SPECIAL eBULLETIN

September 2015

3RD QUARTER 2015 UPDATE

CHANGES TO THE HIGHMARK MEDICARE-APPROVED DRUG FORMULARIES

The following is the 3rd Quarter 2015 update to the Highmark Medicare-approved Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the enclosed changes reflect the decisions made in June 2015 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Highmark's Medicare-approved Drug Formularies apply to all members enrolled in our Medicare Advantage Freedom Blue PPO product offered in the Highmark Blue Cross Blue Shield West Virginia service area. The formularies also apply to all members enrolled in our Medicare Prescription Drug plan, Blue Rx.

For your convenience, you can search the Highmark Medicare-approved Drug Formularies online at **http://highmark.medicare-approvedformularies.com**.

If you have any questions regarding this Special *e*Bulletin or our Medicare-approved Formularies, please contact your Provider Relations Representative.

(continued)

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Important Drug Safety Updates

Risk of Permanent Skin Color Changes with Use of Daytrana Patch (methylphenidate transdermal system)

On June 24, 2015, the FDA released a Drug Safety Communication warning that permanent loss of skin color may occur with use of Daytrana patch for Attention Deficit Hyperactivity Disorder (ADHD). As a result of this, a new warning was added to the drug label to address this skin condition (chemical leukoderma). This condition may be disfiguring, but is not physically harmful. Patients should not stop using the patches, however, unless the prescriber changes therapy. The Daytrana patch is currently indicated for the treatment of ADHD among patients who are between 6 years old and 17 years old. Any discoloration of the skin should be reported to the provider as well as the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Risk of Serious Side Effect with Use of Codeine Cough and Cold Medicines in Children

On July 1, 2015, the FDA released a Drug Safety Communication warning of the potential risk of serious side effects, such as slowed or difficulty breathing, with use of codeine cough and cold medicines in children under 18 years of age. The FDA will be considering the European Medicines Agency (EMA) recommendations to avoid use of codeine to treat coughs and colds in children younger than 12 years of age or between 12 and 18 years of age with breathing problems. This was a follow-up warning to the 2013 warning against use of codeine in children who recently had surgery to remove their tonsils and/or adenoids. Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Program.

Increased Risk of Cardiovascular Events with Use of Non-aspirin, Nonsteroidal, Anti-inflammatory Drugs (NSAIDs)

On July 9, 2015, the FDA released a Drug Safety Communication warning of increased chance of heart attack or stroke with use of NSAIDs. The collective body of evidence with the new safety information led the FDA to require updates to the drug labels of all prescription and over-the-counter (OTC) non-aspirin NSAID drug facts labeling. Prescription labels for NSAIDs, such as naproxen, ibuprofen, diclofenac and celecoxib, will be required to include recommendations from the FDA advisory committee and safety review detailing heart attack and stroke risks associated with NSAIDs. The risk of cardiovascular events appears to be greater with higher doses or prolonged use of NSAIDs, impacting those with or without heart disease or risk factors for heart disease. Adverse events related to the use of NSAIDs should be reported to the prescriber and the FDA MedWatch Program.

Highmark Medicare-approved Formulary Update, August 2015

A. Changes to the Highmark Medicare-approved 5-Tier Incentive Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare-approved Formularies online at: **http://client.formularynavigator.com/clients/hm/default.html**.

Table 1: Preferred Products
(Effective immediately pending Centers for Medicare & Medicaid (CMS) approval and upon completion of internal review and operationalization, unless otherwise noted)

Brand Name	Generic Name	Alternatives/Comments
Toujeo®	insulin glargine	Indicated to improve glycemic control in adults with diabetes mellitus type I or II.
ProAir® RespiClick	albuterol sulfate	Indicated in patients 12 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm. *Effective date 08/01/2015*

Table 2: Non-Preferred Products
(Effective immediately pending CMS approval and upon completion of internal review and operationalization, unless otherwise noted)

Brand Name	Generic Name	Alternatives/Comments
Elepsia™ XR	levetiracetam extended-release	levetiracetam ER, carbamazepine
Corlanor®	ivabradine	Provider discretion
Quadracel™	DTaP-IPV	Not applicable
Aptensio™XR	methylphenidate extended-release	methylphenidate ER
Stiolto Respimat®	tiotropium bromide and olodaterol	Provider discretion

B. Changes to the Highmark Medicare-approved 5-Tier Closed Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare-approved Formularies online at: http://client.formularynavigator.com/clients/hm/default.html. Note: You must click the hyperlink to access the 5-Tier Closed Formulary.

