

Blue Care Network Quality Interchange Program

January 2011

The Blue Care Network Quality Interchange Program helps ensure that safe, high-quality cost-effective drug therapy is prescribed prior to the use of more expensive agents that may not have proven value over current formulary medications. This program makes use of drug utilization management tools including prior authorization and step therapy. If a drug requires prior authorization, certain clinical criteria must be met, or other information must be provided, before coverage is approved. Drugs subject to step therapy require previous treatment with one or more formulary agents prior to coverage. The criteria for approval are based on current medical information and are approved by the BCBSM/BCN Pharmacy and Therapeutics Committee.

Most BCN members do not have coverage for *nonformulary drugs*. Requests for these *nonformulary drugs* will only be considered when the following criteria have been met:

- 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.
- The member meets any clinical criteria established for the prescribed drug or drug class.
- The prescriber and BCN agree that it is medically necessary.

Authorization requests that do not include documentation of medical necessity and failure of formulary alternatives will be denied.

Brand-name drugs that physicians prescribe or members request to be dispensed as written (DAW), but are available as generics, are covered only when determined to be medically necessary by the physician and approved by BCN. The physician must submit a completed MedWatch form to the FDA with a copy to BCN to document serious adverse events or a quality issue with the covered generic. Information regarding the FDA MedWatch program and online forms are available at www.accessdata.fda.gov/scripts/medwatch. If a DAW prescription is not authorized, BCN members are required to pay the difference in cost between the brand-name and generic versions in addition to their usual brand-name copay amount.

Quantity limits may also apply to certain drugs. Please visit us online at MiBCN.com for more information.

This information applies to members with a BCN commercial drug benefit. Criteria for BCN AdvantageSM and BlueCaid[®] members can be viewed on our Web site: MiBCN.com.

(g)=generic available

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

ANTI-INFECTIVES (Cont.)

Tetracyclines

Nonformulary:

Adoxa[®](g), CK, TT; Oracea[®],
Solodyn[®](g)

Nonformulary agents:

Adoxa(g), CK, TT; Oracea: Requires documentation that the member has experienced treatment failure of or intolerance to generic doxycycline 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 generic doxycycline.

Solodyn(g): Requires documentation that the member has experienced treatment failure of or intolerance to generic minocycline 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 generic minocycline.

ANTINEOPLASTICS & IMMUNOSUPPRESSANTS

Hormonal Agents

Formulary:

Arimidex[®](g) (anastrozole),
Aromasin[®] (exemestane),
Femara[®] (letrozole)

PA for males only: Approved only for ER-positive breast cancer treatment and other literature supported cancer therapies.

Immunomodulators

Formulary:

Arcalyst[™] (rilonacept)

Formulary agent:

Arcalyst: Approved for the treatment of cryopyrin-associated periodic syndrome in members ≥12 years of age.

Nonformulary:

Revlimid[®]

Nonformulary agent:

Revlimid: Approved for treatment of transfusion-dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes (MDS) with deletion 5q abnormality; multiple myeloma in members whom have experienced treatment failure of or intolerance to or have a contraindication to thalidomide; 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.

Kinase Inhibitors & Molecular Target Inhibitors

Formulary:

Afinitor[®] (everolimus),
Hycamtin[®] (topotecan),
Iressa[®] (gefitinib),
Nexavar[®] (sorafenib),
Sprycel[®] (dasatinib),
Sutent[®] (sunitinib),

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Formulary agents:

Afinitor: 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 of enrollment in a Phase II-IV investigative study approved by an appropriate IRB.

Hycamtin: Approved for treatment of relapsed small cell lung cancer, OR requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB.

Iressa: Approved only for members continuing existing therapy prior to the 09/2005 FDA label revisions.

Nexavar: Approved for treatment of advanced or recurrent renal cell carcinoma or hepatocellular carcinoma, OR requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB.

Sprycel: 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; OR requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB.

Sutent: Approved for treatment of advanced renal cell carcinoma or gastrointestinal stromal tumor, OR requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB. Evidence of disease progression or intolerance to Gleevec must be provided for members with gastrointestinal stromal tumor.

