

Special eBulletin

November 2010

4th Quarter Update:

Highmark Medicare-Approved Drug Formulary*

Following is the 4th Quarter 2010 update to Highmark's Medicare-Approved Select/Choice Formulary and related pharmaceutical management procedures. The formulary and pharmaceutical management procedures are updated on a quarterly basis, based on recommendations made by our Pharmacy and Therapeutics Committee and within the guidelines established by the Centers for Medicare and Medicaid Services (CMS).

The following changes reflect the decisions made in September 2010 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Highmark's Medicare-Approved Select/Choice Formulary applies to all members enrolled in Highmark's Medicare Prescription Drug plan, BlueRxSM. Highmark's Medicare-Approved Select/Choice Formulary also applies to all members enrolled in the Medicare Advantage FreedomBlueSM PPO product offered by Highmark Health Insurance Company (HHIC) in the Mountain State Blue Cross Blue Shield service area.

As an added convenience, you can also search the Highmark Medicare-Approved Select/Choice Formulary online at <http://highmark.medicare-approvedformularies.com>. This function allows you to search by the drug name or therapeutic class. You can also find other helpful information regarding the prescription drug program on our online Provider Resource Center. Simply visit www.highmarkblueshield.com, click on the *Providers* tab at right near the top of the page and then look under the *Pharmacy/Formulary Information* link. Additionally, an electronic copy of the formulary for use with a portable handheld device can be downloaded free by visiting www.epocrates.com.

If you have any questions regarding this Special eBulletin or Highmark's Medicare-Approved Select/Choice Formulary, please contact your Provider Relations representative.

***PLEASE NOTE: This formulary *doesn't* apply to members enrolled in Mountain State Blue Cross Blue Shield's traditional Medicare products.**

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An Independent Licensee of the Blue Cross and Blue Shield Association

Highmark Medicare-Approved Formulary Update November 2010

SECTION I: Highmark Medicare-Approved Select/Choice Formulary

A. Changes to the Highmark Medicare-Approved Select/Choice Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the following tables. As a reminder, the Highmark Medicare-Approved Select/Choice Formulary applies only to **Highmark** Medicare Advantage and BlueRxSM members. For your convenience, you can search the Highmark Medicare-Approved Select/Choice Formulary online at <http://highmark.medicare-approvedformularies.com>.

Products to be Added

There are no formulary additions for this quarter.

Table 1: Products Not Added*

Brand Name	Generic Name	Comments
Aricept [®] 23 mg	donepezil	Aricept [®] and Exelon [®] are on the formulary.
Astepro [™]	azelastine nasal spray	Astelin is on the formulary.
Butrans [™]	buprenorphine transdermal patch	OxyContin [®] and morphine sulfate SR are on the formulary.
Carpine [®]	pilocarpine ophthalmic solution	Pilocarpine is on the formulary.
Cuvposa [™]	glycopyrrolate oral solution	Glycopyrrolate is on the formulary.
Dulera [®]	mometasone furoate/formoterol fumarate inh aerosol	Advair [®] and Symbicort [®] are on the formulary.
Glassia [™]	alpha1-antitrypsin	For treatment of emphysema due to congenital Alpha1-Antitrypsin Deficiency.
Jevtana [®]	cabazitaxel	For treatment of patients with hormone refractory metastatic prostate cancer.
Lumizyme [®]	alglucosidase alfa	A lysosomal glycogen-specific enzyme for late (non-infantile) onset Pompe disease (acid α -glucosidase (GAA) deficiency).
Namenda XR [™]	memantine hydrochloride	Namenda [®] is on the formulary.
Pancreaze [™]	pancrelipase	Creon [®] and Zenpep [®] are on the formulary.
Sprix [™]	ketorolac tromethamine nasal spray	Multiple generic NSAIDs are on the formulary.
Veltin [™]	clindamycin phosphate/tretinoin gel	Clindamycin and tretinoin are on the formulary.
Zortress [®]	everolimus	Prograf [®] is on the formulary.
Zuplenz [®]	ondansetron orally dissolving film	Ondansetron is on the formulary.
Zymaxid [™]	gatifloxacin ophthalmic solution	Ciprofloxacin ophthalmic solution and ofloxacin ophthalmic solution are on the formulary.

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be found on Page 8 of the 2010 Highmark Drug Formulary book. You may also access the form online in Highmark's Provider Resource Center; under *Provider Forms*, select *Miscellaneous Forms*, and select the link titled *Request for Drug Coverage from Pharmaceutical Management Program*.

