

# Blue Care Network Custom Drug List Prior Approval and Step Therapy Guidelines October 2017

Blue Care Network’s Prior Approval and Step Therapy Guidelines 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 preferred medications. Our prior approval and step therapy criteria are based on current medical information and have been approved by the Blue Cross and BCN Pharmacy and Therapeutics Committee. These guidelines apply to all BCN members whose prescription benefit includes *Blue Cross and BCN Custom Drug List*.

**PRIOR APPROVAL (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 preferred 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 are limited to a 15-day supply for all fills and members will pay half of their copayment.
- BCN members with a two-tier closed drug plan do not have coverage for nonpreferred drugs. Requests for coverage of nonpreferred 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 preferred agents, or the available preferred agents would pose unnecessary risk to the member.

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

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

(g)=generic available

ANTI-INFECTIVES	
<b>Antimalarials</b> <span style="float: right;">Approval duration: up to 6 weeks</span>	
<b>Preferred:</b> Daraprim®	Coverage is provided for malaria chemoprophylaxis and the treatment of malaria or toxoplasmosis.
<b>Antituberculars</b> <span style="float: right;">Approval duration: up to 6 months</span>	
<b>Preferred:</b> Sirturo™	Coverage is provided for members 18 years of age or older for the treatment of pulmonary multi-drug resistant tuberculosis (MDR-TB).
<b>Anti-Virals</b> <span style="float: right;">Approval duration: up to 3 months</span>	
<b>Preferred:</b> Eplusa®  Cont. on the next page...	<b>Preferred agents:</b> <b>Eplusa:</b> Coverage is provided for members 18 years of age or older for the treatment of chronic hepatitis C for genotypes 2, 3, 5, and 6 with a fibrosis staging score ≥ F2 who meet clinical criteria.

**ANTI-INFECTIVES (cont.)****Anti-Virals (cont.)**

Approval duration: up to 3 months

**Preferred:**

Zepatier™

**Preferred agents:**

**Zepatier:** Coverage is provided for members 18 years of age or older for the treatment of chronic hepatitis C for genotypes 1 and 4 with a fibrosis staging score  $\geq$  F2 who meet clinical criteria.

**Nonpreferred:**

Daklinza™, Harvoni®, Olysio™, Sovaldi™, Technivie™

**Nonpreferred agents:**

Coverage is provided for members 18 years of age or older for the treatment of chronic hepatitis C with a fibrosis staging score of  $\geq$  F2 who meet clinical criteria.

**Daklinza:** Members taking Daklinza must be receiving combination therapy with Sovaldi. Trial and failure to Zepatier (genotype 1) or Epclusa (genotype 3) is required.

**Harvoni:** Trial and failure to Zepatier (genotypes 1 and 4) or Epclusa (genotypes 5 and 6) is required.

**Olysio:** Members taking Olysio must be receiving combination therapy with Sovaldi OR peginterferon alfa plus ribavirin. Trial and failure to Zepatier is required.

**Sovaldi:** Members taking Sovaldi must be receiving combination therapy with peg-interferon and/or ribavirin. Trial and failure to Zepatier (genotypes 1 and 4) or Epclusa (genotypes 2 and 3) is required.

**Technivie:** Members taking Technivie must be receiving combination therapy with ribavirin. Trial and failure to Zepatier is required.

**Tetracyclines**

Approval duration: up to 10 years

**Preferred:**

Adoxa® capsule (g) (doxycycline monohydrate), Doryx® (g) (doxycycline hyclate)

**Preferred agents\*:**

**Adoxa capsule(g):** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Monodox(g).

**Doryx(g):** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Doxycycline 20mg(g) or Vibramycin(g).

**Nonpreferred:**

Doryx® MPC, Doxycycline IR-DR, Oracea®

**Nonpreferred agents\*:**

**Doryx MPC:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Doxycycline 20 mg(g) or Vibramycin(g).

**Doxycycline IR-DR, Oracea:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Monodox(g).

**\*Note:** 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 an adverse effect or quality issue with a preferred agent.

**ANTINEOPLASTICS & IMMUNOSUPPRESSANTS\*\*****Antimetabolites**

Approval duration: up to 1 year

**Preferred:**

Lonsurf®

Coverage is provided for the treatment of the FDA approved indications.

**Hormonal Agents**

Approval duration: up to 1 year

**Preferred:**

Arimidex® (g) (anastrozole), Aromasin® (g) (exemestane), Evista® (g) (raloxifene), Femara® (g) (letrozole), Tamoxifen (g) (tamoxifen), Xtandi®

**Preferred agents:**

**Arimidex(g), Aromasin(g), Femara(g):** PA required for males: Coverage is provided for the treatment of ER-positive breast cancer.

**Evista(g), Tamoxifen(g):** Female members qualify for a \$0 copayment when the following clinical criteria are met: Coverage is provided for primary prevention of breast cancer in women age 35 years or older with documented risk factors showing the member is at high risk for developing breast cancer and the member has no history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), or a personal/family history of venous thromboembolic events.

Approval duration: up to 5 years

**Xtandi:** Coverage is provided for the treatment of the FDA approved indications.

**Nonpreferred agents:**

Zytiga®

**Nonpreferred agents:**

**Zytiga:** Coverage is provided for the treatment of the FDA approved indications.

## ANTINEOPLASTICS & IMMUNOSUPPRESSANTS\*\* (cont.)

Immunomodulators		Approval duration: up to 1 year
<p><b>Preferred:</b> Arcalyst™</p> <p><b>Nonpreferred:</b> Pomalyst®, Revlimid®</p>	<p><b>Preferred agents:</b> Coverage is provided for the treatment of cryopyrin-associated periodic syndrome in members age 12 years or older. Initial approval: 3 months</p> <p><b>Nonpreferred agents:</b> Coverage is provided for the treatment of the FDA approved indications.</p>	
Kinase Inhibitors & Molecular Target Inhibitors		Approval duration: up to 1 year
<p><b>Preferred:</b> Afinitor®, Disperz™, Alecensa®, Bosulif®, Cabometyx™, Caprelsa®, Cometriq™, Cotellic™, Gilotrif™, Ibrance®, Iclusig®, Idhifa®, Imbruvica™, Inlyta®, Iressa®, Jakafi®, Kisqali®, Kisqali®-Femara® co-pack, Lenvima™, Lynparza™, Mekinist®, Nexavar®, Ninlaro®, Rydapt®, Sprycel®, Stivarga®, Sutent®, Tafinlar®, Tagrisso™, Tarceva®, Tasigna®, Tykerb®, Venclexta™, Votrient®, Xalkori®, Zejula™, Zelboraf®, Zydelig™, Zykadia™</p> <p><b>Nonpreferred:</b> Alunbrig™</p>	<p>Coverage is provided for the treatment of the FDA approved indications.</p>	
Miscellaneous Antineoplastic Agents		Approval duration: up to 1 year
<p><b>Preferred:</b> Erivedge™, Farydak®, Hycamtin®, Odomzo®, Rubraca, Targretin® capsules (g) (bexarotene), Zolanza®</p>	<p>Coverage is provided for the treatment of the FDA approved indications.</p> <p><b>Targretin capsules(g):</b> Coverage is provided for the treatment of cutaneous T-cell lymphoma (CTCL) in situations where the member has experienced treatment failure of or intolerance to at least one systemic therapy.</p>	
<p>**Note: Coverage also may be provided if the member is enrolled in a Phase II-IV investigative study and documentation of enrollment and study approval by an appropriate investigational review board (IRB) is submitted to the plan.</p>		
CARDIOVASCULAR, HYPERTENSION, CHOLESTEROL		
ACE-Inhibitors and Combinations		Approval duration: up to 10 years
<p><b>Nonpreferred:</b> Prestalia®</p>	<p>Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Lotrel(g) AND the individual agents used in combination at doses similar to the combination product. A credible explanation as to why Prestalia is expected to work if the individual agents in combination did not must be provided to the plan.</p>	
Alpha-adrenergic Agents		Approval duration: up to 1 year
<p><b>Preferred:</b> Dibenzylamine® (g) (phenoxybenzamine hcl)</p>	<p>Coverage is provided for the treatment of hypertension and sweating episodes due to pheochromocytoma:</p> <p><b>Preoperative treatment:</b> for members who have experienced treatment failure of or intolerance to a preferred selective alpha1-adrenergic receptor blocker (such as Cardura(g)) in combination with a preferred calcium channel blocker (such as Norvasc(g)).</p> <p>Approval duration: up to 14 days</p> <p><b>Non-preoperative treatment:</b> for members who have experienced treatment failure of or intolerance to TWO selective alpha1-adrenergic receptor blockers (such as Cardura(g)) where both are used in combination with a preferred calcium channel blocker (such as Norvasc(g)).</p>	

**CARDIOVASCULAR, HYPERTENSION, CHOLESTEROL (cont.)****Angiotensin II Receptor Blockers (ARBs) and Combinations**

Approval duration: up to 10 years

<p><b>Preferred:</b> Azor® (g) (amlodipine bes/olmesartan), Benicar® (g) (olmesartan medoxomil), Benicar HCT (g) (olmesartan/ hydrochlorothiazide) Tribenzor™ (g) (olmesartan/amlodipine/ hydrochlorothiazide)</p> <p><b>Nonpreferred:</b> Edarbi®, Edarbyclor®, Entresto™</p>	<p><b>Preferred agents:</b> <b>Azor(g), Tribenzor(g):</b> Coverage is provided in situations where the member has experienced successful treatment for at least three months with the individual agents used in combination. Additional coverage criteria may apply to the individual agents. <b>Benicar(g), Benicar HCT(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to a preferred generic ARB (such as Atacand(g)/HCT(g), Avalide(g), Avapro(g), Cozaar(g), Diovan(g)/HCT(g), Hyzaar(g), or Teveten(g)).</p> <p><b>Nonpreferred agents:</b> <b>Edarbi, Edarbyclor:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to a preferred generic ARB (such as Atacand(g), Avapro(g), or Cozaar(g)) AND Benicar(g)/HCT(g). <b>Entresto:</b> Coverage is provided for the treatment of NYHA class II to IV heart failure in members with left ventricular ejection fraction <math>\leq 35\%</math> that are currently taking or have documented contraindication to Coreg(g), Toprol XL(g), or Zebeta(g) AND have experienced treatment failure of or intolerance to both an angiotensin converting enzyme (ACE)-inhibitor (such as Prinivil(g)) AND Diovan(g). All agents must be used at optimal doses per the ACCF/AHA guidelines.</p>
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**Beta Blockers**