ANTINEOPLASTICS & IMMUNOSUPPRESSANTS (Cont.)	
Kinase Inhibitors & Molecular Target Inhibitors (cont.)	
Formulary: Tarceva® (erlotinib), Tykerb® (lapatinib), Votrient™ (pazopanib)	Formulary agents: Tarceva: 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, OR requires documentation of enrollment in a Phase II-IV investigative study approved by an appropriate IRB. Tykerb: 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, OR requires documentation of enrollment in phase II-IV investigative study approved by an appropriate IRB. Votrient: Approved for treatment of advanced renal cell carcinoma OR requires documentation of enrollment in phase II-IV investigative study approved by an appropriate IRB.
Miscellaneous Antineoplastic Agents	
Formulary: Zolinza™ (vorinostat)	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 (Targretin), 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.
CARDIOVASCULAR, HYPERTENSION, CHOLESTEROL	
Angiotensin Converting Enzyme Inhibitors (ACE-Inhibitor)	
Nonformulary: Altace® Tablets	Requires documentation that member has experienced failure of or intolerance to Altace(g) capsules.
Angiotensin II Receptor Blockers (ARBs)	
Formulary: Benicar® (olmesartan medoxomil), HCT	Formulary agents: Benicar, HCT: Requires documentation that the member has experienced intolerance to an ACE inhibitor such as Prinivil/Zestril(g), Monopril(g), Lotensin(g), Vasotec(g), Accupril(g), etc.
Nonformulary: Atacand®, HCT; Avapro®, Avalide®; Azor®, Diovan®, HCT; Exforge®, HCT; Micardis®, HCT; Teveten®, HCT; Tribenzor™, Twynsta®, Valturna®	Nonformulary agents: Atacand, HCT; Avapro, Avalide; Diovan, HCT; Micardis, HCT; Teveten, HCT: Requires documentation that the member has experienced intolerance to an ACE inhibitor and experienced treatment failure of or intolerance to a formulary ARB (Cozaar(g), Hyzaar(g); Benicar, HCT) Azor, Exforge, Tribenzor, Twynsta, Valturna: Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage. Exforge HCT: Requires inadequate response with at least three months of therapy with Exforge.
Beta Blockers	
Nonformulary: Bystolic®, Coreg CR™	Bystolic: 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. Coreg CR: Requires documentation that the member experienced treatment failure of or intolerance to both carvedilol immediate-release (Coreg(g)) AND metoprolol succinate (Toprol XL(g)).
Cardiovascular Treatment	
Nonformulary: Ranexa®	Ranexa: 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.

CARDIOVASCULAR, HYPERTENSION, CHOLESTEROL (Cont.)

Cholesterol-Lowering Agents

Formulary:

Crestor® (rosuvastatin),
Zetia® (ezetimibe)

Nonformulary:

Advicor®, Altoprev®, Caduet®,
Lescol®, XL; Lipitor®, Livalo®,
Simcor®, TriLipix®, Vytorin®

Formulary agents:

Crestor: Requires documentation that member has experienced failure of or intolerance to at least one high dose ($\geq 40\text{mg}$) generic statin (Mevacor®(g), Zocor®(g), or Pravachol®(g)).
Zetia: Requires documentation that member has experienced failure of or intolerance to at least two generic statins (Mevacor(g), Zocor(g), or Pravachol(g)) OR approved when added to a high dose ($\geq 40\text{mg}$) generic statin (Mevacor(g), Zocor(g), or Pravachol(g)).

Nonformulary agents:

Altoprev, Caduet, Lescol, XL, Lipitor, Livalo, Vytorin: Requires documentation that member has experienced treatment failure of or intolerance to at least one high dose ($\geq 40\text{mg}$) generic statin (Mevacor(g), Zocor(g), or Pravachol(g)) AND at least one formulary brand agent (Crestor or Zetia).
Advicor, Simcor: Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage.
TriLipix: Requires documentation that the member has experienced treatment failure of or intolerance to ALL generic fibrates, such as Lofibra(g) and Lopid(g), AND supporting evidence for the use of this agent. Concomitant use of a statin does not satisfy criteria.

Miscellaneous Antihypertensives

Nonformulary:

Tekamlo™; Tekturna®, HCT

Tekamlo: Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage.

Tekturna, HCT: 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

Nonformulary:

Lyrica®

Requires documentation that the member has at least one of the following 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 ≤ 64 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.

Antidepressants

Formulary:

Lexapro® (escitalopram)

Nonformulary:

Aplenzin™

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Formulary agents: Requires documentation that member has experienced treatment failure of or intolerance to at least one generic antidepressant (Prozac(g), Celexa(g), Paxil(g), Effexor(g), Zoloft(g), or Wellbutrin SR, XL(g)).

