SPECIAL eBULLETIN

May 2016

SECOND QUARTER 2016 UPDATE

CHANGES TO THE HIGHMARK MEDICARE PART D DRUG FORMULARIES

The following is the Second Quarter 2016 update to the Highmark Medicare Part D Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the following changes reflect the decisions made in March 2016 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Highmark's Medicare Part D 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.

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the Pharmacy/Formulary Information link from the menu on the left.

HIGHMARK® West Virginia

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Important Drug Safety Updates

New Warnings for SGLT2 Inhibitors

On December 4, 2015, the FDA announced changes to the labels of sodium-glucose cotransporter-2 (SGLT2) inhibitors, including addition of warnings about the risks of too much acid in the blood and serious urinary tract infections. Both conditions can result in hospitalization. A review of the FDA Adverse Event Reporting System (FAERS) database from March 2013 to May 2015 identified 73 cases of ketoacidosis in patients with type 1 or type 2 diabetes treated with SGLT2 inhibitors and 19 cases of life-threatening blood infections (urosepsis) and kidney infections (pyelonephritis) that started as urinary tract infections from March 2013 to October 2014. The FDA added new Warnings and Precautions to the labels of all SGLT2 inhibitors to describe these two safety issues and to provide prescribing and monitoring recommendations. The FDA is also requiring manufacturers of SGLT2 inhibitors to conduct a required post marketing study. The FDA recommends that consumers stop taking SGLT2 Inhibitors and seek medical attention immediately if they have any symptoms of ketoacidosis. The FDA urges health care professionals and patients to report side effects involving SGLT2 inhibitors to the FDA MedWatch program.

Potential Baclofen Contamination

On December 09, 2015, the FDA issued a warning to drug compounders that certain lots of baclofen active pharmacy ingredient (API) manufactured by Taizhou Xinyou Pharmaceutical and Chemical Company may be at risk for contamination with particulates and should not be used to compound sterile injectable drugs. The affected API poses a safety risk for patients who receive injectable drug products compounded with the affected baclofen, especially when administered directly into the spinal column. There is also a potential risk that the baclofen API may be contaminated by endotoxin or microorganisms. The FDA is continuing investigation and recommended that no baclofen API from Taizhou be used to manufacture or compound any injectable drugs.

Children's Guaifenesin Grape Liquid and Guaifenesin DM Cherry Liquid Recall

On January 11, 2016, Perrigo announced a voluntary recall of its children's guaifenesin grape liquid (100mg/ 5mL) and its children's guaifenesin DM cherry liquid (100mg guaifenesin and 5mg dextromethorphan HBr/ 5mL) sold in 4 oz. bottles. The recall was initiated because some packages contained an oral dosing cup with incorrect dose markings. At the time of the recall there were no reports of adverse events as a result of the incorrect dosage markings. The FDA recommended that consumers contact their physician or health care provider if they have any questions, or if they or their children experience any problem that could possibly be related to this drug product. Health care professionals and patients are encouraged to report side effects involving these products to the FDA's MedWatch Program.

Unidentified Morphine in Licorice Coughing Liquid

On January 16, 2016, the FDA warned consumers not to use Licorice Coughing Liquid, a cough syrup product sold over-the-counter, because it contains unidentified morphine. The cough syrup's labeling contains information written in English and Chinese, but the product labeling does not identify the presence of morphine in English. Consumers who are hypersensitive to morphine could suffer severe allergic reactions if they take this product, and other effects of morphine can include, but are not limited to respiratory depression and death. The FDA recommends that consumers refrain from purchasing the cough syrup and anyone who has the product should not use it. Health care

professionals and patients are encouraged to report side effects involving this product to the FDA's MedWatch Program.

Loose Plastic Safety Seals for Eye Drops

On March 15, 2016, the FDA announced that it is investigating eye drop bottles that have loose plastic safety seals or tamper evident rings below the bottle cap that may fall onto the eye when the product is used. The FDA has received reports of six adverse events associated with loose safety seals on eye drop bottles. The FDA is in the process of identifying all relevant products and will require a change in the package design. The FDA recommends that consumers refrain from attempting to remove the ring or seal because there is potential to contaminate the tip of the dropper. Health care professionals and patients are encouraged to report side effects involving these products to the FDA's MedWatch Program.