Approval duration: up to 10 years

<p><b>Nonpreferred:</b> Bystolic®, Coreg CR™</p>	<p><b>Bystolic:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least two preferred cardioselective beta blockers, such as Kerlone(g), Sectral(g), Tenormin(g), Toprol XL(g), or Zebeta(g). <b>Coreg CR:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to both Coreg(g) AND Toprol XL(g).</p>
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**Cardiovascular Treatment**

Approval duration: up to 10 years

<p><b>Preferred:</b> Corlanor®</p> <p><b>Nonpreferred:</b> Northera®, Ranexa®, Vecamyl®</p>	<p><b>Preferred agents:</b> Coverage is provided for members with heart failure and a left ventricular ejection fraction <math>\leq 35\%</math> in situations where the member is currently stable on a maximally tolerated dose of a beta blocker (such as Toprol XL(g)) or has a documented contraindication to beta blocker use. Coverage is not provided for use in combination with Entresto.</p> <p><b>Nonpreferred agents:</b> <b>Northera:</b> Coverage is provided for members 18 years of age or older for the treatment of symptomatic neurogenic orthostatic hypotension in situations where the member has experienced treatment failure of or intolerance to Florinef(g) AND Proamatine(g). <b>Ranexa:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to both a beta-blocker (such as Toprol XL(g)) and a maintenance nitrate (such as Imdur(g)) given around-the-clock. <b>Vecamyl:</b> Coverage is provided for the treatment of moderately severe to severe primary hypertension or uncomplicated cases of malignant hypertension in members who have experienced treatment failure of or intolerance to three antihypertensive drug combinations (such as Zestoril(g) plus Diuril(g) or Lopressor HCT(g)).</p>
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**Cholesterol-Lowering Agents**

Approval duration: up to 10 years

<p><b>Preferred:</b> Kynamro®, Lovaza® (g) (omega-3 acid ethyl esters)</p> <p>Cont. on the next page...</p>	<p><b>Preferred agents:</b> <b>Kynamro:</b> Coverage is provided for the treatment of homozygous familial hypercholesterolemia (HoFH) in situations where the member is receiving optimal adjunctive treatment with a statin (such as Zocor(g)), a low-fat diet, and other oral lipid lowering treatments. <b>Lovaza(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to all of the following: Lopid(g), an over-the-counter (OTC) Omega-3 fatty acid at a dose of at least 3 grams/day, and a generic fenofibrate (such as Antara(g), Lofibra(g), or Tricor(g)). Also requires triglyceride levels <math>\geq 500</math>mg/dl.</p>
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**CARDIOVASCULAR, HYPERTENSION, CHOLESTEROL (cont.)****Cholesterol-Lowering Agents (cont.)**

Approval duration: up to 10 years

**Nonpreferred:**  
Juxtapid™, Livalo®, Praluent™,  
Repatha™, Vascepa™

**Nonpreferred agents:**

**Livalo:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic statins, one of which must be high dose ( $\geq 40\text{mg}$ ) Lipitor(**g**).

**Juxtapid:** Coverage is provided for the treatment of homozygous familial hypercholesterolemia (HoFH) in situations where the member is receiving optimal adjunctive treatment with a statin (such as Zocor(**g**)), a low-fat diet and other oral lipid lowering treatments; and has experienced treatment failure of or intolerance to Kynamro.

**Praluent, Repatha:** Coverage is provided for FDA approved indications in members with uncontrolled LDL despite adherence with maximally tolerated concurrent treatment with all of the following for a minimum of three months unless contraindicated:

- i. Lifestyle modification (e.g. heart-healthy diet, regular exercise, tobacco avoidance)
- ii. High intensity statin (such as Crestor 20mg(**g**))
- iii. Zetia(**g**)
- iv. A preferred bile acid sequestrant (such as Welchol(**g**))
- v. Prescriber must be a cardiologist, endocrinologist, or board certified lipidologist.
- vi. Members with statin intolerance must have tried at least 3 different statins in the absence of drug interactions (consider at least one non-daily long-acting statin dosing regimen).

**Vascepa:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to ALL of the following: Lopid(**g**), an OTC Omega-3 fatty acid at a dose of at least 3 grams/day, a generic fenofibrate (i.e. Antara(**g**), Lofibra(**g**), or Tricor(**g**)), AND Lovaza(**g**). Also requires triglyceride levels  $\geq 500\text{mg/dl}$ .

**CENTRAL NERVOUS SYSTEM****Alzheimer's Therapy**

Approval duration: up to 10 years

**Preferred:**  
Aricept® 23mg (**g**) (donepezil hcl)

**Preferred agents:**

**Aricept 23mg(**g**):** Coverage is provided for the treatment of progressive-type dementia in situations where the member has experienced successful treatment with Aricept 10mg(**g**) for three months.

**Nonpreferred:**  
Namenda XR™, Namzaric™

**Nonpreferred agents:**

**Namenda XR:** Coverage is provided for the treatment of moderate to severe Alzheimer's disease in situations where the member has experienced treatment failure of or intolerance to Aricept(**g**).

**Namzaric:** Coverage is provided for members who are stabilized (at least 3 months of therapy) on the individual agents used in combination at the doses requested. A credible explanation as to why Namzaric is medically necessary when the member is experiencing successful therapy with the individual agents in combination must be submitted to the plan.

**CENTRAL NERVOUS SYSTEM (cont.)**

CENTRAL NERVOUS SYSTEM (cont.)	
Approval duration: up to 10 years	
<b>Anticonvulsants</b>	
<p><b>Nonpreferred:</b> Acthar® HP, Aptiom®, Briviact®, Lyrica®, Onfi®, Qudexy™ XR, Spritam®, Topiramate ER, Trokendi XR™</p>	<p><b>Acthar HP:</b> Coverage is provided for the treatment of infantile spasms (West Syndrome). Approval duration: up to 1 month</p> <p><b>Aptiom:</b> Coverage is provided for members 18 years of age or older as adjunctive therapy in the treatment of partial-onset seizures who have experienced treatment failure of or intolerance to at least two generic preferred alternatives, one of which must be Tegretol(g).</p> <p><b>Briviact:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Keppra(g) AND two other generic anticonvulsants (such as Tegretol(g) and Topamax(g)).</p> <p><b>Lyrica:</b></p> <ul style="list-style-type: none"> <li>• <b>Seizure disorder:</b> Coverage is provided in situations where the member is being treated concurrently with other anticonvulsants.</li> <li>• <b>Neuropathic pain:</b> Coverage is provided for diabetic peripheral neuropathy, post-herpetic neuralgia or neuropathy associated with spinal cord injury in situations where the member has experienced treatment failure of or intolerance to Neurontin(g). Members younger than 65 years of age must also experience treatment failure of or intolerance to a tricyclic antidepressant (such as Elavil(g)).</li> <li>• <b>Fibromyalgia:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Neurontin(g) AND at least three of the following: a tricyclic antidepressant (such as Elavil(g)), a selective serotonin reuptake inhibitor (SSRI) (such as Prozac(g)), a serotonin-norepinephrine reuptake inhibitor (SNRI) (such as Effexor(g)), Flexeril(g), or Ultram(g).</li> </ul> <p><b>Onfi:</b> Coverage is provided for members 2 years of age or older for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in situations where the member has experienced treatment failure of or intolerance to at least two generic anticonvulsants, one of which is Klonopin(g).</p> <p><b>Qudexy XR, Topiramate ER, Trokendi XR:</b></p> <ul style="list-style-type: none"> <li>• <b>Seizure disorder:</b> Coverage is provided for the treatment of seizure disorders in situations where the member has experienced treatment failure of or intolerance to at least two generic anticonvulsants, one of which must be Topamax(g). In addition, a credible explanation why topiramate extended-release is expected to work if Topamax(g) has not must be submitted to the plan. <b>Qudexy XR:</b> Coverage also requires documentation that the member is unable to swallow tablets/capsules.</li> <li>• <b>Migraine prophylaxis:</b> Coverage is provided for members 12 years of age or older for migraine prophylaxis in situations where the member has experienced treatment failure of or intolerance to at least three generic alternatives for migraine prophylaxis, one of which must be Topamax(g). In addition, a credible explanation why topiramate extended-release is expected to work if Topamax(g) has not must be submitted to the plan.</li> </ul> <p><b>Spritam:</b> Coverage is provided for members currently unable to swallow tablets/capsules in situations where the member has experienced treatment failure of or intolerance to Keppra(g) solution and two other generic anticonvulsants. A credible explanation why Spritam is expected to work if Keppra(g) solution has not must also be provided to the plan.</p>
Approval duration: up to 10 years	
<b>Antidepressants</b>	
<p><b>Preferred:</b> Pristiq® (g) (desvenlafaxine succinate)</p> <p><b>Nonpreferred:</b> Aplenzin™, Desvenlafaxine ER, Fetzima, Khedezla</p> <p>Cont. on the next page...</p>	<p><b>Preferred agents:</b></p> <p><b>Pristiq(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least two generic SSRIs (such as Prozac(g) or Zoloft(g)) AND one generic SNRI (such as Effexor(g)).</p> <p><b>Nonpreferred agents:</b></p> <p><b>Aplenzin:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least three generic antidepressants, one of which is Wellbutrin SR/XL(g).</p> <p><b>Desvenlafaxine ER, Fetzima, Khedezla:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least two generic SSRIs (such as Prozac(g) or Zoloft(g)) AND one generic SNRI (such as Effexor(g)).</p>