Nonformulary agents:

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

CENTRAL NERVOUS SYSTEM (Cont.)

Antidepressants (cont.)

Nonformulary:

Cymbalta®, Luvox CR®, Oleptro™, Pexeva®, Pristiq®, Savella®

Nonformulary agents:

Cymbalta: Depression and/or anxiety: Requires documentation that the member has experienced treatment failure of or intolerance to at least one generic antidepressant AND one brand name formulary antidepressant. **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.

Luvox CR: Requires documentation that the member has experienced treatment failure of or intolerance to at least one generic antidepressant and one brand name formulary antidepressant AND documentation that continued use of Luvox(g) will adversely affect the member's mental health.

Oleptro: Approved for major depressive disorder in members who have experienced treatment failure of or intolerance to Desyre®(g) AND documentation that continued use of Desyre(g) will adversely affect the member's mental health.

Pexeva: Requires documentation that the member has experienced treatment failure of or intolerance to at least one generic antidepressant and one brand name formulary antidepressant AND documentation that continued use of Paxil(g) will adversely affect the member's mental health.

Pristiq: Requires documentation that the member has experienced treatment failure of or intolerance to at least one generic antidepressant and one brand name formulary antidepressant AND documentation that continued use of Effexor(g) or Effexor XR(g) will adversely affect the member's mental health.

Savella: 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.

Antipsychotics

Nonformulary:

Invega®, Seroquel XR®

Requires documentation that the member has experienced treatment failure of or intolerance to all formulary atypical antipsychotic agents. Maximum dose of Invega is limited to 12 mg per day.

CNS Stimulants

Formulary:

Adderall XR® (amphet asp/amphet/d-amphet)(g), Provigil® (modafinil)

Formulary agents:

Adderall XR(g): Requires documentation that member has experienced treatment failure of or intolerance to brand name Adderall XR.

Provigil: Approved only for members with narcolepsy, obstructive sleep apnea, or an indication supported by peer-reviewed literature. Dosage limited to a maximum of 400mg per day. Shift-work sleep disorder is not covered since treatment is not medically necessary.

Nonformulary:

Nuvigil®, Procentra™

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Nonformulary agents:

Nuvigil: Approved for treatment of narcolepsy or obstructive sleep apnea and requires documentation that member has experienced treatment failure of or intolerance to Provigil.

Procentra: 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.

CENTRAL NERVOUS SYSTEM (Cont.)

CNS Stimulants (cont.)

Nonformulary: Strattera™, Vyvanse™	Nonformulary agents: Strattera: Approvable when stimulants are contraindicated by medical history OR the following criteria by age: For BCN members age 5 to 20: Requires documentation that the member has experienced treatment failure of or intolerance to both a methylphenidate (such as Ritalin(g) or Concerta) AND an amphetamine (such as Adderall(g)). For BCN members age 21 and older: Requires documentation that the member has experienced treatment failure of or intolerance to either a methylphenidate OR an amphetamine. Note: The use of Strattera in members ≤ 4 years of age is not recommended or supported by literature. Vyvanse: Requires documentation that the member has experienced treatment failure of or intolerance to both a methylphenidate (such as Ritalin(g) or Concerta) AND an amphetamine (such as Adderall(g)).
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Migraine Therapy

Formulary: Amerge® (g) (naratriptan), Maxalt®, MLT® (rizatriptan)	Formulary agents: Amerge(g): Requires documentation that member has experienced failure of or intolerance to both sumatriptan (Imitrex(g)) and Maxalt. Maxalt, MLT: Requires documentation that member has experienced treatment failure of or intolerance to sumatriptan (Imitrex(g)).
Nonformulary: Alsuma™, Axert®, Frova®, Relpax®, Sumavel™ DosePro™, Treximet®, Zomig®, ZMT®, nasal spray	Nonformulary agents: Alsuma, Axert, Frova, Relpax, Sumavel DosePro; Zomig, ZMT, nasal spray: Requires documentation that member has experienced failure of or intolerance to both sumatriptan (Imitrex(g)) and Maxalt. Treximet: 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.

