SPECIAL eBULLETIN

November 2015

FOURTH QUARTER 2015 UPDATE

CHANGES TO THE HIGHMARK MEDICARE-APPROVED DRUG FORMULARIES

The following is the Fourth 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 September 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

Brintellix® (vortioxetine) and Brilinta® (ticagrelor) Brand Name Confusion Resulting in Prescribing and Dispensing Errors

On July 30, 2015, the FDA released a Drug Safety Communication warning of the wrong medication being prescribed or dispensed due to the similarity of the brand names for two different medications: the antidepressant Brintellix and the anti-blood clotting medication Brilinta. There have been reports of prescribing and dispensing errors, but no reports of patients ingesting the wrong medication. Suggestions for reducing the risk of confusion include adding the generic name and indication in addition to the brand name when prescribing the medication. Health care professionals and patients are encouraged to report name confusion and medication errors involving these two medications to the FDA's MedWatch Program.

Cases of Rare Brain Infection with MS drug Gilenya® (fingolimod)

On Aug. 4, 2015, the FDA released a Drug Safety Communication warning of a case of definite progressive multifocal leukoencephalopathy (PML) and a case of probable PML in patients taking Gilenya (fingolimod) for multiple sclerosis (MS) without prior or concurrent exposure to other immunosuppressant drugs. The drug label was revised to include this warning. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, leading to death or severe disability. Typical symptoms associated with PML can progress over days to weeks, are diverse, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory and orientation leading to confusion and personality changes. Health care professionals and patients are encouraged to report side effects involving Gilenya to the FDA's MedWatch Program.

Severe Adverse Events with Application of Picato® (ingenol mebutate) Gel for Skin Condition

On Aug. 21, 2015, the FDA released a Drug Safety Communication warning of severe allergic reactions and herpes zoster (shingles) associated with the use of Picato gel (ingenol mebutate), used to treat actinic keratosis. Label changes were warranted to also capture reports of cases involving severe eye injuries and skin reactions associated with the application of Picato gel. Patients should be advised to use Picato gel as prescribed, and not to use on an area of skin larger or for a longer period than instructed on the drug label. Health care professionals and patients are encouraged to report side effects or medication errors involving Picato gel to the FDA's MedWatch Program.

DPP-4 Inhibitors for Type 2 Diabetes May Cause Severe Joint Pain

On Aug. 28, 2015, the FDA released a Drug Safety Communication warning of severe and disabling joint pain associated with the class of type 2 diabetes medicines, dipeptidyl peptidase-4 (DPP-4) inhibitors, which include sitagliptin, saxagliptin, linagliptin and alogliptin. These medicines are available as single agents and in combination with other diabetes medications such as metformin. Patients should contact their health care professionals prior to stopping their DPP-4 inhibitor medicine if they experience severe and persistent joint pain. Health care professionals and patients are encouraged to report side effects related to the use of these products to the FDA's MedWatch Program.

Epocrates® Access to Highmark Formulary Soon to End

Highmark's prescription drug formulary will soon no longer be available through Epocrates®. Providers who use a personal digital assistant (PDA) or handheld device can access up-to-date formulary information from the **Provider Resource Center** and then **Pharmacy/Formulary Information** using the navigation bar. The **Pharmacy/Formulary** link allows providers to access information about pharmacy and formulary policies, benefits and more.

The Epocrates® link will be removed from the **Pharmacy/Formulary Information** page. With the evolution of mobile device technology and availability of web-based formulary resources, there are additional applications, such as Medscape or Fingertip Formulary®, to access Highmark's formularies while in the office, the exam room and beyond.

Highmark Medicare-approved Formulary Update, September 2015

A. Changes to the Highmark Medicare-approved Five-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: 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
Epiduo® Forte	Epiduo Forte	adapalene gel, clindamycin gel
Viberzi™	eluxadoline	dicyclomine
Albenza®	albendazole	Provider discretion
Spritam®	levetiracetam	levetiracetam, carbamazepine
Entresto™	sacubitril/valsartan	lisinopril, quinapril, candesartan, valsartan
Envarsus XR	tacrolimus	cyclosporine, Astagraf XL®, Sandimmune®, Cellcept®
Finacea®	azelaic acid 15% foam	metronidazole 0.75% cream, gel, lotion

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

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

Brand Name	Generic Name	Preferred Alternatives/Comments
Albenza®	albendazole	Provider discretion
Spritam®	levetiracetam	levetiracetam, carbamazepine
Envarsus® XR	tacrolimus	cyclosporine, Astagraf XL, Sandimmune, Cellcept