**CENTRAL NERVOUS SYSTEM (cont.)**

<b>Antidepressants (cont.)</b>		Approval duration: up to 10 years
<b>Nonpreferred:</b> Pexeva®, Trintellix®, Viibryd™	<b>Nonpreferred agents:</b> <b>Pexeva:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least three generic antidepressants, one of which is Paxil(g). <b>Trintellix, Viibryd:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least three generic antidepressants (such as Effexor(g), Prozac(g), Zoloft(g)).	
<b>Antipsychotics</b>		Approval duration: up to 10 years
<b>Preferred:</b> Fazaclo®(g) (clozapine), Invega® (g) (paliperidone), Seroquel XR® (g) (quetiapine fumarate)	<b>Preferred agents:</b> <b>Fazaclo(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Clozaril(g) tablets, unless the member is unable to swallow tablets/capsules. <b>Invega(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic 2nd generation antipsychotics, one of which is Risperdal(g). <b>Seroquel XR(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic 2nd generation antipsychotics, one of which is Seroquel(g) immediate release.	
<b>Nonpreferred:</b> Fanapt®, Fazaclo® 150mg, 200mg, Latuda®, Nuplazid™, Rexulti®, Saphris®, Vraylar™	<b>Nonpreferred agents:</b> <b>Fanapt, Latuda, Saphris, Vraylar:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic 2nd generation antipsychotics (such as Abilify(g) or Seroquel(g)). <b>Fazaclo 150, 200mg:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Clozaril(g) tablets, unless the member is unable to swallow tablets/capsules. <b>Nuplazid:</b> Coverage is provided for the treatment of Parkinson's disease psychosis. <b>Rexulti:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic second generation antipsychotic drugs, one of which is Abilify(g).	
<b>CNS Stimulants</b>		Approval duration: up to 5 years
<b>Preferred:</b> Adderall XR® (g) (amphet asp/amphet/d-amphet), Nuvigil® (g) (armodafinil), Procentra™ (g) (dextroamphetamine), Provigil® (g) (modafinil)	<b>Preferred agents:</b> <b>Adderall XR(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to brand name Adderall XR. <b>Nuvigil(g):</b> Coverage is provided for the treatment of narcolepsy or obstructive sleep apnea in situations where the member has experienced treatment failure of or intolerance to Provigil(g). Coverage is not provided for shift-work sleep disorder. Approval duration: up to 10 years <b>Procentra(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Adderall XR AND Metadate CD(g), both of which may be opened and sprinkled on applesauce. <b>Provigil(g):</b> Coverage is provided for the treatment of narcolepsy or obstructive sleep apnea. Coverage is not provided for shift-work sleep disorder. Approval duration: up to 10 years	
<b>Nonpreferred:</b> Adzenys XR-ODT™, Dyanavel™ XR, Quillichew ER™, Quillivant XR™	<b>Nonpreferred agents:</b> <b>Adzenys XR-ODT, Dyanavel XR, Quillichew ER, Quillivant XR:</b> Coverage is provided for members 6 years of age or older for the treatment of attention deficit hyperactivity disorder (ADHD) in situations where the member has experienced treatment failure of or intolerance to both a methylphenidate product (such as Concerta(g) or Ritalin(g)) AND an amphetamine product (such as Adderall(g)), one of which must be a generic long acting formulation OR the physician provides documentation the member cannot swallow tablets/capsules and has experienced treatment failure of or intolerance to one of the agents that can be opened and sprinkled on applesauce (such as Adderall XR or Metadate CD(g)).	
<b>Migraine Therapy</b>		Approval duration: up to 10 years
<b>Preferred:</b> Frova® (g) (frovatriptan succinate), Relpax® (g) (eletriptan) Cont. on the next page...	<b>Preferred agents:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic triptans (such as Imitrex(g) or Maxalt(g)).	

**CENTRAL NERVOUS SYSTEM (cont.)**

**Migraine Therapy (cont.)**

Approval duration: up to 10 years

**Nonpreferred:**

Onzetra™ Xsail™, Sumavel®  
DosePro®, Treximet®, Zembrace™  
Symtouch™, Zomig nasal spray

**Nonpreferred agents:**

**Onzetra Xsail:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Imitrex(g) nasal spray AND one other generic triptan (such as Maxalt(g)/MLT(g)). In addition, a credible explanation why Onzetra Xsail is expected to work when Imitrex(g) nasal spray did not must also be provided to the plan.

**Zomig nasal spray:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two generic triptans (such as Imitrex(g) or Maxalt(g)).

**Sumavel DosePro, Zembrace Symtouch:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Imitrex(g) injection AND one other generic triptan (such as Maxalt(g)/MLT(g)). In addition, a credible explanation why Sumavel DosePro or Zembrace Symtouch is expected to work when Imitrex(g) injection did not must also be provided to the plan.

**Treximet:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to a combination of Imitrex(g) with naproxen, and one other generic triptan (such as Maxalt (g)/MLT(g)).

**Miscellaneous CNS**

Approval duration: up to 10 years

**Preferred:**

Nuedexta®, Xenazine® (g)  
(tetrabenazine)

**Preferred agents:**

**Nuedexta:** Coverage is provided for the treatment of pseudobulbar affect (PBA) due to a documented underlying neurological condition (such as multiple sclerosis or stroke).

**Xenazine(g):** Coverage is provided for the treatment of chorea associated with Huntington's disease.

**Nonpreferred:**

Austedo™, Gralise™, Horizant™,  
Ingrezza, Savella®, Xyrem®

**Nonpreferred agents:**

**Austedo:** Coverage is provided for the treatment of chorea associated with Huntington's disease.

**Gralise:** Coverage is provided for the treatment of neuropathic pain associated with post-herpetic neuralgia in situations where the member has experienced treatment failure of or intolerance to Neurontin(g). Members 65 years of age or younger must also experience treatment failure of or intolerance to a tricyclic antidepressant (such as Elavil(g)). A credible explanation as to why Gralise is expected to work if Neurontin(g) did not must be submitted to the plan.

**Horizant:**

**Restless Legs Syndrome (RLS):** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Mirapex(g), Neurontin(g), and Requip(g)/XL(g), and a credible explanation as to why Horizant is expected to work if Neurontin(g) did not must be submitted to the plan.

**Post-herpetic neuralgia:** Coverage is provided for members 65 years of age or older old who have experienced treatment failure of or intolerance to Neurontin(g). Members less than 65 years of age also require treatment failure of or intolerance to a tricyclic antidepressant (such as Elavil(g)).

**Ingrezza:** Coverage is provided for members 18 years of age or older for the treatment of tardative dyskinesia when prescribed by a psychiatrist or neurologist.

**Savella:** Coverage is provided for the treatment of fibromyalgia in situations where the member has experienced treatment failure of or intolerance to Neurontin(g) and at least three of the following: a tricyclic antidepressant (such as Elavil(g)), a SSRI (such as Prozac(g)), a SNRI (such as Effexor(g)), Flexeril(g), or Ultram(g).

**Xyrem:** Coverage is provided for the treatment of narcolepsy with cataplexy. For members with a confirmed diagnosis of narcolepsy with excessive day time sleepiness, coverage is provided in situations where the member has experienced treatment failure of or intolerance to either a generic methylphenidate product (such as Concerta(g) or Ritalin(g)) or an amphetamine product (such as Adderall(g)) AND Provigil(g) at doses up to 400 mg per day.



**CENTRAL NERVOUS SYSTEM (cont.)**

<b>Narcotics</b>		Approval duration: up to 5 years
<p><b>Preferred:</b> Actiq® (g) (fentanyl citrate), Exalgo™(g) (hydromorphone), Opana ER(g) (oxymorphone)</p> <p><b>Nonpreferred:</b> Abstral™, Embeda®, Fentora®, Hysingla® ER, Lazanda®, Nucynta®, Nucynta® ER, Oxycodone hcl ER, Oxycontin®, Subsys™, Zohydro ER®</p>	<p><b>Preferred agents:</b> <b>Actiq(g):</b> Coverage is provided for the treatment of breakthrough cancer pain in members that are tolerant of high dose narcotics and are currently receiving a long-acting narcotic (such as MS Contin(g)). The member must also have experienced treatment failure of or intolerance to the use of other oral immediate-release narcotics (such as MSIR(g) or oxycodone immediate-release) for the management of breakthrough pain. <b>Exalgo(g)*:</b> Coverage is provided for the management of moderate to severe pain in opioid tolerant members requiring continuous around the clock analgesia AND requires treatment failure of or intolerance to at least TWO of the following long-acting preferred agents: Duragesic(g), methadone, or MS Contin(g). <b>Opana ER(g)*:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to an adequate trial with at least two dose titrations to doses up to 400mg/day of MS Contin(g) AND 100mcg per application of Duragesic(g).</p> <p><b>Nonpreferred agents:</b> <b>Abstral, Fentora, Lazanda, Subsys:</b> Coverage is provided 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. <b>Embeda*, Hysingla ER*, Oxycodone hcl ER*, Oxycontin*, Zohydro ER*:</b> Coverage is provided for the treatment of moderate to severe chronic pain requiring around-the-clock, long-term opioid treatment in situations where the member has experienced treatment failure of or intolerance to an adequate trial with at least two dose titrations to doses up to 400mg/day of MS Contin(g) AND 100mcg per application of Duragesic(g). <b>Nucynta:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Ultram(g)/ER(g) or Ultracet(g) AND two preferred immediate-release narcotics (such as MSIR(g) or oxycodone immediate-release). If use is to exceed 30 days, Nucynta must be used in combination with a long-acting narcotic (such as Duragesic(g), methadone, or MS Contin(g)). Approval Duration: 30 days <b>Nucynta ER*:</b> <b>Moderate to severe chronic pain:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Ultram ER(g) AND two of the following preferred long-acting agents: Duragesic(g), methadone or MS Contin(g). <b>Post-herpetic neuralgia or diabetic peripheral neuropathy:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to:  <ul style="list-style-type: none"> <li>• Members &lt; 65 years: Neurontin(g), a tricyclic antidepressant (such as Elavil(g)) and Cymbalta(g)</li> <li>• Members ≥ 65 years: Neurontin(g) and Cymbalta(g)</li> </ul> <b>*Note:</b> Coverage will not be provided if the patient is on more than one long acting narcotic concurrently.</p>	
<b>Narcotic/Analgesic Combinations</b>		Approval duration: up to 10 years
<p><b>Preferred:</b> Fioricet® 50/300/40mg(g) (butalbital/apap/caffeine), Fioricet with Codeine 50/300/30mg(g) (butalbital/apap/caffeine/codeine)</p>	<p><b>Preferred agents:</b> <b>Fioricet 50/300/40mg(g), Fioricet with Codeine 50/300/30mg(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to a similar product containing 325mg of acetaminophen (such as Esgic(g) (50/325/40mg)), a credible explanation as to why the 300mg acetaminophen product is expected to work when the 325mg acetaminophen product did not must be submitted to the plan, AND a completed MedWatch form has been submitted to the FDA and to the plan documenting an adverse effect or quality issue with the 325mg of acetaminophen product.</p>	
<b>Narcotic Mixed Agonist/Antagonist</b>		Approval duration: up to 5 years
<p><b>Preferred:</b> Subutex®(g) (buprenorphine)</p> <p>Cont. on the next page...</p>	<p><b>Preferred agents:</b> Coverage under the pharmacy benefit is provided for the treatment of opioid dependence in situations where the member is currently pregnant or breastfeeding. Approval duration: up to 1 year</p>	