Table 2: Products to be Removed* from the Formulary (effective January 1, 2011 unless otherwise noted)

Brand Name	Generic Name	Comments
Accolate [®]	zafirlukast	Singulair [®] is on the formulary.
Acular LS [®]	ketorolac tromethamine	Generic is on the formulary.
Allegra-D [®] 12 Hour	fexofenadine/pseudoephedrine	Generic is on the formulary.
Amerge [®]	naratriptan HCl	Maxalt [®] and sumatriptan are on the formulary.
Aricept [®] ; Aricept [®] ODT	donepezil	Generic is on the formulary.
Astelin [®]	azelastine	Generic is on the formulary.
Axert [®]	almotriptan malate	Maxalt [®] and sumatriptan are on the formulary.
Estring [®]	estradiol vaginal ring	Multiple estrogen products are on the formulary.

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Femhrt [®] 1/5; Femhrt [®] Low Dose	norethindrone acetate/ethinyl estradiol	Multiple estrogen-progestin combination preparations are on the formulary.
Imitrex [®]	sumatriptan	Generic is on the formulary.
Kaon-Cl [®] ; K-Tab [®] ; Klor-Con M15 [®]	potassium chloride	Multiple generic potassium chloride preparations are on the formulary.
Menest [®]	esterified estrogens	Multiple estrogen products are on the formulary.
Miacalcin [®] Nasal Spray	calcitonin-salmon	Generic is on the formulary.
Mirapex ^{®§}	pramipexole	Generic is on the formulary.
Proventil [®] HFA	albuterol sulfate	ProAir [®] HFA and Ventolin [®] HFA are on the formulary.
Relpax [®]	eletriptan hydrobromide	Maxalt [®] and sumatriptan are on the formulary.
Rozerem [®]	ramelteon	Zolpidem and zaleplon are on the formulary.
Semprex-D [®]	acrivastine/pseudoephedrine	Fexofenadine/pseudoephedrine is on the formulary.
Subutex [®]	buprenorphine	Generic is on the formulary.
Valtrex [®]	valacyclovir	Generic is on the formulary.
Zomig [®]	zolmitriptan	Maxalt [®] and sumatriptan are on the formulary.

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be found on Page 8 of the 2010 Highmark Drug Formulary book. You may also access the form online in Highmark's Provider Resource Center, under *Provider Forms*, select *Miscellaneous Forms*, and select the link titled *Request for Drug Coverage from Pharmaceutical Management Program*.

§Effective October 1, 2010

B. Updates to the Prior Authorization Program (If approved, authorization may be granted for up to one year unless otherwise noted)

Drug Name	Policy Effective Date	Approval Criteria
Butrans [™] (buprenorphine patch)	Immediately upon CMS approval	<ul style="list-style-type: none"> Moderate to severe chronic pain requiring a continuous, around-the-clock opioid analgesic for an extended period of time, AND Have failed at least 2 other long-acting opioid analgesics.
Prolia [™] (denosumab)	Immediately upon CMS approval	<ul style="list-style-type: none"> Documented osteoporosis, AND either Intolerant to, or have a contraindication to, at least 2 other osteoporosis therapies including at least 1 bisphosphonate, OR Have had a documented failure of at least 1 bisphosphonate.

C. Updates to the Managed Prescription Drug Coverage (MRxC) Program (If approved, authorization may be granted for up to one year unless otherwise noted)

Drug Name	Policy Effective Date	Automatic Approval Criteria*	Standard Prior Auth Criteria
Abilify [®] (aripiprazole),	January 1, 2011	<ul style="list-style-type: none"> The member as at least one (1) paid claim from the following categories within the past 12 months: a) mood stabilizers (e.g., Lithium) OR b) antipsychotics (e.g., Haldol, Risperidone, Seroquel etc) OR The member has a least one paid claim for two (2) different antidepressants (e.g., SNRI, SSRI, TCA) including an active claim for 1 antidepressant within the past 12 months. OR 	<ul style="list-style-type: none"> Abilify, Symbyax or Seroquel XR is being prescribed as adjunctive treatment of major depressive disorder in adults (> 18 years old) AND The member has tried and failed at least 1 other agent used for treatment of major depressive disorder OR The member has a diagnosis of schizophrenia OR The member has a diagnosis of bipolar disorder OR The member has a diagnosis of autism spectrum disorder.

