



**Blue Care
Network
of Michigan**

A nonprofit corporation and independent licensee
of the Blue Cross and Blue Shield Association

Quality Interchange Program January 2007

Prior Authorization or Step Therapy may be necessary for coverage of certain medications for BCN's Commercial members. Clinical criteria, based on current medical information as approved by the BCBSM/BCN Pharmacy and Therapeutics Committee must be met, or other information must be provided, before coverage is approved for these drugs. Drugs subject to Step Therapy may require previous treatment with one or more formulary agents prior to coverage. The criteria for Prior Authorization and Step Therapy are documented in this BCN Quality Interchange Program. This program helps ensure that safe, high quality, cost-effective drug therapy is prescribed prior to the use of more expensive agents, or drugs that have not been proven to offer additional value over current formulary medications.

Please note that 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:

1. The member has tried and failed to respond to an adequate trial of a formulary agent(s) from the same drug class, **AND/OR**
2. Use of the available formulary agent(s) would pose unnecessary risk to the member, **AND**
3. 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.

In addition, quantity limits may apply to certain drugs. Please visit us online at:

www.bcbsm.com/providers/physicians/physicians_rx_bcn.shtml for more details on our quantity limits.

MEDICATION/ DRUG CLASS	CRITERIA
Nonformulary Adoxa™ (doxycycline monohydrate) Oracea® (doxycycline) Solodyn™ (doxycycline)	Requires submission of a completed MedWatch form to the FDA with a copy to BCN to document failure of or intolerance to generic doxycycline monohydrate.
Angiotensin II Receptor Blockers (ARBs) Benicar®, HCT; Cozaar®/Hyzaar® <i>Nonformulary: Atacand®, HCT;</i> <i>Avapro®/Avalide®, Diovan®, HCT; Micardis®,</i> <i>HCT; Teveten®, HCT</i>	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.
Antidepressants-Reuptake Inhibitors Formulary: Lexapro®, Effexor® XR	Formulary: Requires documentation that member has experienced failure of or intolerance to at least one generic agent (e.g., Prozac(g), Celexa(g), Paxil(g), Effexor(g) and Wellbutrin, SR(g)).
Antidepressants-Reuptake Inhibitors Nonformulary: Cymbalta®, Paxil CR™, Pexeva™, Prozac Weekly®, Wellbutrin XL™	Nonformulary agents: Requires documentation that member has experienced failure of or intolerance to at least two formulary agents. Paxil CR, Pexeva: Requires all of the above plus documentation that continued use of Paxil(g) will adversely affect the member's mental health. Wellbutrin XL: Requires all of the above plus documentation that continued use of Wellbutrin SR(g) will adversely affect the member's mental health. Prozac Weekly: Requires prior treatment with at least two months of successful continuous, daily Prozac(g) and documentation that continued use of daily Prozac(g) would adversely affect the member's mental health.
Aranesp® (darbepoetin) <i>Nonformulary</i>	Requires documentation that member has experienced failure of or intolerance to Procrit (formulary epoetin).

MEDICATION/ DRUG CLASS	CRITERIA
Bidil[®] (isosorb dinit/hydralazine) <i>Nonformulary</i>	Requires documentation that member has experienced failure of or intolerance to both a beta-blocker and long-acting nitrates.
Byetta[®] (exenatide) <i>Nonformulary</i>	Requires documentation that member has a diagnosis of Type 2 diabetes and is currently being prescribed either metformin and/or sulfonylurea. Covered only when insulin has failed and is limited to 1 cartridge per month.
Cholesterol-lowering Crestor [®] , Zetia [®] <i>Nonformulary: Adivcor[®], Altoprev[®], Caduet[®], Lescol[®], XL, Lipitor[®], Vytorin[®]</i>	<p>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)).</p> <p>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)).</p> <p>Nonformulary agents: 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)) AND one formulary brand agent (Crestor or Zetia).</p>
Nonformulary Cipro[®] XR (ciprofloxacin-betaine) Proquin[®] XR (ciprofloxacin)	Approved only for uncomplicated UTI (cystitis). Alternatives include Cipro(g) 100-250mg BID x 3 days and Bactrim DS(g) BID x 3-5 days.
COX-2 Preferential/GI Protective NSAIDS <i>Nonformulary: Arthrotec[®], Celebrex[®]</i>	<p>Arthrotec: Requires age > 60 or concomitant use of anticoagulants or oral steroids or risk of GI bleed (history of PUD, previous GI bleed or alcoholism).</p> <p>Celebrex: Requires age > 60 or oral steroids or risk of GI bleed and no history or evidence of cardiovascular and thromboembolic disease. No concomitant use with an anticoagulant. (Note that Lodine(g) is more selective than Celebrex for the COX-2 enzyme.)</p>
Dispense-as-Written Member pays the difference between the brand and generic versions plus normal copay amount unless criteria are met.	Requires submission of a completed MedWatch form to the FDA with a copy to BCN to document a serious adverse event with a generic drug or potential quality issue with a generic drug or documentation of medical necessity for consideration of coverage with a brand name drug. In many cases, the manufacturer of the original branded product is the manufacturer of the generic. Requests for members who received a generic version that was produced by the original manufacturer will not be approved. Information and online forms are available at https://www.accessdata.fda.gov/scripts/medwatch/
Erectile Dysfunction Viagra [®] , Caverject [®] , Cialis [®] , Muse [®] <i>Nonformulary: Edex[®], Levitra[®]</i>	Approved (maximum 6 doses/28 days) for men age > 35 with a diagnosis of erectile dysfunction. For men ≤ 35 , must provide medical cause of erectile dysfunction. No concomitant nitrates; avoid use of alpha blockers with oral erectile dysfunction agents.
Exjade[®] (deferasirox) <i>Nonformulary</i>	New agent used to treat chronic iron overload due to transfusions in patients over 2 years old. Requires appropriate diagnosis for coverage and documentation of treatment failure or intolerance to Desferal(g). Coverage for members with other conditions resulting in iron overload will be considered if published evidence supports such use.