Table 2: Products Not Added*
(Effective immediately pending CMS approval and upon completion of internal review and operationalization)

Brand Name	Generic Name	Preferred Alternatives/Comments
Epiduo® Forte	Epiduo Forte	adapalene gel, clindamycin gel
Viberzi™	eluxadoline	dicyclomine
Entresto™	sacubitril/valsartan	lisinopril, quinapril, candesartan, valsartan
Finacea®	azelaic acid 15% foam	metronidazole 0.75% cream, gel, lotion; Finacea 15% gel

*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
Odomzo®	sonidegib
Praluent®	alirocumab
Repatha™	evolocumab
Technivie™	ombitasvir/paritaprevir/ritonavir
Daklinza™	daclatasvir
Rexulti®	brexpiprazole
Promacta®	eltrombopag powder for oral suspension
Iressa®	gefitinib
Orkambi™	lumacaftor/ivacaftor
Keveyis™ **	dichlorphenamide

** Addition to Specialty Tier pending CMS approval (RxCUI)

D. Updates to the Pharmacy Utilization Management Programs

1. Updates to the Prior Authorization Program

Policy Name	Policy Effective Date	Updates and Approval Criteria
Entyvio (vedolizumab) — Medicare Only	TBD	New Medicare policy created for ulcerative colitis and Crohn's disease. Approval Criteria requires trial and failure of one preferred subcutaneous TNF-blocker biologic agent Humira or Remicade.
Cerdelga (eliglustat) — Medicare Only	TBD	New Medicare policy created due to more restrictive changes made to the old combined commercial and Medicare policy J-406. Policy includes approval criteria to be in line with FDA-approved indication and dosing for eliglustat. Policy criteria include use in adults with type I Gaucher disease with the CYP2D6 metabolizer status identified via an FDA-cleared test. Policy also includes appropriate quantity limits based on type of metabolizer (once-daily vs. twice-daily dosing of eliglustat for extensive compared to poor metabolizers, respectively).
Entresto (sacubitril/valsartan) — Commercial and Medicare	TBD	New policy created to ensure appropriate use of sacubitril/valsartan (Entresto), indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (HF) (NYHA Class II-IV) and reduced ejection fraction, with the following approval criteria: • Chronic heart failure (NYHA Class II-IV) ***AND*** • Systolic dysfunction [left ventricular ejection fraction (LVEF) ≤ 40%] ***AND*** • Concomitant beta-blocker use, unless contraindicated or not tolerated ***AND*** • No concomitant use of ACE inhibitors or another ARB.
Orkambi (lumacaftor/ivacaftor) — Commercial and Medicare	TBD	New policy created to ensure appropriate use of lumacaftor/ivacaftor (Orkambi), indicated for the treatment of cystic fibrosis in patients 12 years and older who are homozygous for the F508del mutation in the CFTR gene, with an initial authorization duration of 6 months, with

Policy Name	Policy Effective Date	Updates and Approval Criteria
		reauthorization criteria showing minimal change in FEV_1 over baseline FEV_1.
Odomzo (sonidegib) — Commercial and Medicare	TBD	New policy created to ensure appropriate use of sonidegib (Odomzo), indicated for the treatment of adult patients with locally advanced basal cell carcinoma (IaBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.
Viberzi (eluxadoline) — Commercial and Medicare	TBD	New policy created to ensure appropriate use of eluxadoline (Viberzi), indicated for treatment of adults with irritable bowel syndrome with diarrhea (IBS-D), with the following documented criteria: • No alcohol abuse, marijuana or illicit drug use in the past 6 months • Member does not have severe (Child-Pugh C) hepatic impairment
Keveyis (dichlorphenamide) — Commercial and Medicare	TBD	New policy created to ensure appropriate use of dichlorphenamide (Keveyis) to be in line with the FDA-approved indication of primary hyperkalemic or hypokalemic periodic paralysis and related variants in adult patients.
Addyi (filbanserin) — Commercial and Medicare	TBD	New policy created to ensure appropriate use in adults for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), with the following criteria: • The member has a diagnosis of HSDD and is premenopausal ***AND*** • The provider has confirmed that HSDD is unrelated to a co-existing medical or psychiatric condition, substance abuse or relationship issue ***AND*** • The member has experienced a failure of behavioral therapy for HSDD, if a covered benefit ***AND*** • The provider has indicated that the member does not have a history or current issue with alcohol or substance abuse and that the member will abstain from alcohol while on therapy.
Zydelig (idelalisib) — Commercial and Medicare	09/03/2015	Policy was revised to be in line with FDA-approved labeling that member should be at least 18 years of age for use of idelalisib (Zydelig). Idelalisib is indicated for: • Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities • Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies • Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
New to Market Drug Policy — Commercial and Medicare	TBD	Policy was clarified that for Med-D, approval under this policy is pending CMS RxCUI Submission.