Miscellaneous CNS

Nonformulary: Aricept® 23mg, Intuniv™	Aricept 23mg: Requires documentation for a progressive-type dementia AND requires successful treatment with Aricept 10mg for three months. Intuniv: 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), an amphetamine (such as Adderall(g)), generic guanfacine immediate-release, and clonidine.
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Narcotics

Formulary: Actiq® (g) (fentanyl citrate), Opana® (g) (oxymorphone HCl)	Formulary agents: Actiq: 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)).
Nonformulary: Butrans™, Exalgo™	Nonformulary agents: 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 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)).

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CENTRAL NERVOUS SYSTEM (Cont.)

Narcotics (cont.)

Nonformulary:
Fentora[®], Onsolis[®], Nucynta[®];
Opana[®] ER; Oxycontin[®]

Nonformulary agents:

Fentora, Onsolis: 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. Also requires documentation that the member has experienced treatment failure of or intolerance to Actiq(g).

Nucynta: Requires documentation that member has experienced treatment failure of or intolerance to a Ultram(g) or Ultracet(g) 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)).

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)).

Narcotic Mixed Agonist/Antagonist

Formulary:
Suboxone[®] SL tablets, Film
(buprenorphine HCl/naloxone HCl),

Nonformulary:
Rybix[™] ODT

Formulary agents:

Suboxone SL tabs, Film: Approved only for the treatment of clinically diagnosed opioid dependence. Requires documentation of validated screening tools used to identify the opioid use problem.

Nonformulary agent:

Rybix ODT: Requires documentation that member cannot swallow ANY oral tramadol tablets OR documentation that the member has had successful treatment with immediate release tramadol for a minimum of three months AND documentation as to why continued use of generic tramadol would harm the member.

Non-Steroidal Anti-Inflammatory Drugs

Nonformulary:
Arthrotec[®]; Celebrex[®], Flector[®] Patch,
Pennsaid[™], Prevacid NapraPAC[™],
Vimovo[™], Voltaren[®] Gel

Arthrotec, Prevacid NapraPAC: 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.

Celebrex: *Approved for members >60 years of age* whom are not at high risk for cardiovascular events, and do not have a previous history of stroke, MI, coronary heart disease, or blood clots. The member must not be receiving concomitant anticoagulant or an antiplatelet therapy. ***Approved for members ≤ 60 years of age*** whom 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. **Note:** Lodine(g) is more selective than Celebrex for the COX-2 enzyme.

Flector Patch: 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).

Pennsaid, Voltaren Gel: Requires treatment failure of or intolerance to Voltaren(g)/XR(g) tablets AND an OTC topical analgesic (Myoflex OR Aspercreme).

Vimovo: Requires documentation that member has had treatment failure of or intolerance to Prilosec(g), Protonix(g) and Prevacid(g) at a twice daily, high dose regimen 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.

Parkinson's Disease and Related Disorders

Nonformulary:
Mirapex ER[®]

Requires a diagnosis of Parkinson's Disease. Must also try and fail Mirapex IR(g) AND documentation that the continued use of it will adversely affect the member's condition.

CENTRAL NERVOUS SYSTEM (Cont.)	
Sedatives/Hypnotics	
Formulary: Ambien CR® (g) Nonformulary: Edluar™, Lunesta®, Rozerem®, Silenor™, ZolpiMist™	Requires documentation that member has experienced treatment failure of or intolerance to an adequate trial of both zolpidem (Ambien®(g)) and zaleplon (Sonata®(g)). Silenor: Requires documentation that member has experienced treatment failure of or intolerance to Sinequan®(g), Ambien(g), Sonata(g) AND Desyre®(g).
DERMATOLOGY	
Acne Treatment	
Nonformulary: Ziana™ gel	Requires documentation of medical necessity to identify why individual agents [Cleocin-T®(g) plus Retin-A®(g)] cannot be used.
Antipsoriatic/Antiseborrheic	
Formulary: Enbrel® (etanercept), Humira® (adalimumab) Nonformulary: Taclonex, Scalp®	Formulary agents: Enbrel, Humira: Moderate to Severe Psoriasis: Requires 3 months of previous treatment with topical corticosteroids and 3 months treatment with PUVA. Nonformulary agent: Taclonex: 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)] PLUS Dovonex.
Miscellaneous Dermatologicals	
Formulary: Elidel® (pimecrolimus) Nonformulary: Protopic®	Formulary agents: Elidel: Approved for members ≥2 years of age with a diagnosis of atopic dermatitis or eczema. Nonformulary agent: Protopic: 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.
Wound & Burn Therapy	
Nonformulary: Regranex®	Requires documentation that the member has a diagnosis of diabetic skin ulcer or may be approved for wound therapy per policy criteria.
DIAGNOSTICS & OTHER MISCELLANEOUS	
Diagnostic & Other Miscellaneous	
Formulary: Carbaglu® (carglumic acid), Kuvan® (sapropterin dihydrochloride), Xenazine® (tetrabenazine) Nonformulary: Campral®, Exjade®	Formulary agents: Carbaglu: Requires documentation that member has a diagnosis of hyperammonemia due to NAGS deficiency. Kuvan: Requires documentation that member has a diagnosis of phenylketonuria (PKU) and will be following a phenylalanine-restricted diet in conjunction with Kuvan. Xenazine: Requires documentation that member has a diagnosis of chorea associated with Huntington's disease. 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. Exjade: Approved for members ≥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®(g) OR requires documentation that the member is enrolled in a Phase II-IV investigative study approved by an appropriate IRB.