MEDICATION/ DRUG CLASS	CRITERIA
<p>Growth Hormone Nutropin[®] (all), Saizen[®] <i>Nonformulary: Genotropin[®], Humatrope[®], Norditropin[®], Omnitrope[®], Serostim[®], Tev-Tropin[®], Zorbtive[™]</i></p>	<p>Children (males <16 years old; females < 15 years old): <i>Initial Treatment:</i> Requires ≥ 6 months of initial height measurements, height < 5th percentile for age (based on initial evaluation), abnormal growth velocity based on ≥ 6 months of measurement, < 50th percentile for age with growth hormone therapy, initial subnormal blood test for growth hormone. <i>To continue:</i> Must have documented growth velocity of ≥ 2.5 cm/year during the first 6 months of treatment & documented growth of ≥ 4.5 cm/year for each succeeding 6 month review period. Treatment may continue until final height or epiphyseal closure has been documented.</p> <p>Adults: Requires initial diagnosis based on growth hormone stimulation test or Hubrecht assay, and documentation that a member does NOT have edema, arthralgias, or carpal tunnel syndrome. May be approved for AIDS-wasting cachexia and Turner's syndrome.</p>
<p>Hypnotics/Sedatives <i>Nonformulary: Ambien CR[™], Lunesta[™], Rozerem[™], Sonata[®]</i></p>	<p>Requires documentation that member has experienced failure of or intolerance to Ambien.</p>
<p>Nonformulary Increlex[™] (mecasermin) iPlex[®] (mecasermin finfabate/pf)</p>	<p>Requires severe IGF-1 deficiency as demonstrated by height standard deviation score ≤ -3 and basal IGF-1 standard deviation score ≤ -3 and normal or elevated growth hormone. Initial approval for 1 year and renewal can be obtained if clinical response with that therapy, as demonstrated by an annual growth of > 5cm in the first year.</p>
<p>Inspra[®] (eplerenone) <i>Nonformulary</i></p>	<p>Requires documentation that the member has tried and failed or is intolerant to Aldactone(g) or Aldactazide(g).</p>
<p>Iressa[®] (gefitinib)</p>	<p>Indicated for the treatment of non-small cell lung cancer (NSCLC), but has not been shown to improve survival. Requires that patient already be on gefitinib and responding to treatment or Phase II-III study approved by an appropriate Investigational Review Board.</p>
<p>Long-Acting Beta₂ Agonists Foradil[®], Serevent Diskus[®]</p>	<p>For persistent asthma: Requires concomitant treatment with an inhaled anti-inflammatory drug, and availability of a short-acting rescue inhaler. Also approved for diagnosis of COPD or exercise-induced asthma without above requirements.</p>
<p>Lotronex[®] (alosectron hydrochloride) <i>Nonformulary</i></p>	<p>Approved for treatment of women ≥ 18 years old with severe, diarrhea predominant irritable bowel syndrome (IBS) who have failed to respond to conventional IBS therapy.</p>
<p>Lyrica[®] (pregabalin) <i>Nonformulary</i></p>	<p>Requires documentation that member has diagnosis of:</p> <ul style="list-style-type: none"> • Seizures, and is being treated concurrently with other anticonvulsants OR • Neuropathic pain associated with either diabetic peripheral neuropathy or post-herpetic neuralgia AND the patient has had an adequate treatment course (30+ days) with the following medications at the specified doses (except where not tolerated or contra-indicated): <ul style="list-style-type: none"> ○ At least ONE tricyclic antidepressant, such as amitriptyline (≥ 75mg/day), desipramine (≥ 50mg/day) or imipramine (≥ 30mg/day); AND ○ Gabapentin (≥ 1200mg/day) AND ○ Carbamazepine (≥ 300 mg/day) • Approvals are granted only at the specific strength requested. • Approved dosage is limited to ≤ 300mg per day for initial treatment and will not exceed 600mg per day if 300mg/day tolerated. • Any previous authorizations are discontinued when a new strength is approved.