Opioid Pain Medicines

On March 22, 2016, The FDA released a warning about several safety issues with the entire class of opioid pain medicines. The FDA reported that opioids can interact with antidepressant and migraine therapies, possibly causing a serious central nervous system reaction called serotonin syndrome. The FDA also reported that long-term use of opioids may be associated with decreased sex hormone levels, and taking opioids may lead to a rare, but serious condition in which the adrenal glands do not produce adequate amounts of the hormone cortisol. Label changes for all opioids are being mandated in order to warn about these risks. The FDA recommends that health professionals discontinue opioid treatment and use of other affected medications if serotonin syndrome is suspected; diagnostic testing should be performed if adrenal insufficiency is suspected. If diagnosed with adrenal insufficiency, providers are recommended to treat patients with corticosteroids and wean the patient off of the opioid if appropriate. For decreased sex hormone levels, health care professionals should conduct laboratory evaluation in patients presenting with such signs and symptoms.

Diabetes Medications Containing Saxagliptin and Alogliptin

On April 05, 2016, the FDA released a warning about type 2 diabetes medications containing saxagliptin and alogliptin. These agents may increase the risk of heart failure, particularly in patients who already have heart or kidney disease. The FDA recommends that health professionals consider discontinuing medications containing saxagliptin and alogliptin in patients who develop heart failure and monitor their diabetes control. Patients who are taking these medications are encouraged to contact their providers right away if they develop signs of heart failure such as unusual shortness of breath during daily activities, trouble breathing when lying down, fatigue, and weight gain with swelling in the ankles, feet, legs, or stomach. Health care professionals and patients are encouraged to report side effects involving these products to the FDA's MedWatch Program.

Metformin Labeling Revision

On April 08, 2016, the FDA released a notification about the required labeling change regarding the recommendations for metformin-containing medications in certain patients with reduced kidney function. The current labeling recommends against use of metformin in some patients whose kidneys do not work normally. After reviewing numerous medical studies regarding the safety of metformin in patients with mild to moderate impairment in kidney function, the FDA concluded that metformin can be used safely in some patients with mild to moderate kidney impairment. Other FDA recommendations include adapting the glomerular filtration rate (eGFR) as the measure for kidney function, because it offers a better estimate of renal function compared to reliance on blood creatinine

concentration, The FDA recommends that health care professionals follow the latest recommendations when prescribing metformin-containing medicines to patients with impaired kidney function.

Highmark Formulary Update – May 2016

A. Changes to the Highmark Medicare Part D 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: https://client.formularynavigator.com/Search.aspx?siteCode=3592395926.

Table 1: Non-Preferred Products
(Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation)

Brand Name	Generic Name	Alternatives/Comments
Emend®	aprepitant	ondansetron
Zurampic®	lenisurad	allopurinol, probenecid
Quillichew ER®	methylphenidate ER	methylphenidate ER, dexmethylphenidate ER
Emverm™	mebendazole	Provider discretion
Onzetra Xsail™	sumatriptan nasal powder	sumatriptan tablet, rizatriptan tablets
Zembrace™	sumatriptan succinate injection	sumatriptan tablet, rizatriptan tablets
Dexilant SoluTab™	dexlansoprazole	omeprazole, pantoprazole, rabeprazole
Adzenys XR-ODT™	amphetamine extended-release orally disintegrating tablet)	amphetamine-dextroamphetamine, methylphenidate
Sernivo™ Spray	betamethasone dipropionate	betamethasone dipropionate, betamethasone valerate
Briviact®	brivaracetam	levetiracetam, carbamazepine, lamotrigine
Cetylev™	acetylcysteine	Provider discretion

B. Changes to the Highmark Medicare Part D 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 Part D Formularies online at: https://client.formularynavigator.com/Search.aspx?siteCode=3589973640

Table 1: Non-Preferred Products
(Effective immediately pending CMS approval and upon completion of internal review and implementation)

Brand Name	Generic Name	Preferred Alternatives/Comments
Emend®	aprepitant	ondansetron
Emverm™	mebendazole	Provider discretion
Onzetra Xsail™	sumatriptan nasal powder	sumatriptan tablet, rizatriptan tablets
Zembrace™	sumatriptan succinate injection	sumatriptan tablet, rizatriptan tablets
Briviact®	brivaracetam	levetiracetam, carbamazepine, lamotrigine