Table 1: Preferred Products
(Effective immediately pending CMS approval and upon completion of internal review and operationalization, unless otherwise noted)

Brand Name	Generic Name	Alternatives/Comments
Toujeo®	insulin glargine	Indicated to improve glycemic control in adults with diabetes mellitus type I or II.
ProAir® RespiClick	albuterol sulfate	Indicated in patients 12 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm. *Effective date 08/01/2015*

Table 2: Non-Preferred Products
(Effective immediately pending CMS approval and upon completion of internal review and operationalization)

Brand Name	Generic Name	Preferred Alternatives/Comments
Elepsia™ XR	levetiracetam extended-release	levetiracetam ER, carbamazepine
Corlanor®	ivabradine	Provider discretion
Aptensio™XR	methylphenidate extended-release	methylphenidate ER
Stiolto Respimat®	tiotropium bromide and olodaterol	Provider discretion

Table 3: Products Not Added*
(Effective immediately pending CMS approval and upon completion of internal review and operationalization)

Brand Name	Generic Name	Preferred Alternatives/Comments
Quadracel™	DTaP-IPV vaccine	Office-administered vaccine given as a single IM injection, indicated for the active immunization against diphtheria, tetanus, pertussis and poliomyelitis for the primary immunization of infants > 2 months and as a booster for children up to 7 years of age. Preferred alternative at provider discretion.

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online in Highmark's Provider Resource Center; under *Provider Forms*, select *Miscellaneous Forms*, and select the form titled *Request for Non-Formulary Drug Coverage*.

C. Additions to the Specialty Tier

(Effective immediately pending CMS approval and upon completion of internal review and operationalization)

Brand Name	Generic Name
Cresemba®	isavuconazonium sulfate (IV and oral tablet formulations)
Unituxin™	dinutuximab
Avycaz™	ceftazidime/avibactam
Zarxio™	filgrastim
Kalydeco®	ivacaftor granules
Jadenu™	deferasirox
Cholbam®	cholic acid
Glatopa™	glatiramer acetate
Invega Trinza™	paliperidone palmitate extended-release injectable

D. Updates to the Pharmacy Utilization Management Programs

1. Updates to the Prior Authorization Program

Policy Name	Policy Effective Date	Updates and Approval Criteria
Unituxin (dinutuximab) – Medicare Only	TBD	New policy created to require confirmation of FDA-approved or medically accepted indication for use of dinutuximab in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoid acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multi-agent, multimodality therapy.
Corlanor (ivabradine)	TBD	Policy aligned with the FDA-approved indication for heart failure, after failure of or contraindication to maximum tolerated dose of two beta-blockers.
Cholbam (cholic acid)	TBD	New policy created to require confirmation of FDA-approved indications of treating bile acid synthesis disorders due to single enzyme defects (SEDs) and as adjunctive therapy for peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who show liver disease manifestations, steatorrhea or complications from decreased fat soluble vitamin absorption.
Programmed Death Receptor Therapies – Medicare Only	TBD	Policy updated with new indication for nivolumab (Opdivo), as it was recently approved for metastatic NSCLC after a platinum-based chemotherapy.
Actemra - Medicare Only	01/01/2016	Policy updated with approval criteria for tocilizumab in patients 2 years of age or older with active polyarticular juvenile idiopathic rheumatoid arthritis (PJIA) and active systemic juvenile idiopathic rheumatoid arthritis (SJIA).
Actimmune (interferon gamma)	06/04/2015	Updated policy to clarify that idiopathic pulmonary fibrosis (IPF) is not a medically accepted indication (MAI) by removing it from the MAI list. Leishmaniasis and Metastatic Renal Cell Carcinoma were added as MAIs.

Policy Name	Policy Effective Date	Updates and Approval Criteria
Korlym (mifepristone)	01/01/2015	Policy revised to clarify that coverage will not be permitted if Cushing's syndrome is due to an identifiable source (such as high dose corticosteroids). Additional criteria were added, to be aligned with studies, requiring failure of one diabetes therapy for patients with diabetes.
Votrient (pazopanib)	06/04/2015	Policy revised with addition of language to clarify criteria for approval. Namely, the clarification states that one, not both, of the following criteria must be met for approval: • Pazopanib is to be used for the treatment of documented advanced renal cell carcinoma (RCC) ***OR*** • Pazopanib is to be used for the treatment of documented advanced soft-tissue sarcoma (excluding adipocytic soft tissue sarcoma and gastrointestinal stromal tumors) after failure of at least one prior chemotherapy regimen (e.g. doxorubicin, carboplatin, cyclophosphamide, dacarbazine, epirubicin, ifosfamide).
Anabolic Steroids	06/04/2015	Policy criteria updated to be aligned with compendia-approved indications, which include: Anadrol-50 (oxymetholone) • Acquired aplastic anemia • Anemia of chronic renal failure • Myelosuppression induced by cancer chemotherapy • Fanconi anemia • Pure red cell aplasia Oxandrin (oxandrolone) • Adjunctive therapy to promote weight gain after weight loss, following extensive surgery, chronic infections or severe trauma and in some patients who, without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids and for the relief of bone pain frequently accompanying osteoporosis Medically Accepted Indications (MAIs): • Amegakaryocytic thrombocytopenia (oxymetholone) • Antithrombin III deficiency, Familial (oxymetholone)
Zykadia (ceritinib)	06/04/2015	Policy criteria clarified to align with FDA-approved indication: • For the treatment of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) ***AND*** • There is documentation of failure on, or intolerance to, crizotinib (Xalkori)