ENDOCRINOLOGY

Growth Hormone & Related Products

Formulary:

Genotropin® (somatropin),
Nutropin®, AQ (somatropin)

Nonformulary:

Humatrope®, Norditropin®,
Omnitrope®, Saizen®, Serostim®,
Tev-Tropin®, Valtropin®, Zorbtive™

Increlex™

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.

Adults (≥18 years of age): Approved for treatment of growth hormone deficiency, AIDS wasting cachexia, Turner's Syndrome, and Short Bowel Syndrome. The diagnosis must be made by an endocrinologist or a nephrologist. Initial diagnosis must be based on two growth hormone stimulation tests, 3 or more pituitary hormone deficiencies with an IGF-1 below 80ng/ml OR 1 growth hormone and at least 1 pituitary hormone deficiency

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. 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 ≥ 2.5cm

Non-Insulin Hypoglycemic Agents

Formulary:

Actos® (pioglitazone);
Actoplus Met® (pioglitazone/
metformin),
Duetact® (pioglitazone/glimepiride)

Nonformulary:

Actoplus Met® XR, Avandamet®,
Avandaryl®, Avandia®, Byetta®,
Januvia®, Janumet®, Onglyza™,
Prandimet®, Symmlin®, Victoza®

Formulary agents:

Actos: Requires documentation that the member has experienced failure with metformin. If the member cannot tolerate metformin or if metformin is contraindicated, physicians are encouraged to prescribe a sulfonylurea, unless contraindicated, prior to treatment with a TZD.

Actoplus Met, Duetact: 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.

Nonformulary agents:

Actoplus Met XR, Avandamet, Avandaryl, Janumet, Prandimet: 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.

Avandia: Requires documentation that the member has had treatment failure of or intolerance to both Glucophage(g) and Actos.

Byetta, Victoza: 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. Insulin must be discontinued.

Januvia, Onglyza: 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.

Symmlin: 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 >7%) despite good compliance with optimal insulin therapy.

GASTROINTESTINAL AGENTS

Antiemetics

Nonformulary:
Sancuso®, Zuplenz®

Sancuso: Requires documentation that the member has experienced treatment failure of or intolerance to both oral Kytril(**g**) AND Zofran(**g**), ODT(**g**).
Zuplenz: Same as above AND documentation that the continued use of Zofran ODT(**g**) would adversely affect the member's condition.

Miscellaneous Gastrointestinal Agents

Formulary:
Relistor® (methylnaltrexone)

Formulary agent:
Relistor: 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**)).

Nonformulary:
Amitiza®, Chenodal™, Cimzia®,
Lotronex®, Xifaxan 550®

Nonformulary agents:
Amitiza: 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.
Chenodal: 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.
Cimzia: Approved for the treatment of Crohn's disease in members ≥18 years of age whom have experienced treatment failure of or intolerance to Humira.
Lotronex: 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**))).
Xifaxan 550: Requires diagnosis of hepatic encephalopathy AND documentation that the member has had treatment failure of or intolerance to lactulose.