Table 2: Products Not Added*

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

Brand Name	Generic Name	Preferred Alternatives/Comments
Zurampic®	lenisurad	allopurinol, probenecid
Quillichew ER®	methylphenidate ER	methylphenidate ER, dexmethylphenidate ER
Dexilant SoluTab™	dexlansoprazole	omeprazole, pantoprazole, rabeprazole
Adzenys XR-ODT™	amphetamine extended-release orally disintegrating tablet	amphetamine-dextroamphetamine, methylphenidate
Sernivo™ Spray	betamethasone dipropionate	betamethasone dipropionate, betamethasone valerate
Cetylev™	acetylcysteine	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 implementation)

Brand Name	Generic Name
Portrazza™	necitumumab
Alecensa®	alectinib
Empliciti ™	elotuzumab
Kanuma™	sebelipase alfa
Bendeka™	bendamustine hydrochloride
Uptravi®	selexipag
Zepatier™	elbasvir and grazoprevir

D. Updates to the Pharmacy Utilization Management Programs

1. Updates to the Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and Approval Criteria
Eosinophilic Severe Asthma — Medicare	TBD	New policy was created to ensure appropriate use of Nucala (mepolizumab) indicated for the treatment of severe eosinophilic asthma.
Kanuma (sebelipase alfa) — Medicare	TBD	New policy was created to ensure appropriate use of Kanuma (sebelipase alfa) indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.
Miscellaneous Immunomodulators — Commercial and Medicare	03/03/2016	Policy revised to include Ninlaro (ixazomib) as a proteasome inhibitor, which is indicated for treatment of multiple myeloma in patients who have received at least one prior therapy.

Policy Name	Policy Effective Date*	Updates and Approval Criteria
C1 Esterase Inhibitors — Medicare	03/03/2016	Policy revised to combine previously separate policies, to include all C1 Esterase Inhibitors Ruconest, Berinert, and Cinryze in for the treatment of Hereditary Angioedema (HAE) in one policy. Policy revised to include the medically accepted indication of Acute ST segment elevation myocardial infarction
Cosentyx (secukinumab) — Medicare	04/01/2016	Policy revised to include two new expanded indications for treatment of adults with active psoriatic arthritis and active ankylosing spondylitis. For both indications, documentation should be provided that demonstrates treatment with both preferred biologic products Enbrel and Humira were ineffective or not tolerated, or both products are contraindicated. The policy also highlights quantity limits for induction and maintenance therapy to ensure appropriate utilization based on product-labeling recommendations.
Gilenya — Medicare	03/03/2016	Policy revised to include the medically accepted indication of autoimmune neuropathy, which is an approvable indication.
Alpha 1-Proteinase Inhibitors — Medicare	03/03/2016	Policy revised to clarify Medicare Part B versus Medicare Part D coverage rules: drug will be covered under part B when furnished incident to a physician service and not self-administered.
Acthar HP — Medicare	03/03/2016	Policy revised to clarify step therapy of two first line gout therapies and removal of step therapy for the diagnosis of acquired epileptic aphasia.
ALK Inhibitors for NSCLC — Commercial and Medicare [formerly: Zykadia (ceritinib)]	TBD	Policy revised to include the newly approved ALK-inhibitor Alecensa (alectinib) for treatment of ALK-positive metastatic non-small cell lung cancer (NSCLC) in patients whose disease has worsened after, or who could not tolerate treatment with Xalkori (crizotinib).
Gleevec (imatinib) — Commercial and Medicare	03/03/2016	Policy revised to remove step therapy with at least one therapeutic regimen (i.e. hydroxyurea, anagrelide, etc.) for myeloproliferative diseases (MPD).
Remicade — Medicare	03/03/2016	Policy revised to include the medically accepted indications for Remicade (infliximab). Remicade (infliximab) may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).
Human Growth Hormone — Medicare	03/03/2016	Policy revised to include updated criteria that aligns with current guidelines for treatment of Growth Hormone Deficiency (GHD) in children, transition patients, and adults.
Ibrance (palbociclib) — Commercial and Medicare	TBD	Policy revised to include approval criteria for concomitant use with Faslodex (fulvestrant) in women with a diagnosis of HR positive, HER2 negative advanced or metastatic breast cancer with disease progression following endocrine therapy such as Aromasin