<b>CENTRAL NERVOUS SYSTEM (cont.)</b>	
<b>Narcotic Mixed Agonist/Antagonist (cont.)</b> Approval duration: up to 5 years	
<b>Nonpreferred:</b> Belbuca™, Buprenorphine patch, Butrans®	<b>Nonpreferred agents:</b> Coverage is provided for the treatment of moderate to severe chronic pain in situations where the member has experienced treatment failure of or intolerance to at least TWO of the following: Duragesic(g), methadone, MS Contin(g) or Ultram ER(g).
<b>Non-Steroidal Anti-Inflammatory Drugs</b> Approval duration: up to 3 months	
<b>Preferred:</b> Pennsaid™ 1.5%(g) (diclofenac sodium)	<b>Preferred agents:</b> <b>Pennsaid 1.5%(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to an OTC topical analgesic (Aspercreme OR Myoflex) and Voltaren(g)/XR(g) tablets.
<b>Nonpreferred:</b> Flector® Patch, Pennsaid 2%	<b>Nonpreferred agents:</b> <b>Flector Patch:</b> Coverage is provided for the treatment of acute sprains, strains and contusions in situations where the member has experienced treatment failure of or intolerance to an OTC topical analgesic (Aspercreme OR Myoflex) and Voltaren(g)/XR(g) tablets. Approval duration: up to 1 month <b>Pennsaid 2%:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to an OTC topical analgesic (Aspercreme OR Myoflex), Pennsaid 1.5%(g) and Voltaren(g)/XR(g) tablets.
<b>Parkinson's Disease and Related Disorders</b> Approval duration: up to 10 years	
<b>Preferred:</b> Duopa™: Mirapex ER®(g) (pramipexole di-hcl)	<b>Preferred agents:</b> <b>Duopa:</b> Coverage is provided for the treatment of advanced Parkinson's disease for members with a feeding tube. <b>Mirapex ER(g):</b> Coverage is provided for the treatment of Parkinson's disease in situations where the member has experienced treatment failure of or intolerance to Mirapex IR(g).
<b>Nonpreferred:</b> Neupro®, Rytary™	<b>Nonpreferred agents:</b> <b>Neupro:</b> Coverage is provided for the treatment of Parkinson's disease or restless leg syndrome in situations where the member has experienced treatment failure of or intolerance to Mirapex(g)/ER(g) AND Requip(g)/XL(g). <b>Restless leg syndrome:</b> Coverage also requires treatment failure of or intolerance to Neurontin(g). <b>Rytary:</b> Coverage is provided for members who have experienced treatment failure of or intolerance to both Sinemet(g) and Sinemet CR(g), and a credible explanation as to why Rytary is expected to work when both the Sinemet(g) and Sinemet CR(g) have not must be submitted to the plan.
<b>Sedatives/Hypnotics</b> Approval duration: up to 1 year	
<b>Preferred:</b> Intermezzo® (g) (zolpidem tartrate)	<b>Preferred agents:</b> <b>Intermezzo:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Ambien CR(g) and either Lunesta(g) or Sonata(g).
<b>Nonpreferred:</b> Belsomra®, Edluar™, Hetlioz®, Rozerem®, Silenor™, Zolpimist™	<b>Nonpreferred agents:</b> <b>Belsomra, Rozerem, Zolpimist:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to three of the following: Ambien(g), Desyrel(g), Lunesta(g) or Sonata(g). <b>Edluar:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Ambien CR(g) and either Lunesta(g) or Sonata(g). <b>Hetlioz:</b> Coverage is provided for the treatment of Non-24-Hour Sleep-Wake Disorder in completely blind members 18 years of age or older in situations where the member has experienced treatment failure of or intolerance to both an OTC melatonin and Rozerem®. <b>Silenor:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Ambien(g), Desyrel®(g), Lunesta(g), Sinequan(g) AND Sonata(g).
<b>Skeletal Muscle Relaxants</b> Approval duration: up to 1 year	
<b>Preferred:</b> Skelaxin®(g) (metaxalone)	<b>Skelaxin(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to at least three of the following: Flexeril(g), Norflex(g), Parafon Forte(g), or Robaxin(g).
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<b>CENTRAL NERVOUS SYSTEM (cont.)</b>	
<b>Skeletal Muscle Relaxants (cont.)</b> Approval duration: up to 1 year	
<b>Preferred:</b> Zanaflex capsules(g) (tizanadine)	<b>Zanaflex capsules(g):</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to ALL of the following: baclofen, Flexeril(g), and Zanaflex tablets(g).
<b>DERMATOLOGY</b>	
<b>Acne Treatment</b> Approval duration: up to 5 months	
<b>Nonpreferred:</b> Absorica®	Coverage is provided in situations where the member has experienced treatment failure of or intolerance to generic isotretinoin (such as Claravis(g)).
<b>Antipsoriatic/Antiseborrheic</b> Approval duration: up to 10 years	
<b>Preferred:</b> Cosentyx®, Enbrel®, Otezla®, Stelara®, Taclonex®(g) (calcipotriene/betamethasone dipropionate)	<b>Preferred agents:</b> <b>Cosentyx, Otezla, Stelara:</b> Coverage is provided for members 18 years of age or older for the treatment of moderate to severe plaque psoriasis. <b>Enbrel:</b> Coverage is provided for the treatment of moderate to severe plaque psoriasis in situations where the member has experienced treatment failure of or intolerance to Humira. Pediatric psoriasis does not require the treatment failure of Humira. <b>Taclonex(g):</b> Coverage is provided in situations where 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 (such as Diprolene ointment(g), Psorcon(g), Temovate(g)) plus Dovonex(g).
<b>Nonpreferred:</b> Enstilar®, Otrexup®, Rasuvo™, Taclonex Scalp, Taltz®, Tremfya	<b>Nonpreferred agents:</b> <b>Enstilar, Taclonex scalp:</b> Coverage is provided in situations where 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 (such as Diprolene ointment(g), Psorcon(g), Temovate(g)) plus Dovonex(g). <b>Enstilar:</b> Also requires trial and failure of Taclonex(g) ointment. <b>Otrexup, Rasuvo:</b> Coverage is provided for the treatment of FDA approved indications in situations where the member has experienced treatment failure of or intolerance to both oral and intramuscular methotrexate and a credible explanation as to why subcutaneous methotrexate is expected to work when the other formulations have not must be submitted to the plan. <b>Taltz, Tremfya:</b> Coverage is provided for members 18 years of age or older for the treatment of moderate to severe plaque psoriasis in situations where the member has experienced treatment failure of or intolerance to at least two of the following: Cosentyx, Humira, Otezla, and Stelara.
<b>Miscellaneous dermatologicals</b> Approval duration up to 1 year	
<b>Nonpreferred:</b> Dupixent®, Eucrisa™	<b>Dupixent:</b> Coverage is provided for the treatment of atopic dermatitis for members 18 years of age or older in situations where the prescription is written by a dermatologist or an allergist and the member has experienced treatment failure of or intolerance to all of the following: phototherapy or photochemotherapy (PUVA), two topical steroid creams, one of which is of medium or high potency (such as Diprosone(g) or Elecon(g)), a topical calcineurin inhibitor (such as Protopic(g)), and an oral systemic agent (such as methotrexate). <b>Eucrisa:</b> Coverage is provided for the treatment of atopic dermatitis in members 2 years of age or older in situations where the member has experienced treatment failure or intolerance to two topical steroids, one of which is medium or high potency (such as Diprosone(g) or Elecon(g) and a topical calcineurin inhibitor (such as Protopic(g)).
<b>Topical Antineoplastic Agents and Immunomodulators</b> Approval duration up to 1 year	
<b>Preferred:</b> Solaraze®(g) (diclofenac sodium)	<b>Preferred agents:</b> <b>Solaraze(g):</b> Coverage is provided for the treatment of actinic keratosis in situations where the member has experienced treatment failure of or intolerance to three different treatment courses of cryotherapy and two formulary alternatives (such as Aldara(g), Efudex(g) or Retin-A(g)).
<b>Nonpreferred:</b> Picato®, Targretin® gel	<b>Nonpreferred agents:</b> <b>Picato:</b> Coverage is provided for the treatment of actinic keratosis in situations where the member has experienced treatment failure of or intolerance to three different treatment courses of cryotherapy and two formulary alternatives (such as Aldara(g), Efudex(g) or Retin-A(g)). <b>Targretin gel:</b> Coverage is provided for the treatment of cutaneous T-cell lymphoma (CTCL) where the member has experienced treatment failure of or intolerance to at least one systemic therapy.
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<b>DERMATOLOGY (cont.)</b>	
<b>Topical Antineoplastic Agents and Immunomodulators (cont.)</b> Approval duration up to 1 year	
<b>Nonpreferred:</b> Valchlor™	<b>Valchlor:</b> Coverage is provided for the treatment of Stage 1A or 1B mycosis fungoides type cutaneous T-cell lymphoma in situations where the member has experienced treatment failure of or intolerance to at least two skin-directed therapies: 1. Topical carmustine or topical retinoid AND 2. Phototherapy or total skin electron beam therapy.
<b>DIAGNOSTICS &amp; OTHER MISCELLANEOUS</b>	
<b>Chelating Agents</b> Approval duration: up to 1 year	
<b>Nonpreferred:</b> Exjade®, Ferriprox®, Jadenu™, Syprine®	<b>Exjade:</b> Coverage is provided for members 2 years of age and older for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) or transfusional iron overload due to thalassemia syndromes in situations where the member has experienced treatment failure of or intolerance to Desferal(g). <b>Ferriprox:</b> Coverage is provided for the treatment of transfusional iron overload due to thalassemia syndromes in situations where the member has experienced treatment failure of or intolerance to Desferal(g) and either Exjade or Jadenu. Additional coverage criteria applies to Exjade or Jadenu. <b>Jadenu:</b> Coverage is provided for the treatment of chronic iron overload due to blood transfusions and non-transfusion dependent thalassemia (NTDT) syndromes in situations where the member has experienced treatment failure of or intolerance to Desferal(g). <b>Syprine:</b> Coverage is provided for the treatment of Wilson's disease in situations where the member has experienced treatment failure of, intolerance to, or contraindication to Depen.
<b>Diagnostic &amp; Other Miscellaneous</b> Approval duration: up to 1 year	
<b>Nonpreferred:</b> Endari™, Keveyis™	<b>Endari:</b> Coverage is provided for members 5 years of age or older for the treatment of sickle cell disease in situations where the member has experienced treatment failure of or intolerance to Hydrea(g). <b>Keveyis:</b> Coverage is provided for the treatment of hyperkalemic or hypokalemic periodic paralysis as confirmed by genetic testing or positive family history in members who have experienced treatment failure of lifestyle modifications (such as dietary and exercise alterations) AND Diamox(g).
<b>ENDOCRINOLOGY</b>	
<b>Androgens</b> Approval duration: up to 1 year	
<b>Preferred:</b> Androderm®, AndroGel®, AndroGel® 1% packet (g) (testosterone), Android® (g) (methyltestosterone), Androxy™ (g) (fluoxymesterone), Testred® (g) (methyltestosterone)	<b>Preferred agents*:</b> <ul style="list-style-type: none"> <li>Coverage is provided for the following: Female to male gender transition</li> <li>As testosterone replacement therapy for male members in situations where the member has confirmed androgen deficiency defined as TWO morning testosterone levels obtained on different days within the past year (FREE testosterone levels are required for body mass index (BMI) of 30kg/m2 or greater) and below the normal range established in the utilized laboratory, AND at least two specific signs/symptoms of testosterone deficiency. [If laboratory documentation is not provided, total testosterone must be less than 300 ng/dL, or free testosterone less than 9 pg/mL for BMI of 30kg/m2 or greater].</li> </ul> <p>[Qualifying specific signs/symptoms of testosterone deficiency include: 1.) incomplete or delayed sexual development, eunuchoidism; 2.) breast discomfort, gynecomastia; 3.) loss of body (axillary and/or pubic) hair, reduced shaving; 4.) height loss, low trauma fracture, low bone mineral density; 5.) hot flushes, sweats.]</p>
<b>Nonpreferred:</b> Axiron®, Fortesta™, Methitest™, Natesto™, Striant®, Testim®, Testosterone (Brand), Vogelxo®	<b>Nonpreferred agents:</b> Coverage is provided for testosterone replacement therapy for male members meeting the criteria for preferred agents and who have experienced treatment failure of or intolerance to Androderm and AndroGel.
<b>Corticosteroids</b> Approval duration: up to 1 year	
<b>Nonpreferred:</b> Emflaza™	<b>Emflaza:</b> Coverage is provided for members 5 years of age or older for the treatment of Duchenne's Muscular Dystrophy in situations where the member has experienced treatment failure of or intolerance to prednisone or prednisolone.