Proton Pump Inhibitors

Formulary:
Prevacid®(**g**) capsule (lansoprazole),
Prevacid Solutab™(**g**),
Prilosec®(**g**) (omeprazole) 40mg,
Protonix®(**g**) (pantoprazole),
Zegerid®(**g**) capsule (omeprazole/
sodium bicarbonate)

Formulary agents:
Prevacid(g**), Solutab(**g**):** Requires documentation that the member has experienced failure of or intolerance to Prilosec OTC(**g**) or Prilosec(**g**).
Prilosec 40mg(g**):** Requires documentation that member has experienced treatment failure with Prilosec OTC(**g**) or Prilosec(**g**) (2 x 20mg).
Protonix(g**):** Requires documentation that member has experienced failure of or intolerance to Prilosec OTC(**g**) or Prilosec(**g**) unless the member is currently receiving Plavix.
Zegerid(g**):** Requires documentation that member has experienced failure of or intolerance to Prilosec OTC(**g**) or Prilosec(**g**) AND Prevacid(**g**) or Prevacid Solutab.

Nonformulary:
Aciphex®, Dexilant™, Nexium®,
Prilosec suspension,
Protonix suspension,
Zegerid® Packet, Vimovo™

Nonformulary agents:
Aciphex, Zegerid Packet: Requires documentation that the member has experienced treatment failure of or intolerance to Prilosec OTC or Prilosec(**g**) AND Prevacid(**g**) or Prevacid Solutab.
Dexilant, Nexium: Requires documentation that the member has experienced treatment failure of or intolerance to both BCN formulary alternatives [either Prilosec OTC or Prilosec(**g**) AND Prevacid(**g**)], one of which is at a twice daily, high dose regimen.
Prilosec suspension, Protonix suspension: Requires documentation that member has experienced treatment failure of or intolerance to Prevacid Solutab.
Vimovo: 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 GI bleeding, and/or alcoholism.

IMMUNOLOGY & HEMATOLOGY

Hematopoietic Agents

<p>Formulary: Procrit® (epoetin alfa)</p> <p>Promacta® (eltrombopag)</p> <p>Nonformulary: Aranesp®, Epogen®</p>	<p>Formulary agents: Procrit: 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. Promacta: Approved for treatment of thrombocytopenia with chronic immune thrombocytopenic purpura, has a platelet count of <400 x 10⁹/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>Nonformulary agents: Also requires documentation that member has experienced failure of or intolerance to formulary epoetin alfa (Procrit) and applicable criteria for Procrit.</p>
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Hepatitis B & C Therapy

<p>Formulary: Infergen (interferon alfacon-1), Intron-A (interferon alfa-2B), Pegasys (peginterferon alfa 2-A), Peg-Intron (peginterferon alfa-2B), ribavirin</p>	<p>Infergen: Approved for the treatment of Hepatitis B. 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. Peg-Intron, Pegasys: Approved for the treatment of Hepatitis B and Hepatitis C. For hepatitis C, approval is 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. For genotypes 2, 3: Approval is for a total of 24 weeks duration. For non-genotypes 2, 3: Approval is for a total of 48 weeks duration. Members must achieve a ≥2 log decrease in viral load after 12 weeks of treatment. Ribavirin: Approved for the treatment of Hepatitis C. Genotype, HIV status, previous therapy and duration must also be provided.</p>
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Interferons and MS Therapy

<p>Nonformulary: Ampyra™ Betaseron®</p>	<p>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. Betaseron: Requires documentation that member has experienced failure of or intolerance to formulary agents (Avonex, Copaxone or Rebif) AND Extavia®.</p>
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LIFESTYLE MODIFICATION PRODUCTS

Impotence

<p>Formulary: Caverject® (alprostadil), Cialis® (tadalafil), Muse® (alprostadil), Viagra® (sildenafil citrate)</p> <p>Nonformulary: Edex®, Levitra®, Staxyn™</p>	<p>For men over the age of 34: requires a diagnosis of erectile dysfunction (ED). For men 34 years and younger: requires a diagnosis of 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.</p>
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LIFESTYLE MODIFICATION PRODUCTS (Cont.)