Policy Name	Policy Effective Date	Updates and Approval Criteria
Miscellaneous Immunomodulators	06/04/2015	Policy criteria revised to align with new FDA-approved indication. Namely, an update was made to Pomalyst (pomalidomide) for the treatment of multiple myeloma, in combination with dexamethasone, in patients who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor and progressed on or within 60 days of last therapy.
Cosentyx (secukinumab)	TBD	Policy was updated to remove step requirement for Enbrel, since Cosentyx has demonstrated superiority over Enbrel in a head-to-head trial.
Savella (milnacipran) - Medicare Only	01/01/2016	Policy requirements updated to include documented trial and failure of duloxetine for the treatment of fibromyalgia.
New to Market Drug Policy	06/04/2015	Policy revised with added language related to FDA-approved maximum daily dosing.
C1 Esterase Inhibitors	TBD	New policy for C1 Esterase Inhibitor [human] (Cinryze), indicated for the management of routine prophylaxis of angioedema attacks in adolescent and adult patients with Hereditary Angioedema (HAE). Approval criteria created based on the different types of HAE.
Hepatitis C – (Medicare Only)	TBD	Policy updated in preparation for the FDA approval of daclatasvir (Daklinza), a treatment for chronic hepatitis C genotype 3.

***All effective dates are tentative and subject to delay pending internal review or approval.**

2. Updates to the Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
Lyrica (pregabalin) - Medicare Only	01/01/2016	Policy updated to include restless leg syndrome as a medically accepted indication. Trial and failure of duloxetine was added as a requirement for the indication of fibromyalgia.
Migraine Therapies - Medicare Only	07/24/2015	Policy updated to reflect new approval criteria, as the need for preventive medications is no longer a requirement for approval of higher quantities of migraine therapies. Approval criteria include documentation by the provider that the number of doses available under a dose restriction for the prescription drug: • Has been ineffective in the treatment of the enrollee's disease or medical condition ***OR*** • Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

***Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.**

3. Updates to the Quantity Level Limit Program*

Drug Name	Up to 34-Day Supply Limit (retail)	35- to 90-Day Supply Limit (retail or mail)
Aptensio™XR	31 capsules	93 capsules
Kalydeco®	62 packets	186 packets
Lumigan® 0.01%	3mL	9mL
Savaysa™ 15mg, 30mg, 60mg	31 tablets	93 tablets
Stiolto Respimat®	1 inhaler	3 inhalers

Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria. All effective dates are tentative and subject to delay, pending internal review or CMS approval.

Highmark's Retail Pharmacy Networks to Change in 2016

Starting Jan. 1, 2016, Highmark will change our three pharmacy networks through which our members purchase prescription medications at the retail point of sale.

The changes — namely which retail pharmacies are in each network — are intended to save pharmacy costs for our group customers who buy Highmark coverage for their employees and/or retirees. Also, the improvements are being made to keep our members' out-of-pocket medication costs in check and offer them access to quality pharmacy networks.

Following is a brief summary of the changes that will be taking place for each of our major pharmacy networks in 2016.

National Plus Network

- As of Jan. 1, 2016, our broadest pharmacy network, which is now called "Premier," will become the "National Plus" network.
- Highmark members transitioning from Premier to National Plus won't see any major changes for 2016; however, some smaller, independent pharmacies will no longer be in the network.

National Network

- The "Premier 2012" network will become the "National" network on Jan. 1, 2016.
- Like Premier 2012, the National network will be a broad network that includes most large chain pharmacies, along with many independent pharmacies.
- Some smaller, independent pharmacies will no longer be in the network.
- Pharmacies at Target stores will be part of the National network.*

Advantage Network

- On Jan. 1, 2016, the "Focused" network will become the "Advantage" network.
- Target and Rite-Aid pharmacies will be in the network.*
- CVS and The Medicine Shoppe will no longer be in the network.
- Some smaller, independent pharmacies will no longer be in the network.

What You Need to Know

As a result of the pharmacy network changes, your Highmark patients' preferred pharmacies on file may change as of Jan. 1, 2016. So, before transmitting an electronic prescription to a pharmacy, please ask the Highmark patient which pharmacy he/she wishes to use. Please confirm and/or update the preferred pharmacy information in the patient's records for future use and to avoid delays or disruption in his/her receipt of medications.

Please note, however, that for existing/current prescriptions that overlap from 2015 into 2016, members won’t need a new prescription if their pharmacy is no longer in the network next year. Members simply need to call or visit their new network pharmacy as of Jan. 1, 2016, and provide the pharmacist with their information to transfer the existing prescription from their old pharmacy.

Educating Our Members
Highmark is educating our members about the 2016 pharmacy network changes through information in benefit open enrollment booklets and on their member website. Additionally, a mailing will be sent to some members' homes in November.

*It was announced recently that CVS has acquired Target pharmacies. In the months ahead, Highmark will advise members regarding any change in Target's network pharmacy participation for 2016.