**ENDOCRINOLOGY (cont.)****Growth Hormone & Related Products**

Approval duration: up to 1 year

**Preferred:**

Genotropin®, Nutropin® AQ, Nuspin

**Preferred agents\*:**

**Children (<18 years of age):** Coverage is provided for the treatment of growth hormone deficiency, growth failure secondary to chronic renal failure/insufficiency 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, test results confirming diagnosis must be provided. The member's height must be below the 5th percentile, and epiphyses must be confirmed as open.
- **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.

**Adults (≥18 years of age):** Coverage is provided for the treatment of growth hormone deficiency, AIDS wasting cachexia, Turner's Syndrome and Short Bowel Syndrome (SBS). The diagnosis of growth hormone deficiency must be based on one of the following: 1) two failed growth hormone stimulation tests, 2) three or more pituitary hormone deficiencies other than growth hormone (for example TSH) with an IGF-1 below 80ng/ml, or 3) failure of one growth hormone stimulation test, and at least one pituitary hormone deficiency OR one GH stimulation test or subnormal IGF-1 level AND any of the following: defined CNS pathology, history of irradiation/surgery/trauma, multiple pituitary hormone deficiency or a genetic defect affecting the growth hormone axis.

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

**Nonpreferred:**

Humatrope®, Increlex™, Norditropin®, Flexpro®, Omnitrope®, Saizen®, Serostim®, Zomacton®, Zorbtive™

**Nonpreferred agents\*:**

Coverage is provided in situations where the member has experienced treatment failure of or intolerance to a preferred agent.

**Increlex:** Coverage is provided for the treatment of severe IGF-1 deficiency, growth hormone gene deletion, and Laron's syndrome in members less than 18 years of age with open epiphyses and height below the 3rd percentile. The member must have a normal or elevated growth hormone level with an IGF-1 level 3 or more standard deviations below normal.

- **To Continue:** Renewal can be obtained if the member has clinical response with therapy, as demonstrated by an annual growth velocity of ≥ 2.5 cm.

\*Note: Treatment for idiopathic short stature is not covered.

**Insulins**

Approval duration: up to 10 years

**Preferred**

Apidra®, Solostar®, Humalog® (except U-200), Humulin® (except U-500)

**Preferred agents:**

Coverage is provided in situations where the member has failed to achieve glycemic control with use of Novolin or Novolog for at least three months.

**Nonpreferred:**

Afrezza®, Soliqua™, Xultophy®

**Nonpreferred agents:**

**Afrezza:** Coverage is provided for the treatment of diabetes mellitus in members who have experienced treatment failure of or intolerance to at least 3 months of therapy with subcutaneous rapid-acting insulin (such as Novolog) and a credible explanation as to why Afrezza is expected to work when the subcutaneous product has not must be submitted to the plan.

**Soliqua\*:** Coverage is provided for the treatment of type 2 diabetes mellitus in members with a hemoglobin A1c value greater than 7% in situations where the member has experienced treatment failure of or intolerance to two preferred oral agents (one of which is Glucophage(g)) and has experienced at least THREE months of successful treatment with the individual agents that are in the combination product (Lantus or Basaglar AND Adlyxin). Additional coverage criteria applies to Adlyxin.

**Xultophy\*:** Coverage is provided for the treatment of type 2 diabetes mellitus in members with a hemoglobin A1c value greater than 7% in situations where the member has experienced treatment failure of or intolerance to two preferred oral agents (one of which is Glucophage(g)) and has experienced at least THREE months of successful treatment with the individual agents that are in the combination product (Tresiba AND Victoza). Additional coverage criteria applies to Victoza.

\*The hemoglobin A1c value submitted to the plan must be obtained within the previous 12 months.



**ENDOCRINOLOGY (cont.)****Non-Insulin Hypoglycemic Agents**

Approval duration: up to 10 years

**Preferred:**

Bydureon™, Farxiga®, Invokamet™, Invokamet™ XR, Invokana™, Victoza®, Xigduo XR™

**Nonpreferred:**

Adlyxin™, Alogliptin, Alogliptin-metformin, Alogliptin-pioglitazone, Avandamet®, Avandia®, Byetta®, Cycloset®, Glyxambi®, Jardiance®, Jentadueto™, Jentadueto® XR, Kazano®, Nesina®, Oseni®, Symlinpen®, Synjardy®, Synjardy® XR, Tanzeum™, Tradjenta™, Trulicity®

**Preferred agents:**

**Bydureon\*, Victoza\*:** Coverage is provided for the treatment of type 2 diabetes in members who are currently taking or have experienced treatment failure of or intolerance to at least ONE of the following: Glucophage(g), a sulfonylurea (such as Glucotrol(g)/XL(g)), Actos(g) or Glucophage(g) in combination (such as Glucovance(g)).

**Farxiga, Invokamet, Invokamet XR, Invokana, Xigduo XR:** Coverage is provided for members who are currently taking or have experienced treatment failure of or intolerance to an agent from at least ONE of the following drug classes: Glucophage(g), a sulfonylurea (such as Glucotrol(g)/XL(g)), or a thiazolidinedione (TZD) (such as Actos(g)).

**Nonpreferred agents:**

**Adlyxin\*, Byetta\*, Tanzeum\*, Trulicity\*:** Coverage is provided for the treatment of type 2 diabetes in members who have experienced treatment failure of or intolerance to all of the following: two oral antidiabetic agents, one of which is Glucophage(g), Bydureon and Victoza.

**Alogliptin, Nesina, Tradjenta:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to the use of both preferred DPP-4 inhibitors (Januvia and Onglyza) AND at least one agent from THREE of the following drug classes: Glucophage(g), basal insulin, a sulfonylurea (such as Glucotrol(g)), and a thiazolidinedione (such as Actos(g)).

**Alogliptin-metformin, Alogliptin-pioglitazone, Avandamet, Jentadueto, Jentadueto XR, Kazano, Oseni:** Coverage is provided in situations where the member has experienced successful treatment for at least three months with the individual agents used in combination. Additional coverage criteria may apply to the individual agents.

**Avandia:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to both Actos(g) and Glucophage(g).

**Cycloset:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to the use of at least one agent from three of the following drug classes: Glucophage(g), basal insulin, a sulfonylurea (such as Glucotrol(g)) and a TZD (such as Actos(g)).

**Glyxambi, Synjardy, Synjardy XR:** Coverage is provided for members who have experienced successful treatment with at least three months of combination therapy with the individual agents that are in the combination product. Additional coverage criteria may apply to the individual agents.

**Jardiance:** Coverage is provided for members who have experienced treatment failure of or intolerance to a preferred SGLT-2 agent (such as Farxiga) AND at least one agent from three of the following drug classes: Glucophage(g), a DPP-4 inhibitor (such as Januvia), a sulfonylurea (such as Glucotrol(g)), and a thiazolidinedione (such as Actos(g)).

**Symlinpen:** Coverage is provided for members 18 years of age or older for the treatment of diabetes mellitus in members who are receiving mealtime insulin therapy and have not achieved desired glucose goal despite good compliance with optimal insulin therapy.

\* The hemoglobin A1c value submitted to the plan must be obtained within the previous 12 months.

**Osteoporosis/Hormonal Treatment**

Approval duration: up to 1 year

**Nonpreferred:**

Duavee™

Coverage is provided for the prevention of postmenopausal osteoporosis in female members who have a higher risk of osteoporosis and experienced treatment failure of or intolerance to at least two preferred oral bisphosphonates (such as Actonel(g), Boniva(g), or Fosamax(g)).

**Miscellaneous Endocrinology**

Approval duration: up to 10 years

**Preferred:**

Carbaglu®

**Preferred agents:**

**Carbaglu:** Coverage is provided for the treatment of hyperammonemia due to a deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) as confirmed by enzyme or DNA mutation analysis.

Initial approval duration: up to 3 months



**ENDOCRINOLOGY (cont.)****Miscellaneous Endocrinology**

Approval duration: up to 10 years

**Preferred:**

Cholbam<sup>®</sup>, Korlym<sup>™</sup>, Kuvan<sup>®</sup>,  
Natpara<sup>®</sup>, Signifor<sup>®</sup>, Strensiq<sup>™</sup>,  
Kermelo<sup>™</sup>

**Preferred agents:**

**Cholbam:** Coverage is provided for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs) or peroxisomal disorders (PDs) (including Zellweger spectrum disorders) with manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption.