Policy Name	Policy Effective Date	Updates and Approval Criteria
Kalydeco (ivafactor) — Commercial and Medicare	09/03/2015	Policy was updated to reflect the expanded indication for patients 2 years of age and older with cystic fibrosis (CF) who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, as confirmed by an FDA-accepted CF mutation test: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R.
EGFR Tyrosine Kinase Inhibitors — Commercial and Medicare	TBD	Policy was updated with added criteria for Iressa (gefitinib), indicated as first-line treatment for patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
Hetlioz (tasmelton) — Commercial and Medicare	09/03/2015	Policy was updated with approval duration of 6 months for commercial members, with renewal of authorization required after 6 months with clinical information that the medication is effective with minimal side effects.
Testosterone (Androgens) — Medicare Only	TBD	Policy was revised to include recently approved testosterone kit (Testone CIK), and to clarify that lab levels are not required for members with double orchiectomy.
Thrombopoesis Stimulating Agents — Commercial and Medicare	TBD	Policy was revised with additional indication for eltrombopag (Promacta) use in pediatric patients aged 1 year and older, for treatment of idiopathic thrombocytopenia purpura and inclusion of the newly approved oral suspension formulation.
Hepatitis C — Medicare Only	09/03/2015	Policy was revised with added criteria for Technivie, a new hepatitis C medication, indicated in combination with ribavirin for the treatment of chronic hepatitis C genotype 4 infection without cirrhosis. In addition, coverage criteria were added for Harvoni plus ribavirin for genotype 3.
PCSK9 Inhibitors — Medicare Only	09/03/2015	Policy criteria were updated based on FDA-approved indications for Praluent and Repatha as follows: • Alirocumab (Praluent) is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C). • Evolocumab (Repatha) is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with homozygous familial hypercholesterolemia, heterozygous familial hypercholesterolemia or clinical ASCVD who require additional lowering of LDL-C.
Homozygous Familial Hypercholesterolemia — Commercial and Medicare	09/03/2015	Policy criteria were updated to require step therapy through evolocumab (Repatha) prior to use of lomitapide (Juxtapid®) or mipomersen (Kynamro®).

Terminated Policies		
Movantik (naloxegol) — Commercial and Medicare	naloxegol (Movantik) — Commercial and Medicare	Policy will be removed, as utilization review reflects appropriate prescribing and use of naloxegol (Movantik), with low risk of abuse potential and off-label use, given the specific FDA-approved indication for use of opioid-induced constipation (OIC) in adult patients with chronic non-cancer related pain.

*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*
Atypical Antipsychotics —Commercial and Medicare	TBD	Policy was revised with the addition of brexipiprazole (Rexulti), based on FDA-approved and medically accepted indications, for the treatment of schizophrenia and as adjunctive treatment of major depressive disorder (MDD).
Egrifta (tesamorelin) — Commercial and Medicare	09/03/2015	Policy was revised with a change in authorization duration of approvals from a lifetime authorization to 12 months.

*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	Limit per 31-Days Supply (retail)	Limit per 93-Days Supply (retail or mail)
Daklinza™	34 tablets	90 tablets
Entresto™ 24mg/26mg, 49mg/51mg, 97mg/103mg	62 tablets	186 tablets
Iressa®	34 tablets	90 tablets
Keveyis™	124 tablets	372 tablets
Orkambi™	124 tablets	372 tablets
Praluent® 75mg/mL, 150mg/mL	2 pens/syringes	6 pens/syringes
Repatha™ [1] 140mg/mL	2 syringes/auto-injectors	6 syringes/auto-injectors
Rexulti®	31 tablets	93 tablets
Technivie™	68 tablets	180 tablets
Viberzi™	62 tablets	186 tablets
Xenical®	93 capsules	279 capsules

[1] Requests exceeding the defined quantity level limits may be clinically appropriate in certain situations.

**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, operationalization, or CMS approval.