetirizine)</p> <p><b>Nonformulary:</b> Clarinet-D®, Clarinet Reditabs®, Clarinet Syrup®, Sempres-D®</p>	<p>Requires documentation that the member has experienced treatment failure of or intolerance to OTC loratadine and OTC cetirizine.</p>
<b>Inhaled Beta-Agonists</b> <span style="float: right;">Approval duration: up to 10 years</span>	
<p><b>Nonformulary:</b> Arcapta® Neohaler, Brovana®, Perforomist™</p>	<p>Requires documentation that the member has experienced treatment failure of or intolerance to both Serevent® and Foradil®.</p>
<b>Miscellaneous</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<p><b>Nonformulary:</b> Daliresp™</p>	<p><b>Daliresp:</b> Requires documentation that the member has a diagnosis of severe chronic obstructive pulmonary disorder (COPD) associated with chronic bronchitis and a history of exacerbations despite therapy with a long acting beta agonist, an anticholinergic and a formulary inhaled steroid.</p>
<b>Pulmonary Arterial Hypertension</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<p><b>Formulary:</b> Letairis™ (ambrisentan), Revatio®(g) (sildenafil), Soln; Tracleer® (bosentan), Tyvaso™ (treprostinil), Ventavis® (iloprost)</p> <p><b>Nonformulary:</b> Adcirca™</p>	<p><b>Formulary agents:</b> <b>Letairis, Revatio(g), Revatio Soln; Tracleer, Tyvaso, Ventavis:</b> Approved for the treatment of pulmonary arterial hypertension (PAH) WHO Class III or IV symptoms.</p> <p><b>Nonformulary agent:</b> <b>Adcirca:</b> Approved for the treatment of pulmonary arterial hypertension (PAH), WHO Class III or IV symptoms AND requires documentation that member has experienced treatment failure of or intolerance to Revatio.</p>
RHEUMATOLOGY & MUSCULOSKELETAL	
<b>Gout Therapy</b> <span style="float: right;">Approval duration: up to 10 years</span>	
<p><b>Formulary:</b> Uloric® (febuxostat)</p>	<p>Approved for the treatment of gout in members that have experienced treatment failure of or intolerance to generic allopurinol. Uloric 80mg requires documentation that the member has had an inadequate response to the 40mg dose.</p>
<b>Miscellaneous Rheumatologic Agents</b> <span style="float: right;">Approval duration: up to 1 year</span>	
<p><b>Formulary:</b> Enbrel®(etanercept), Humira® (adalimumab)</p> <p>Cont. next page...</p>	<p><b>Formulary agents:</b> <b>Enbrel, Humira:</b> Requires a three month trial with two concurrent oral disease modifying antirheumatic drugs (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine.</p>



<b>RHEUMATOLOGY &amp; MUSCULOSKELETAL (cont.)</b>	
<b>Miscellaneous Rheumatologic Agents (cont.)</b> Approval duration: up to 1 year	
<b>Nonformulary:</b> Cimzia®, Kineret®, Orencia® SC, Simponi™	<b>Nonformulary agents:</b> <b>Cimzia, Kineret, Orencia SC, Simponi:</b> Requires that the member has experienced treatment failure of or intolerance to Enbrel and Humira.
<b>Osteoporosis/Bone Resorption Inhibitors</b> Approval duration: up to 10 years	
<b>Formulary:</b> Actonel® (risedronate), Boniva® (ibandronate) (g)	<b>Formulary agents:</b> <b>Boniva(g):</b> Requires documentation that member has experienced treatment failure of or intolerance to alendronate (Fosamax(g)). <b>Actonel:</b> Requires documentation that member has experienced treatment failure of or intolerance to alendronate (Fosamax(g)) or Boniva(g).
<b>Nonformulary:</b> Atelvia™, Binosto™, Fosamax D™, Forteo™	<b>Nonformulary agents:</b> <b>Atelvia, Binosto, Fosamax D:</b> Requires documentation that member has experienced treatment failure of or intolerance to both alendronate (Fosamax(g)) and Actonel. <b>Forteo:</b> Approved for the treatment of osteoporosis (T-score <= -2.5) AND requires documentation that the member has a contraindication to or experienced treatment failure of or intolerance to a bisphosphonate. Approval duration: up to 2 years
<b>UROLOGY</b>	
<b>Bladder Control</b> Approval duration: up to 5 year	
<b>Nonformulary:</b> Myrbetriq®	<b>Myrbetriq:</b> Approved when the member has experience treatment failure of or intolerance to at least 1 of the following generics (Detrol(g), Ditropan (g), XL(g) ; Sanctura (g), XR(g)) and Detrol LA.
<b>BPH Treatment</b> Approval duration: up to 1 year	
<b>Formulary:</b> Cialis® (tadalafil), Jalyn™ (dutasteride/tamsulosin)	<b>Cialis:</b> Approved when the member has experience treatment failure of or intolerance to both an alpha blocker, 5-alpha reductase inhibitor, and that the member has an IPSS score >=13. <b>Jalyn:</b> Requires successful treatment of at least one month of therapy of either an alpha blocker, 5-alpha-reductase inhibitor or Jalyn.