**Korlym:** Coverage is provided for members 18 years of age or older with Cushing's syndrome for the treatment of the following:

- **Diabetes mellitus:** in situations where the member has experienced treatment failure of or intolerance to ALL of the following: surgery or radiotherapy, at least 3 months of insulin therapy, and a steroidogenesis inhibitor (such as Nizoral<sup>(g)</sup>). A Hgb A1c level within the past year must also be submitted.
- **Glucose intolerance:** Coverage is provided secondary to hypercortisolism in situations where the member has experienced treatment failure of or intolerance to surgery or radiotherapy AND a steroidogenesis inhibitor (such as Nizoral<sup>(g)</sup>). A 2-h oral glucose tolerance test (OGTT) within the past year must also be submitted.

Initial approval duration: up to 6 months. The member must demonstrate clinically significant improvement in glucose control for continuation of therapy.

**Kuvan:** Coverage is provided for the treatment of phenylketonuria (PKU) in members following a phenylalanine-restricted diet in conjunction with Kuvan use.

**Natpara:** Coverage is provided for the treatment of hypocalcemia associated with documented hypoparathyroidism in situations where the member is currently being treated with both calcium and Rocaltrol<sup>(g)</sup> and is not well controlled.

**Signifor:** Coverage is provided for members 18 years of age or older who meet the following criteria:

- a) Hypercortisolism as a result of endogenous Cushing's syndrome.
- b) Surgical treatment has been ineffective or are not candidates for surgery.
- c) Treatment failure of or intolerance to Nizoral<sup>(g)</sup> or Lysodren.

Approval duration: up to 1 year

**Strensiq:** Coverage is provided for the treatment of pediatric-onset hypophosphatasia in situations where clinical documentation of the member's active disease manifestations has been submitted to the plan.

**Kermelo:** Coverage is provided for members 18 years of age or older for the treatment of carcinoid syndrome diarrhea when written by an oncologist or gastroenterologist in situations where the member has experienced treatment failure of or intolerance to a somatostatin analog (such as Sandostatin<sup>(g)</sup>) and will be using the medication in combination with a somatostatin analog.

**Nonpreferred:**

Cerdelga<sup>®</sup>, Egrifta<sup>®</sup>, Myalept<sup>™</sup>,  
Ravicti<sup>™</sup>, Rayaldee<sup>®</sup>, Signifor<sup>®</sup> LAR,  
Zavesca<sup>®</sup>

**Nonpreferred agents:**

**Cerdelga, Zavesca:** Coverage is provided for members 18 years of age or older for the treatment of Type 1 Gaucher's disease in situations where the member has experienced treatment failure of or intolerance to enzyme replacement therapy, such as Cerezyme.

**Cerdelga:** Coverage also requires that the member's CYP2D6 genotype metabolizer status be provided to the plan.

**Egrifta:** Coverage is provided for members 18 years of age or older for the treatment of excess abdominal fat in HIV-associated lipodystrophy who are receiving antiretroviral therapy.

Approval duration: up to 1 year

**Myalept:** Coverage is provided for the treatment of generalized lipodystrophy in situations where the member is optimally treated with insulin and a statin (such as Zocor<sup>(g)</sup>).

**Ravicti:** Coverage is provided for the treatment of any chronic urea cycle disorder (except for NAGS deficiency) in situations where the member has experienced treatment failure of or intolerance to Buphenyl.

**Rayaldee:** Coverage is provided for the treatment of FDA approved indications in situations where the member has experienced treatment failure of or intolerance to three preferred vitamin D analogues (such as Hectorol<sup>(g)</sup>, Rocaltrol<sup>(g)</sup>, or Zemplar<sup>(g)</sup>).

**Signifor LAR:** Coverage is provided for the treatment of acromegaly in situations where the member has experienced treatment failure of or intolerance to ALL of the following: Sandostatin<sup>(g)</sup>/LAR, Somatuline Depot, and Somavert. Use of the 60mg also requires inadequate response to therapy with the 40mg strength.

## GASTROINTESTINAL AGENTS

<b>Antidiarrheals and Antispasmodics</b>		Approval duration: up to 1 year
<b>Preferred:</b> Mytesi™	Coverage is provided for members with HIV/AIDS who are currently on antiretroviral therapy for the treatment of symptomatic relief of non-infectious diarrhea.	
<b>Antiemetics</b>		Approval duration: up to 1 year
<b>Nonpreferred:</b> Akynzeo®, Diclegis®, Sancuso®, Varubi™, Zuplenz®	<p><b>Akynzeo:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to an anti-emetic regimen containing ALL of the following: a generic 5-HT3 receptor antagonist (such as Zofran(g)), a preferred NK-1 receptor antagonist (such as Emend(g)), and a glucocorticoid (such as dexamethasone); AND where the requested medication will be used in combination with dexamethasone.</p> <p><b>Diclegis:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Zofran(g) and OTC pyridoxine and OTC doxylamine used in combination, AND a credible explanation why Diclegis is expected to work when the individual agents in combination did not is provided to the plan. Approval duration: up to 9 months</p> <p><b>Sancuso, Zuplenz:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to oral Kytril(g) AND Zofran(g)/ODT(g).</p> <p><b>Varubi:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to an anti-emetic regimen containing ALL of the following used in combination: 1) a generic 5-HT3 receptor antagonist (such as Zofran(g)), 2) a preferred NK-1 receptor antagonist (such as Emend(g)), and 3) a glucocorticoid (such as dexamethasone); AND where the requested medication will be used in combination with dexamethasone and a 5-HT3 receptor antagonist (such as Zofran(g)).</p>	
<b>Miscellaneous Gastrointestinal Agents</b>		Approval duration: up to 10 years
<b>Preferred:</b> Gattex®, Ocaliva™, Relistor® syringe, Relistor® vial, Stelara®	<p><b>Preferred agents:</b></p> <p><b>Gattex:</b> Coverage is provided for members 18 years of age or older with a diagnosis of Short Bowel Syndrome (SBS) AND dependence on parenteral support <math>\geq</math> 12 months. Approval duration: up to 1 year</p> <p><b>Ocaliva:</b> Coverage is provided for the treatment of primary biliary cirrhosis (PBC) that has been confirmed by at least two of the following tests: 1) positive antimitochondrial antibody (AMA); 2) elevated serum alkaline phosphatase (ALP); 3) histologic evidence of PBC based on liver biopsy. In addition, the member must have experienced an inadequate response to at least one year of treatment with ursodeoxycholic acid (such as Actigall(g)) and treatment must be continued in combination with Ocaliva. Continued coverage is provided in situations where the member has experienced an improvement in biochemical response (i.e., ALP levels less than 1.67 x ULN, at least 15% decrease in ALP for patients whose baseline ALP levels were between 1.67 and 2.0 x ULN, and/or total bilirubin &lt; ULN at 12 months.)</p> <p><b>Relistor syringe, Relistor vial:</b> Coverage is provided for the treatment of opioid-induced constipation in members who are currently receiving opioid therapy and have experienced treatment failure of or intolerance to ALL of the following: osmotic laxatives (such as Miralax(g)), saline laxatives (such as Fleet(g)), and stimulant laxatives (such as Dulcolax(g)) in combination with a stool softener (such as Colace(g)).</p> <p><b>Stelara:</b> Coverage is provided for the treatment of Crohn's disease in members 18 years of age or older who have experienced treatment failure of or intolerance to Humira.</p>	
<b>Nonpreferred:</b> Amitiza®, Chenodal™, Linzess™, Trulance™	<p><b>Nonpreferred agents:</b></p> <p><b>Amitiza, Linzess, Trulance:</b> Coverage is provided for the treatment of chronic idiopathic constipation (fewer than 3 bowel movements/week) or constipation predominant irritable bowel syndrome (IBS) in members 18 years of age or older who have experienced treatment failure of or intolerance to ALL of the following: an increase in dietary fiber or use of bulk laxatives (such as Metamucil(g)), osmotic laxatives (such as Miralax(g)), and a short course of stimulant laxatives (such as Dulcolax(g)) in combination with a stool softener (such as Colace(g)).</p> <p><b>Amitiza:</b> Coverage is also provided for the treatment of opioid induced constipation in members 18 years of age or older who are currently receiving opioid therapy and have experienced treatment failure of or intolerance to ALL of the following: osmotic laxatives (such as Miralax(g)) and a short course of stimulant laxatives (such as Dulcolax(g)) in combination with a stool softener (such as Colace(g)).</p> <p><b>Chenodal:</b> Coverage is provided for the treatment of cholelithiasis (gallstones) in members ineligible for surgery who have experienced treatment failure of or intolerance to Actigall(g). Approval duration: up to 2 years.</p>	
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**GASTROINTESTINAL AGENTS (cont.)****Miscellaneous Gastrointestinal Agents (cont.)**

Approval duration: up to 10 years

**Nonpreferred:**

Movantik™, Relistor® tablets, Uceris®, Uceris® Foam, Viberzi™, Xifaxan 550®

**Nonpreferred agents:**

**Movantik:** Coverage is provided for the treatment of opioid-induced chronic constipation in members 18 years of age or older who are currently receiving opioid therapy and have experienced treatment failure of or intolerance to ALL of the following: osmotic laxatives (such as Miralax(g)) and a short course of stimulant laxatives (such as Dulcolax(g)) in combination with a stool softener (such as Colace(g)).

**Relistor tablets:** Coverage is provided for the treatment of opioid-induced constipation in members who are currently receiving opioid therapy and have experienced treatment failure of or intolerance to ALL of the following: osmotic laxatives (such as, Miralax(g)), saline laxatives (such as, Fleet(g)) and stimulant laxatives (such as, Dulcolax(g)) in combination with a stool softener (such as, Colace(g)).

**Uceris:** Coverage is provided for the treatment of active, mild to moderate ulcerative colitis in situations where the member has experienced treatment failure of or intolerance to an oral aminosalicylate (5-ASA) AND two oral, locally active corticosteroids, one of which is Entocort EC™(g).

Approval duration: up to 8 weeks

**Uceris Foam:** Coverage is provided for the treatment of active mild to moderate distal ulcerative colitis in situations where the member has experienced treatment failure of or intolerance to a preferred corticosteroid enema/foam (such as Cortenema(g)) AND a generic rectal mesalamine (such as Rowasa(g)).

Approval duration: up to 6 weeks

**Viberzi:** Coverage is provided for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) in adult members who have experienced treatment failure of or intolerance to ALL of the following: Imodium(g); a tricyclic antidepressant (for example, Pamelor(g)) OR selective serotonin reuptake inhibitor (for example (Prozac(g))); and an antispasmodic (for example, Bentyl(g)).

**Xifaxan 550:** Coverage is provided for the treatment of the following:

- **Hepatic encephalopathy:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Lactulose(g).
- **Diarrhea-predominant irritable bowel syndrome (IBS-D):** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to ALL of the following: Imodium(g); a tricyclic antidepressant (such as Pamelor(g)) OR selective serotonin reuptake inhibitor (such as Prozac(g)); and an antispasmodic (such as Bentyl(g)).