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		<ul style="list-style-type: none"> The member has a previous claim for Abilify within the last 180 days. 	
Cialis® 2.5 mg and 5 mg tablets	Immediately upon completion of internal review and CMS approval	<ul style="list-style-type: none"> Up to 30 tablets for a 34-day supply or up to 90 tablets for a 35- to 90-day supply for members who have impotency coverage. 	<ul style="list-style-type: none"> Up to 30 tablets for a 34-day supply or up to 90 tablets for a 35- to 90-day supply for members who have impotency coverage.
Pristiq® (desvenlafaxine)	January 1, 2011	<ul style="list-style-type: none"> The member has at least one claim for 2 different antidepressants in prescription drug claim history within the past 24 months OR The member has a previous paid claim for desvenlafaxine within the previous 120 days. 	<ul style="list-style-type: none"> The member has a diagnosis of major depressive disorder (MDD) and has tried and failed at least 2 other antidepressants.
Staxyn™ (vardeafil)	Immediately upon CMS approval	<ul style="list-style-type: none"> Up to 6 tablets for a 34-day supply or up to 18 tablets for a 35- to 90-day supply for members who have impotency coverage. 	<ul style="list-style-type: none"> Up to 6 tablets for a 34-day supply or up to 18 tablets for a 35- to 90-day supply for members who have impotency coverage.

* Members who meet the automatic approval criteria above will receive automatic authorization at the level of the pharmacy without documentation of additional information. For members who do not meet the automatic approval criteria, the dispensing pharmacist will be prompted that prior authorization is required. Prior authorization criteria are listed above.

D. Additions to Highmark's Pharmaceutical Management Procedures

Additions to the Specialty Tier Copay Option:

Effective immediately upon CMS approval, Chenodal™ (chenodiol), Carbaglu® (N-carbamylglutamate), Cayston® (aztreonam solution for inhalation), Hizentra™ [immune globulin subcutaneous (Human)], Xiaflex® (collagenase clostridium histolyticum), Prolia™ (denosumab), Glassia™ (alpha1-antitrypsin), Jevtana® (cabazitaxel), Zortress® (everolimus) 0.75 mg and Lumizyme® (alglucosidase alfa) will be added to the specialty tier copay program for Medicare Advantage and BlueRxSM members.

E. Medication Coverage under Medicare Part B vs. Medicare Part D

Based on CMS regulations, certain medications are always covered under the Medicare Part B benefit, while others may be covered under the Part B or Part D benefit, depending upon such variables as the setting in which the medication is administered or the clinical diagnosis for which the medication is being used. The following is intended to assist providers in understanding these situations.

1. When are drugs covered under Medicare Part B?

Medicare Part B covers a limited set of drugs. Injectable and infusible drugs that are not usually self-administered and that are furnished and administered as part of a physician service are typically covered under Part B. If the injection is usually self-administered or is not furnished and administered as part of a physician service, it may not be covered by Part B. In addition, the following agents are always covered under Medicare Part B:

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Oral Anti-cancer agents

Alkeran (melphalan)
Temodar (temozolomide)
Cytosan (cyclophosphamide)
VePesid (etoposide)
Myleran (busulfan)
Xeloda (capecitabine)

Other

Antigens
Diabetic test strips and lancets
Influenza vaccine
Intrathecal baclofen
Pneumococcal vaccine

2. How to access Medicare Part B drugs?

In order to access a drug under the Medicare Part B benefit, you will need to make sure that the pharmacy or supplier is a participating durable medical equipment (DME) provider in the Medicare Part B program or find a pharmacy or supplier that is a provider with the Medicare Part B Durable Medical Equipment Regional Carrier (DMERC). A Prescription Drug Medication Request Form **does not** have to be submitted to Highmark for review.

3. When are drugs covered under Medicare Part D?

Medicare Part D-covered drugs are defined as: drugs available only by prescription, used and sold in the United States, and used for a medically accepted indication. The definition also includes medical supplies associated with the injection of insulin (syringes, needles, alcohol swabs and gauze). Certain drugs or classes of drugs, or their medical uses, are excluded by law from Part D coverage.

4. How to access Medicare Part D drugs?

Prescription drugs that are eligible under Medicare Part D are available at retail pharmacies. A beneficiary must go to a pharmacy in the plan's network in order for the drug to be covered under the Part D benefit. If the medication in question is managed under Highmark's clinical management programs (Prior Authorization or MRxC) a *Prescription Drug Medication Request Form* should be submitted to Highmark Pharmacy Affairs (Fax: 1-412-544-7546).