Policy Name	Policy Effective Date*	Updates and Approval Criteria
		(exemestane), Femara (letrozole), Arimidex (anastrozole), etc.
Programmed Death Receptor Therapies — Medicare	03/03/2016	Policy revised to include approval criteria for Opdivo (nivolumab) as a single agent in patients with BRAF V600 wild type or mutation-positive metastatic melanoma.
Administrative Prior Auth for Medicare Part D Plans — Medicare	TBD	Policy revised to include approval criteria for interferon alpha products, addition of injectable methotrexate, and removal of DermaPak as it is no longer eligible for coverage under Part D. The policy criteria for coverage of antitussive medications was also updated based on CMS guidance.
Hepatitis C Oral Agents — Medicare	TBD	Policy revised with addition of indications for new FDA-approved product Zepatier (elbasvir/grazoprevir), consistent with labeling and AASLD guidelines.
Pulmonary Hypertension — Medicare	04/01/2016	Policy revised with the addition of Uptravi (selexipag) for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and reduce the risk of hospitalization for PAH.
Procysbi (cysteamine bitartrate) — Commercial and Medicare	03/03/2016	Policy revised to better align with FDA-approved labeling, allowing coverage for management of nephrotic cystinosis in adults and children ages 2 years and older, as opposed to the previous criteria which were restricted to children at least 6 years of age and older.

*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*
Gout Therapies — Medicare	TBD	New policy created specifically for Medicare, mirroring commercial requirements for chronic management of hyperuricemia in patients with gout. The policy includes newly FDA-approved product, Zurampic (lesinurad).
Atypical Antipsychotics — Medicare	03/03/2016	Policy revised with removal of Seroquel XR (quetiapine fumarate extended-release) and Symbyax (olanzapine/fluoxetine) from Prior Authorization (PA) review criteria, as they are not subject to PA criteria for Medicare members.
Opioid Dependence Therapy — Medicare	TBD	Policy revised with addition of quantity level limits for new strengths of Zubsolv (buprenorphine and naloxone sublingual tablets), 11.4-2.9mg (62 units per retail fill) & 2.9-0.71 mg (93 units per retail fill).
Migraine Therapies	TBD	Policy revised with addition of a quantity level limit for

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
— Medicare		Migranal 0.5mg/spray, generic Axert (almotriptan) and new migraine therapies, Zembrace SymTouch (sumatriptan succinate subcutaneous injection) and Onzetra Xsail (sumatriptan nasal powder).
Extended Release Opioid Management — Medicare	TBD	Policy revised with a quantity limit increase of Duragesic (fentanyl) 100mcg patch from 9 units per fill to 10 units per fill and the addition of a quantity limit for Avinza.
High Risk Meds — Medicare	04/01/2016	Policy revised to include Surmontil (trimipramine), Lanoxin (digoxin) 250mg, and nitrofurantoin 25mg capsules as high-risk medications in the elderly with corresponding approval criteria. The purpose of this policy is to ensure safe and appropriate utilization of medications considered high-risk in the elderly population, as outlined in the Beers criteria by the American Geriatric Society.
Immediate Release Opioid Management — Medicare	04/01/2016	Policy revised to increase the quantity limit of hydrocodone-ibuprofen from 50 units to 150 units per month.

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

3. Updates to the Quantity Level Limit (QLL) Program*

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Added		
Zubsolv® 2.9-0.71 mg	93 tablets	279 tablets
Zubsolv® 11.4-2.9mg	62 tablets	186 tablets
Migranal®	8mL	24mL
almotriptan 6.25mg	16 tablets	48 tablets
almotriptan 12.5mg	8 tablets	24 tablets
Zembrace SymTouch™	8mL	24mL
Onzetra Xsail™	176 mg (16 nosepieces)	528 mg (48 nosepieces)
Actemra® solution 20mg/ml	40mL	120mL
Alecensa®	248 capsules	744 capsules
Lamisil® 250mg	90 tablets	90 tablets
Lamisil® 125mg	180 packets	180 packets
Lamisil® 187.5mg	120 packets	120 packets
Zepatier™	28 tablets	84 tablets
Zurampic®	31 tablets	93 tablets
Veltassa®	30 packets	90 packets
nitrofurantoin macrocrystal 25mg	360 capsules	360 capsules
terbinafine 250mg	90 tablets	90 tablets
Removed		
Pradaxa®	62 capsules	93 capsules

Xarelto® 10mg, 20mg	31 tablets	93 tablets
Xarelto® 15mg	52 tablets	156 tablets
Xarelto® dose pack	51 tablets	153 tablets
Eliquis®	62 tablets	186 tablets

Requests for coverage exceeding the defined quantity level limits can be submitted for clinical review.

All effective dates are tentative and subject to delay, pending, CMS approval, internal review, and implementation.