Approval duration: 14 days. Maximum 3 treatment courses per lifetime.

**IMMUNOLOGY & HEMATOLOGY****Hematopoietic Agents**

Approval duration: up to 3 months

**Preferred:**

Procrit®, Promacta®

**Preferred agents:**

**Procrit:** Coverage is provided for treatment of FDA approved indications in situations where the member has a hemoglobin level less than 10g/dL for initial therapy. For continued coverage, the member's hemoglobin level must be less than 12 g/dL.

Approval duration: initial up to 3 months, renewal 1 year

**Promacta:** Coverage is provided for treatment of FDA approved indications in situations where the member's current platelet count is submitted to the plan. Continued coverage is approved for members with a current platelet count less than 400,000/mcL.

Approval duration: initial up to 6 months, renewal 1 year.

**Nonpreferred:**

Aranesp®, Epogen®, Mircera®

**Nonpreferred agents:**

Coverage is provided for the treatment of FDA approved indications in situations where the member has experienced treatment failure of or intolerance to Procrit.

Approval duration: initial up to 3 months, renewal 1 year.

**IMMUNOLOGY & HEMATOLOGY (cont.)**

<b>Immunoglobulins</b>		Approval duration: up to 1 year
<b>Nonpreferred:</b> Cuvitru, Gammagard® liquid, Gammaked® liquid, Gamunex-C® sub-q, Hizentra®, Hyqvia®	<b>Nonpreferred agents:</b> <b>Cuvitru, Hyqvia:</b> Coverage is provided for the treatment of primary humoral immunodeficiency when clinical criteria is met. <b>Gammagard liquid, Gammaked liquid, Gamunex-C sub-q, Hizentra:</b> Coverage is provided for treatment of the following indications when clinical criteria is met: acquired factor VIII inhibitor, allogeneic bone marrow transplant, autoimmune hemolytic anemia (AIHA), dermatomyositis, fetal alloimmune thrombocytopenia, HIV Infection, hypogammaglobulinemia, inflammatory demyelinating polyneuropathy, idiopathic thrombocytopenia purpura, Kawasaki syndrome, Lambert-Eaton myasthenic syndrome, multifocal motor neuropathy, multiple myeloma, myasthenia gravis, pediatric intractable epilepsy, polymyositis, post-transfusion purpura, primary humoral immunodeficiency, pure red cell aplasia, refractory pemphigus foliaceus, solid organ transplant, stiff person syndrome, systemic lupus erythematosus.	
<b>Interferons and MS Therapy</b>		Approval duration: up to 10 years
<b>Nonpreferred:</b> Ampyra™, Aubagio™, Betaseron®, Extavia®, Plegridy®, Zinbryta™	<b>Ampyra:</b> <b>Initial treatment:</b> Coverage is provided for the treatment of multiple sclerosis in situations where the member experiences difficulty walking resulting in significant limitations of instrumental activities of daily living and when two timed 25-foot walk (T25FW) measurements that are within 10% variability and demonstrates that the member is able to walk 25 feet in 8-45 seconds are submitted to the plan, and where the member is on current disease-modifying therapy. <b>To continue:</b> Coverage is provided in situations where the member's walking speed has improved by at least 20% as assessed by the T25FW AND that limitations of instrumental activities of daily living have improved as a result of increased walking speed within the first 2 months of therapy. Coverage thereafter will be provided if there is documentation that the member has maintained or experienced improved walking speed from the previous measurement, and where the member is on current disease-modifying therapy. Approval duration: initial approval 6 months, renewal up to 1 year. <b>Aubagio:</b> Coverage is provided for members 18 years of age or older for the treatment of a relapsing form of multiple sclerosis in situations where the member has experienced treatment failure of or intolerance to all of the following: an interferon beta product (such as Avonex), Copaxone, Gilenya and Tecfidera. <b>Betaseron, Extavia, Plegridy, Zinbryta:</b> Coverage is provided for the treatment of relapsing forms of multiple sclerosis in situations where the member has experienced treatment failure of or intolerance to ALL of the following: an interferon beta product (such as Avonex), Copaxone, Gilenya and Tecfidera.	
<b>Immunology and Hepatology Miscellaneous</b>		Approval duration: up to 1 year
<b>Nonpreferred:</b> Firazyr®, Ruconest®	Coverage is provided for members 18 years of age or older with a confirmed diagnosis of type 1 or type 2 hereditary angioedema (HAE) for the treatment of acute attacks, or short-term prophylaxis in members who have experienced treatment failure of or intolerance to an attenuated androgen (such as Danocrine(g) or Oxandrin(g)).	
<b>LIFESTYLE MODIFICATION PRODUCTS</b>		
<b>Sexual Dysfunction</b>		Approval duration: up to 10 years
<b>Preferred:</b> Cialis®, Viagra®	<b>Preferred agents:</b> <b>Cialis, Viagra:</b> Coverage is provided for male members for the treatment of erectile dysfunction in situations where the member has experienced treatment failure of or intolerance to Revatio(g). Maximum of 6 doses per 28 days.	
<b>Nonpreferred:</b> Addyi™, Levitra®, Staxyn®, Stendra™	<b>Nonpreferred agents:</b> <b>Addyi:</b> Coverage is provided for the treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) ongoing for a duration of at least 6 months in premenopausal females. Other causes (such as relationship difficulties or medication side effects) must be ruled out. <b>Levitra, Staxyn, Stendra:</b> Coverage is provided for male members for the treatment of erectile dysfunction in situations where the member has experienced treatment failure of or intolerance to Revatio(g). Maximum of 6 doses per 28 days.	

<b>LIFESTYLE MODIFICATION PRODUCTS (cont.)</b>	
<b>Smoking Cessation</b> Approval duration: up to 6 months	
<b>Nonpreferred:</b> Nicotrol®, NS	Coverage is provided in situations where the member has experienced treatment failure of or intolerance to a generic nicotine replacement product (gum, lozenge, or patch) or Zyban(g).
<b>Weight Loss Products</b> Approval duration: up to 1 year	
<b>Nonpreferred:</b> Belviq®, Belviq XR®, Contrave® ER, Qsymia™, Saxenda®, Xenical®	<b>Nonpreferred agents*:</b> Coverage is provided for members 18 years of age or older with a Body Mass Index (BMI) of ≥ 30 kg/m <sup>2</sup> or ≥ 27 kg/m <sup>2</sup> with documentation of one or more of the following risk factors: hypertension, congestive heart failure, coronary artery disease, diabetes or dyslipidemia. <b>Qsymia:</b> Coverage also requires that the member has experienced treatment failure of or intolerance to generic phentermine. *Maximum benefit is limited to 12 months of treatment; 24 months of treatment for Xenical.
<b>MISCELLANEOUS</b> Approval duration: up to 6 months	
<b>Compounds</b>	Coverage criteria include all the below: • The compound is medically necessary for the member's condition • The compound contains only FDA approved medications. • There are no appropriate FDA approved commercial formulations of the compound available. <b>Note:</b> U6Ws (bulk powders) are not covered.
<b>OBSTETRICS AND GYNECOLOGY</b>	
<b>Infertility treatment</b> Approval duration: up to 1 year	
<b>Preferred:</b> Bravelle®, Cetrotide®, Crinone® 8%, Endometrin®, Ganirelix acetate®, Gonal-F®, RFF, Redi-ject; Novarel®/Pregnyl®, Ovidrel®	<b>Preferred agents:</b> Coverage is provided for most BCN members with an infertility benefit, for treatment of an FDA-approved indication, 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), or gamete in vitro fertilization transfer (GIFT). Requests for additional coverage will be based on documentation that the member is being treated according to accepted medical practice.
<b>Nonpreferred:</b> Follistim® AQ, Luveris®, Menopur®	<b>Nonpreferred agents:</b> Coverage also requires treatment failure of or intolerance to Gonal-F, -RFF, Redi-ject.
<b>Miscellaneous</b> Approval duration: up to 10 years	
<b>Nonpreferred:</b> Brisdelle™, Duavee®	<b>Brisdelle:</b> Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Effexor(g) and Paxil(g) and an explanation as to why Brisdelle is expected to work when Paxil(g) has not must be submitted to the plan. <b>Duavee:</b> Coverage is provided for female members for the treatment of moderate to severe vasomotor symptoms associated with menopause in situations where the member has experienced treatment failure of or intolerance to at least three of the following: a SSRI (such as Prozac(g)), a SNRI (such as Effexor(g)), an estrogen/progesterone combination (such as FemHRT(g)), a beta-blocker (such as Inderal(g)) and Neurontin(g).
<b>OPHTHALMIC AGENTS</b>	
<b>Miscellaneous</b> Approval duration: up to 1 year	
<b>Preferred:</b> Cystaran™	Coverage is provided for the treatment of cystinosis for members who are also taking oral cysteamine (such as Cystagon).
<b>RESPIRATORY COUGH &amp; COLD</b>	
<b>Cystic Fibrosis Agents</b> Approval duration: up to 6 months	
<b>Preferred:</b> Kalydeco™, Orkambi®	<b>Preferred agents:</b> <b>Kalydeco:</b> Coverage is provided for the treatment of FDA approved indications when genetic testing has been submitted to the plan to document the appropriate gene mutation. Approval duration: up to 10 years <b>Orkambi:</b> Coverage is provided for the treatment of cystic fibrosis in members 6 years of age or older in situations where the member has confirmed two copies of the F508del mutation in the CFTR gene AND where genetic testing results are submitted to the plan. In addition, the member must have a baseline FEV1 predicted of 30% or greater and must be receiving other chronic maintenance treatment (such as hypertonic saline or dornase alfa). Approval duration: up to 10 years
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**RESPIRATORY COUGH & COLD (cont.)****Cystic Fibrosis Agents (cont.)**

Approval duration: up to 6 months

**Nonpreferred:**Bethkis<sup>®</sup>, Cayston<sup>®</sup>, Tobi<sup>®</sup> Podhaler<sup>™</sup>**Nonpreferred agents:**

**Bethkis, Tobi Podhaler:** Coverage is provided for the treatment of Pseudomonas aeruginosa infection in cystic fibrosis in situations where the member has experienced treatment failure of or intolerance to generic inhaled tobramycin (such as Tobi(g)) and a credible explanation as to why the requested product is expected to work when the generic product has not been submitted to the plan.