Weight Loss Products

Formulary: phentermine and related products	Requires verification that member's Body Mass Index (BMI) is ≥ 30 kg/m ² or >27 kg/m ² with co-morbidities. and concurrent lifestyle modification plan. Initial 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 for Xenical.
Nonformulary: Xenical [®]	

OBSTETRICS AND GYNECOLOGY

Infertility treatment

Formulary: Bravelle [®] (urofollitropin), Cetrotide [®] (cetorelix 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.
Nonformulary: Follistim [®] AQ, Luveris [®] , Menopur [®]	

OTIC & NASAL PREPARATIONS

Intranasal Steroids

Formulary: Nasacort AQ [®] (triamcinolone acetoneide)	Formulary agent: Nasacort AQ: Requires documentation that member has experienced treatment failure of or intolerance to fluticasone (Flonase ^(g)) or flunisolide (Nasalide ^(g) /Nasarel ^(g)).
Nonformulary: Beconase AQ [®] , Nasonex [®] , Omnaris [™] , Rhinocort Aqua [®] , Veramyst [™]	Nonformulary agents: Requires documentation that member has experienced treatment failure of or intolerance to fluticasone (Flonase ^(g)) or flunisolide (Nasalide ^(g) /Nasarel ^(g)) AND Nasacort AQ.

RESPIRATORY COUGH & COLD

Antihistamines and Combinations

Formulary: Allegra-D [®] (g) (p-ephed/fexofenadine), Xyzal [®] (g) (levocetirizine)	Formulary agent: Allegra-D(g): Requires documentation that the member has experienced treatment failure of or intolerance to OTC loratadine D or OTC cetirizine D Xyzal (g): Requires documentation that the member has experienced treatment failure of or intolerance to OTC loratadine or OTC cetirizine, AND generic fexofenadine (Allegra ^(g) or Allegra-D ^(g)) in appropriate dosage form for requested drug.
Nonformulary: Allegra [®] suspension, Allegra [®] ODT, Clarinex [®] , Clarinex-D [®] , Clarinex Reditabs [®] , Clarinex Syrup [®] , Semprex-D [®] , Xyzal [®] Oral Solution	Nonformulary agents: Requires documentation that the member has experienced treatment failure of or intolerance to OTC loratadine or OTC cetirizine, AND generic fexofenadine (Allegra ^(g) or Allegra-D ^(g)) in appropriate dosage form for requested drug.

Inhaled Beta-Agonists

Nonformulary: Brovana [®] , Perforomist [™]	Requires documentation that the member has experienced treatment failure of or intolerance to BOTH Serevent [®] AND Foradil [®] .
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RESPIRATORY COUGH & COLD (Cont.)

Pulmonary Arterial Hypertension

Formulary:

Letairis™ (ambrisentan), Revatio® (sildenafil), Tracleer® (bosentan), Tyvaso™ (treprostinil), Ventavis® (iloprost)

Nonformulary:

Adcirca™

Formulary agents:

Letairis, Revatio, Tracleer, Tyvaso, Ventavis: Approved for the treatment of pulmonary arterial hypertension (PAH) WHO Class III or IV symptoms.

Nonformulary agent:

Adcirca: 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.

RHEUMATOLOGY & MUSCULOSKELETAL

Gout Therapy

Nonformulary:

Uloric®

Approved for the treatment of gout and hyperuricemia in members that have experienced treatment failure of, at appropriate dose, or intolerance to generic allopurinol. Uloric 80mg requires documentation that the member has had an inadequate response to the 40mg dose.

Miscellaneous Rheumatologic Agents

Formulary:

Enbrel® (etanercept), Humira® (adalimumab)

Nonformulary:

Cimzia®, Kineret®, Simponi™

Formulary agents:

Enbrel, Humira: Requires four month trial with two concurrent disease modifying antirheumatic drugs (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine.

Nonformulary agent:

Cimzia, Kineret, Simponi: Approved for the treatment of moderate to severe rheumatoid arthritis and requires documentation that the member has experienced treatment failure of or intolerance to Enbrel and Humira.

Osteoporosis/Bone Resorption Inhibitors

Formulary:

Actonel® (risedronate); Actonel® plus Calcium

Nonformulary:

Boniva®, Forteo™, Fosamax D™

Formulary agents:

Actonel, Actonel plus Calcium: Requires documentation that member has experienced treatment failure of or intolerance to alendronate (Fosamax(g)).

Nonformulary agents:

Boniva, Fosamax D: Requires documentation that member has experienced treatment failure of or intolerance to both alendronate (Fosamax(g)) and Actonel.
Forteo: 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.

UROLOGY

BPH Treatment

Nonformulary:

Jalyn™

Requires successful treatment of at least three months of therapy with the individual agents contained in the requested medication at the prescribed dosage.