MEDICATION/ DRUG CLASS	CRITERIA
Nexavar[®] (sorafenib tosylate)	New agent indicated for the treatment of renal cell carcinoma (RCC). Requires appropriate diagnosis for coverage. This agent is also covered if the member is enrolled in an approved Phase II thru IV investigative study approved by an appropriate Investigational Review Board. Prior authorization required to document patient enrollment in the study.
Non-Sedating Antihistamines Allegra [®] (g), Allegra-D [®] <i>Nonformulary: Clarinex[®], Clarinex Reditabs[®], Clarinex-D[®], Zyrtec[®], Zyrtec-D[®]</i>	Allegra(g), Allegra-D: Requires documentation that member has experienced treatment failure of or intolerance to OTC loratadine. Clarinex/D, Zyrtec/D: Requires documentation that member has experienced treatment failure of or intolerance to OTC loratadine.
Oral Hypoglycemics Actos [®] and Avandia [®] (pioglitazone and rosiglitazone) <i>Nonformulary: Actoplus Met[®], Avandamet[®], AvandarylTM, DuetactTM, JanuviaTM</i>	Actos, Avandia: 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. Nonformulary agents <i>Actoplus Met, Avandamet:</i> Requires documentation that the member has experienced failure with metformin and a TZD as individual agents. <i>Avandaryl, Duetact:</i> Requires documentation that the member has experienced failure with sulfonylurea and a TZD as individual agents. <i>Januvia:</i> Requires documentation that member has experienced failure with or is intolerant to metformin.
Plavix[®] (clopidrogel bisulfate)	Approved for members who have had a recent myocardial infarction (MI) or stroke, or have established peripheral arterial disease, or are at increased risk of having a future ischemic event. Members must have documented aspirin allergy or intolerance, or experienced treatment failure with aspirin.
Provigil[®] (modafinil)	Approved only for members with narcolepsy and for other indications supported by well-documented, published clinical studies.
Proton Pump Inhibitors Formulary: Prevacid [®]	Formulary <i>Prevacid:</i> Requires documentation that member has experienced failure of or intolerance to Prilosec OTC or Prilosec(g).
Proton Pump Inhibitors Nonformulary: Aciphex [®] , Prevacid [®] Naprapac, Prevacid [®] Solutab TM , Prilosec [®] 40mg, Protonix [®] , Zegerid TM , Nexium [®]	Nonformulary agents <i>Aciphex, Prilosec 40mg, Protonix, Prevacid Naprapac, Prevacid Solutab, Zegerid:</i> Requires treatment failure with Prilosec OTC and Prevacid. <i>Nexium:</i> Requires treatment failure with Prilosec OTC and Prevacid (must have tried high dose).
Ranexa[®] (ranolazine) <i>Nonformulary</i>	Requires documentation that member has experienced failure of or intolerance to both a beta-blocker and nitrates. Also requires no history of cancer or high risk of cancer.
Regranex[®] (becaplermin topical) <i>Nonformulary</i>	Requires approval by BCN's Care Management team.
Retinoids (topical) Differin [®] <i>Nonformulary: Azelex[®], FinaceaTM</i>	For members' age > 30, requires diagnosis of acne or related disorder.
Revlimid[®] (lenalidomide) <i>Nonformulary</i>	Coverage limited to members with the "5Q deletion" form of MDS (myelodysplastic syndrome). This agent is also covered if the member is enrolled in an approved Phase II thru IV investigative study approved by an appropriate Investigational Review Board. Prior authorization required to document patient enrollment in the study.