**Cayston:** Coverage is provided for the treatment of Pseudomonas aeruginosa infection in cystic fibrosis.

**Inhaled Beta-Agonists**

Approval duration: up to 10 years

**Nonpreferred:**Brovana<sup>®</sup>, Perforomist<sup>™</sup>

Coverage is provided in situations where the member has experienced treatment failure of or intolerance to both salmeterol (such as Advair or Serevent) AND formoterol (such as Dulera, Foradil, or Symbicort).

**Miscellaneous**

Approval duration: up to 1 year

**Preferred:**Esbriet<sup>®</sup>, Glassia<sup>®</sup>**Preferred agents:**

**Esbriet:** Coverage is provided for the treatment of idiopathic pulmonary fibrosis (IPF).

**Glassia:** Coverage is provided for the treatment of emphysema associated with alpha-1 antitrypsin deficiency in situations where all of the following criteria is met: 1) the member is a nonsmoker, 2) the member has evidence of deteriorating pulmonary function (as demonstrated by an FEV1 between 35% and 60% predicted), and 3) the member has a baseline plasma alpha-1 antitrypsin level less than 80 mg/dL.

**Nonpreferred:**Daliresp<sup>™</sup>, Grastek<sup>®</sup>, Ofev<sup>®</sup>, Oralair<sup>®</sup>, Ragwitek<sup>®</sup>**Nonpreferred agents:**

**Daliresp:** Coverage is provided for the treatment of severe chronic obstructive pulmonary disorder (COPD) associated with chronic bronchitis and a history of exacerbations despite optimal therapy with a long acting beta agonist (such as Serevent), an inhaled anticholinergic (such as Spiriva), and a generic inhaled corticosteroid (such as Qvar).

Approval duration: up to 10 years

**Grastek, Oralair and Ragwitek:** Coverage is provided for the treatment of allergic rhinitis with or without conjunctivitis with confirmed sensitivity to at least one allergen contained in the requested agent in members who have experienced treatment failure of or intolerance to all of the following drug classes: an intranasal corticosteroid (such as Flonase(g)), an antihistamine (such as Zyrtec(g)) and a leukotriene inhibitor (such as Singulair(g)).

Approval duration: up to 3 years

**Ofev:** Coverage is provided for the treatment of idiopathic pulmonary fibrosis (IPF).

**Pulmonary Arterial Hypertension (PAH)**

Approval duration: up to 10 years

**Preferred:**Adcirca<sup>®</sup>, Adempas<sup>®</sup>, Letairis<sup>™</sup>, Opsumit<sup>®</sup>, Orenitram<sup>®</sup> ER, Revatio suspension; Tracleer<sup>®</sup>, Tyvaso<sup>™</sup>, Uptravi<sup>®</sup>, Ventavis<sup>®</sup>

Coverage is provided for the treatment of pulmonary arterial hypertension (WHO Group 1) in members with pulmonary arterial pressure (PAPm) greater than 25 mmHg confirmed through right heart catheterization.

**Adcirca:** Coverage also requires treatment failure of or intolerance to Revatio(g).

**Adempas:** Coverage is also provided for the treatment of chronic thromboembolic pulmonary hypertension (WHO Group 4) confirmed through right heart catheterization and pulmonary angiogram in members who are ineligible or refractory to surgical treatment.

**Revatio suspension:** Coverage also requires the member is unable to swallow tablets/capsules.

**RHEUMATOLOGY & MUSCULOSKELETAL****Gout Therapy**

Approval duration: up to 10 years

**Preferred:**Uloric<sup>®</sup>**Preferred agents:**

Coverage is provided for the treatment of gout in situations where the member has experienced treatment failure of or intolerance to Zyloprim(g), **Uloric 80mg:** Coverage also requires treatment failure of or intolerance to Uloric 40mg.

**Nonpreferred:**Zurampic<sup>®</sup>**Nonpreferred agents:**

**Zurampic:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to Zyloprim(g) and Uloric at maximally tolerated doses and where Zurampic will be used in combination with a xanthine oxidase inhibitor (such as Zyloprim(g)). Treatment failure is defined as serum uric acid level > 6mg/dL despite treatment with maximally tolerated doses of Zyloprim(g) and Uloric. Additional coverage criteria applies to Uloric.



**RHEUMATOLOGY & MUSCULOSKELETAL (cont.)**

**Miscellaneous Rheumatologic Agents** Approval duration: up to 10 years

<p><b>Nonpreferred:</b> Otrexup, Rasuvo™, Rayos™</p>	<p><b>Otrexup, Rasuvo:</b> Coverage is provided for the treatment of FDA approved indications in situations where the member has experienced treatment failure of or intolerance to both oral and intramuscular methotrexate. In addition, a credible explanation as to why subcutaneous methotrexate is expected to work when the other formulations have not must be submitted to the plan.</p> <p><b>Rayos:</b> Coverage is provided for the treatment of rheumatoid arthritis in situations where the member has experienced treatment failure of or intolerance to two generic oral corticosteroids, one of which must be prednisone immediate-release. In addition, a credible explanation as to why Rayos is expected to work if prednisone immediate-release has not must be submitted to the plan.</p>
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**Non-Tumor Necrosis Factor (TNF) Blocking Agents** Approval duration: up to 10 years

<p><b>Preferred:</b> Actemra® syringe, Cosentyx®, Xeljanz®/XR, Otezla®, Stelara®</p> <p><b>Nonpreferred:</b> Kineret®, Orencia® SC</p>	<p><b>Preferred agents:</b> <b>Actemra syringe, Xeljanz/XR:</b> Coverage is provided for members 18 years of age or older for the treatment of rheumatoid arthritis. <b>Cosentyx:</b> Coverage is provided for members 18 years of age or older for the treatment of ankylosing spondylitis and psoriatic arthritis. <b>Otezla:</b> Coverage is provided for members 18 years of age or older for the treatment of psoriatic arthritis in situations where the member has experienced treatment failure of or intolerance to ONE of the following: Cosentyx, Enbrel, Humira, or Stelara. <b>Stelara:</b> Coverage is provided for members 18 years of age or older for the treatment of psoriatic arthritis.</p> <p><b>Nonpreferred agents:</b> <b>Kineret, Orencia:</b> Coverage is provided for members 18 years of age or older for the treatment of rheumatoid arthritis in situations where the member has experienced treatment failure of or intolerance to TWO of the following: Actemra, Enbrel, Humira, or Xeljanz/XR.</p>
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**Tumor Necrosis Factor (TNF) blocking agents** Approval duration: up to 1 year

<p><b>Preferred:</b> Enbrel®</p> <p><b>Nonpreferred:</b> Cimzia®, Simponi® 50mg, Simponi® 100mg</p>	<p><b>Preferred agents:</b> <b>Enbrel:</b> Coverage is provided for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis.</p> <p><b>Nonpreferred agents:</b> <b>Cimzia:</b> Coverage is provided for the treatment of Crohn’s disease in members 18 years of age or older who have experienced treatment failure of or intolerance to Humira. <b>Cimzia, Simponi 50mg:</b> Coverage is provided for members 18 years of age or older for the treatment of:  <ul style="list-style-type: none"> <li>• Ankylosing spondylitis in situations where the member has experienced treatment failure of or intolerance to TWO of the following: Cosentyx, Enbrel, or Humira.</li> <li>• Moderate to severe rheumatoid arthritis in situations where the member has experienced treatment failure of or intolerance to TWO of the following: Actemra, Enbrel, Humira, or Xeljanz/XR.</li> <li>• Psoriatic arthritis in situations where the member has experienced treatment failure of or intolerance to TWO of the following: Cosentyx, Enbrel, Humira or Stelara.</li> </ul> <b>Simponi 100mg:</b> Coverage is provided for the treatment of ulcerative colitis in members 18 years of age or older who have experienced treatment failure of or intolerance to Humira.</p>
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**RHEUMATOLOGY & MUSCULOSKELETAL (cont.)****Osteoporosis/Bone Resorption Inhibitors**

Approval duration: up to 10 years

**Preferred:**

Atelvia™ (g) (risedronate sodium)

**Preferred agents:**

Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two of the following preferred alternatives: Actonel(g), Boniva(g), or Fosamax(g).

**Nonpreferred:**

Binosto™, Forteo™, Fosamax D™, Tymlos™

**Nonpreferred agents:****Binosto, Fosamax D:** Coverage is provided in situations where the member has experienced treatment failure of or intolerance to two of the following preferred alternatives: Actonel(g), Boniva(g), or Fosamax(g).**Forteo, Tymlos:** Coverage is provided for the treatment of osteoporosis (T-score  $\leq$  -2.5) in situations where the member has a contraindication to or has experienced treatment failure of or intolerance to a preferred bisphosphonate (such as Actonel(g)).

Approval duration: up to 2 years

**UROLOGY****Bladder Control**

Approval duration: up to 10 years

**Nonpreferred:**

Myrbetriq®

Coverage is provided in situations where the member has experience treatment failure of or intolerance to at least two generic alternatives (such as Detrol(g) or Ditropan(g)).

**BPH Treatment**

Approval duration: up to 10 years

**Preferred:**

Cialis® 2.5mg, 5mg; Jalyn™ (g) (dutasteride/tamsulosin hcl)

**Cialis 2.5mg, 5mg:** Coverage is provided for the treatment of benign prostatic hyperplasia (BPH) in situations where the member has experienced treatment failure of or intolerance to an alpha blocker (such as Cardura(g)) AND a 5-alpha reductase inhibitor (such as Proscar(g)), and documentation of an IPSS score  $\geq$  13 is submitted to the plan.**Jalyn(g):** Coverage is provided for members who have experienced treatment failure of or intolerance to an alpha blocker (such as Cardura(g)) or a 5-alpha reductase inhibitor (such as Proscar(g)).**Miscellaneous Urology**

Approval duration: up to 1 year

**Preferred:**

Xuriden™

**Preferred agents:****Xuriden:** Coverage is provided for the treatment of hereditary orotic aciduria.

Approval duration: up to 10 years

**Nonpreferred:**

Procysbi®, Thiola®

**Nonpreferred agents:****Procysbi:** Coverage is provided for the treatment of nephropathic cystinosis in situations where the member has experienced treatment failure of or intolerance to Cystagon® and a credible explanation as to why Procysbi is expected to work when Cystagon has not is submitted to the plan.

Approval duration: up to 10 years

**Thiola:** Coverage is provided for the prevention of cystine (kidney) stone formation for members with a urinary cystine concentration greater than 500mg/day who are refractory to ALL of the following treatments: increased fluid intake, restriction of sodium and animal protein, and urine alkalization therapy with Urocit-K(g). Continuation of therapy requires urinary cystine concentration less than 250mg/L.