5. Are there circumstances when a drug may be eligible under Medicare Part B or Medicare Part D?

Yes, however Part D sponsors may rely upon information included with the medication request, such as diagnosis or location of administration to determine if a drug is covered under Part B or Part D. Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following **under Medicare Part B:**

- **Durable Medical Equipment (DME) Supply Drugs.** These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump). The largest Medicare expenditures for drugs furnished as a DME supply are for *inhalation drugs*, which are administered in the home with the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). The other category of drugs Medicare covers as a DME supply includes drugs for which administration with an *infusion pump* in the home is medically necessary (e.g., some chemotherapeutic agents). Insulin, when administered via an *insulin pump*, would also be covered under the Medicare Part B benefit. Durable Medical Equipment (DME) Supply Drugs administered in the LTC facility would be the exception to this rule, as they are covered under Medicare Part D.
- **Immunosuppressive Drugs.** Drugs used as immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare-covered organ transplant. Immunosuppressive drugs used for other diagnoses are covered under Medicare Part D.
- **Oral Anti-Cancer Drugs.** Drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered and were administered as incident to a physician's professional service.

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- **Oral Anti-emetic Drugs.** Oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.
- **Prophylactic Vaccines**
 - *Hepatitis B vaccine.* The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B. Hepatitis B vaccine given in any other situation would be covered under Medicare Part D.
 - Vaccines given directly related to the treatment of an injury or direct exposure related to a disease or condition are always covered under Part B. All other prophylactic vaccines would be covered under Medicare Part D.
- **Erythropoietin (EPO).** EPO is covered under Medicare Part B when used for the treatment of anemia for persons with chronic renal failure who are on dialysis.
- **Parenteral Nutrition.** Parenteral nutrition is covered under the prosthetic benefit. They are covered under the Medicare Part B benefit when used for patients with a “permanent dysfunction of the digestive tract.” For all other situations, parenteral nutrition would be covered under Medicare Part D.

For a complete list of drugs that are covered under the Medicare Part B benefit and those drugs that CMS excludes from the Medicare Part D prescription drug benefit please visit:

http://highwire.highmark.com/corp/medical-programs/secure-pdf/pharmacy-policy/Part_B_Drugs_07_15_08.pdf.

For additional information regarding coverage determinations, please contact member services at 1-800-600-2227.

Section II: Updates

A. Medvantx

To encourage the prescribing of generic pharmaceuticals, Highmark has partnered with MedVantx, a vendor that has developed an automated system to provide samples of various generic medications. This automated kiosk is located in the physician’s office at the point of care. This system provides no-cost samples of high-quality generic medications to our members. There is no cost to the physician, and members typically receive a full 30 days’ supply of medication.

Highmark has no ownership interest in Medvantx. Participation in this program is voluntary. Highmark does not provide legal advice to its participating providers. Please have your legal counsel read and review all information regarding the Medvantx program to ensure that they do not have any legal, HIPAA or other concerns as to your potential participation in the program.

B. Corrections

In the 2nd Quarter 2010 Formulary Update, Seroquel[®] and Seroquel XR[®] were listed as additions to the Managed Prescription Drug Coverage (MRxC) policy for Atypical Antipsychotics for Highmark commercial members. Only Seroquel XR was added to this policy. Seroquel[®] is not currently managed under the Managed Prescription Drug Coverage (MRxC) policy for Atypical Antipsychotics.

In the 3rd Quarter 200 Formulary Update, Exalgo[™] (hydromorphone extended release) and Xifaxan[®] 550 mg (rifaximin) were listed as additions to the Managed Prescription Drug Coverage (MRxC) Program with an effective date of September 1, 2010 for Medicare Advantage and BlueRxSM members. The effective date for these additions will be March 1, 2010.

C. Proton Pump Inhibitors and COX-II Inhibitors

As a reminder to Mountain State providers, Highmark utilizes online edits to encourage the safe and effective use of Proton Pump Inhibitors and COX-II Inhibitors. The initial review of these medications is automated through Medco, our claims processor, in order to reduce the administrative burden on physicians and to reduce member disruption. In the event that this initial review results in a denial, providers should contact our claims processor at **1-800-753-2851** when requesting coverage for COX-II inhibitors and Proton Pump Inhibitors.