MEDICATION/ DRUG CLASS	CRITERIA
Sarafem[®] (fluoxetine) <i>Nonformulary</i>	Approved for women with documentation that the use of fluoxetine will adversely affect the member's mental health.
Singulair[®] (montelukast)	Approved for members with asthma or reactive airway disease. <u>For allergic rhinitis:</u> Requires documentation that the member has experienced a treatment failure with a formulary nasal steroid or a formulary non-sedating antihistamine.
Smoking Cessation Products (Rx Only) <i>Nonformulary: Nicotrol[®], Nasal Spray, Inhaler, Chantix[™]</i>	Most members requires current enrollment in Quit the Nic (800-811-1764) for coverage. Coverage for nicotine-replacement products is limited to 3 months every 12 months. Coverage increases to 3 months every 6 months if member re-enrolls in Quit the Nic. Initial coverage for Chantix is limited to 12 wks. Coverage for an additional 12 wks is provided if there is documentation that member has stopped smoking and continues enrollment in Quit the Nic. Maximum coverage of 24 weeks every 52 weeks.
Smoking Cessation Products (OTC) Nicotine-replacement patches, gum & lozenge	Requires current enrollment in Quit the Nic (1-800-811-1764). Coverage for all OTC smoking cessation nicotine-replacement products is limited to 3 months every 12 months. Coverage increases to 3 months every 6 months if re-enrolled in Quit the Nic.
Sprycel[®] (dasatinib) <i>Nonformulary</i>	Requires treatment failure of first line chemotherapy for chronic myeloid leukemia (CML), or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL), or Phase II-III study approved by an appropriate Investigational Review Board. Prior authorization required to document patient enrollment in the study.
Strattera[™] (atomoxetine) <i>Nonformulary</i>	Approvable when stimulants are contraindicated by medical history. <u>For BCN members age 5-21:</u> Requires documentation that member has experienced failure of or intolerance to both a methylphenidate product (such as Ritalin(g) or Concerta) and an amphetamine (such as Adderall(g)). <u>For BCN members age >21:</u> Requires documentation that the member has experienced failure of or intolerance to either a methylphenidate product or an amphetamine.
Sutent[®] (sunitinib malate)	New agent indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinub. May also be used for advanced RCC. Requires appropriate diagnosis for coverage. This agent is also covered if the member is enrolled in an approved Phase II thru IV investigative study approved by an appropriate Investigational Review Board. Prior authorization required to document patient enrollment in the study.
Symlin[®] (pramlintide) <i>Nonformulary</i>	Requires failure of intensive treatment with insulin alone and concurrent claims with an insulin product.
Tarceva[®] (erlotinib)	Requires appropriate diagnosis for coverage. Indicated for the treatment of non-small cell lung cancer (NSCLC). Also has published evidence of efficacy in metastatic colorectal cancer, glioblastoma, advanced prostate cancer and metastatic RCC. This agent is also covered if the member is enrolled in an approved Phase II thru IV investigative study approved by an appropriate Investigational Review Board. Prior authorization required to document patient enrollment in the study.
Topical Immunomodulators Elidel [®] (pimecrolimus) <i>Nonformulary: Protopic[®]</i>	Not covered for children under 2 years old. <u>Elidel:</u> 1% strength for members age 2 and older. <u>Protopic:</u> Requires documentation member has experienced failure of or intolerance to Elidel. For members age 2-15 years old, only 0.03% may be used.

MEDICATION/ DRUG CLASS	CRITERIA
<p>TNF-alpha agents and related products Enbrel[®] (etanercept) <i>Nonformulary: Humira[®], Kineret[®]</i></p>	<p>Rheumatoid Arthritis: Requires four-month trial with two concurrent DMARDs (one must be methotrexate unless contraindicated). Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquin/chloroquin, cyclosporine, gold and penicillamine.</p> <p>Nonformulary agents: Requires documentation that member has experienced failure of or intolerance to formulary agent, Enbrel.</p> <p>Moderate to Severe Psoriasis (Enbrel only): Requires 3 months of previous treatment with topical corticosteroids and 3 months treatment with PUVA.</p>
<p>Tracleer[™] (bosentan) Ventavis[®] (iloprost) Revatio[®] (sildenafil)</p>	<p>Requires a diagnosis of Pulmonary Arterial Hypertension (PAH) in patients with WHO Class III or IV symptoms.</p>
<p>Weight Loss Products Phentermine and related products <i>Nonformulary: Meridia[®], Xenical[®]</i></p>	<p>Requires verification that member's Body Mass Index (BMI) is ≥ 30, (> 27 if co-morbidities) and concurrent lifestyle modification plan. Coverage for all anorexiant and related drugs is limited to 3 months. Additional coverage requires documentation of weight loss of at least 2 pounds per month. Maximum benefit is 12 months of treatment per lifetime; 24 months for Xenical.</p>
<p>Nonformulary Zelnorm[™] (tegaserod maleate) Amitiza[®] (lubiprostone)</p>	<p>For IBS (Zelnorm only): Approved for the short-term treatment of women ≥ 18 years old with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation. A total of 12 wks every 6 mo can be approved.</p> <p>For Chronic Constipation (<3 BMs/week): Approved for mbrs ≥ 18 and < 65 years of age who are NOT on medications causing constipation and who have failed treatment that include <u>all</u> of the following: dietary advice, trials of bulk laxatives, stool softeners and a short course of stimulant laxatives. A total of 12 weeks can be approved, with renewal, only if improvement in bowl freq with initial trial.</p>