SPECIAL eBULLETIN

November 2015

CHANGES TO THE HIGHMARK DRUG FORMULARIES

FOURTH QUARTER UPDATE

The Fourth Quarter 2015 update to our Drug Formularies and pharmaceutical management procedures is attached to this Special Bulletin. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the attached changes reflect the decisions made in September 2015 by the Highmark Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout the document.

Please reference the guide below to navigate this communication:

Highmark Comprehensive and Progressive Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Health Care Reform Formulary
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    3. Updates to the Quantity Level Limit (QLL) Program

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

If you have any questions regarding this pharmacy communication or the formularies, please contact your Highmark Blue Cross Blue Shield Delaware Provider Relations Representative.

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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) 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®, that can be used to access Highmark's formularies while in the office, the exam room and beyond.

Highmark Formulary Update — September 2015

SECTION I. Highmark Comprehensive and Progressive Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Health Care Reform Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Comprehensive Closed/Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Closed/Incentive Formulary are automatically added to the Open Formulary. These updates are effective as of the dates noted throughout this document. For your convenience, you can search the Highmark Comprehensive Formulary or the Highmark Comprehensive Health Care Reform Formulary online at **http://highmark.formularies.com**. Note: You must click the hyperlink for the Highmark Comprehensive Health Care Reform formulary.

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes to promote adherence to maintenance products and improve the overall health of our members.

Table 1: Products Added (All products added to the formulary effective immediately unless otherwise noted)

Brand Name	Generic Name	Comments
Farxiga®	dapagliflozin	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. *Effective Date: 10/01/2015*
Xigduo™ XR	dapagliflozin/metformin HCl extended release	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. *Effective Date: 10/01/2015*
Movantik™	naloxegol	Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. *Effective Date: 10/01/2015*
Promacta®	eltrombopag powder for oral suspension	Indicated for the treatment of thrombocytopenia in adults and pediatric patients 1 year and older with chronic immune idiopathic thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. *Effective Date: 10/15/2015*
Stiolto™ Respimat®	tiotropium bromide/olodaterol oral inhalation spray	Indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). *Effective Date: 11/01/2015*

Table 2: Products Not Added*

Brand Name	Generic Name	Preferred Alternatives
Epiduo® Forte	adapalene/benzoyl peroxide	adapalene gel, clindamycin gel
Odomzo®	sonidegib	Provider discretion
Addyi™	filbanserin	Provider discretion
Praluent®	alirocumab	atorvastatin, Crestor®
Repatha™	evolocumab	atorvastatin, Crestor
Viberzi™	eluxadoline	dicyclomine
Technivie™	ombitasvir/paritaprevir/ritonavir	Provider discretion
Daklinza™	daclatasvir	Provider discretion
Albenza®	albendazole	Provider discretion
Keveyis™	dichlorphenamide	Provider discretion
Spritam®	levetiracetam	levetiracetam, carbamazepine
codeine phosphate/chlorpheniramine maleate extended release	codeine phosphate/chlorpheniramine maleate extended release	Cheratussin Ac, codeine-guaifenesin syrup, benzonatate
Rexulti®	brexpiprazole	risperidone, quetiapine
Iressa®	gefitinib	Provider discretion
Entresto™	sacubitril/valsartan	lisinopril, quinapril, valsartan
Envarsus® XR	tacrolimus	azathioprine, cyclosporine, tacrolimus, mycophenolate
Orkambi™	lumacaftor/ivacaftor	Provider discretion
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**.

Table 3: Products To Be Removed — Effective Jan. 1, 2015

Product Name	Generic Name	Preferred Alternatives
All Commercial Comprehensive Products		
Actonel®	risedronate	risedronate, alendronate
Acular® LS	ketorolac tromethamine	ketorolac eye drops, diclofenac eye drops
Aggrenox®	aspirin/extended-release dipyridamole	aspirin/dipyridamole capsules, dipyridamole tablet
Analpram-HC®	hydrocortisone/pramoxine	hydrocortisone-pramioxine rectal cream, Proctosol HC rectal cream
Antabuse®	disulfiram	disulfiram tablet, acamprosate tablet
Aricept®	donepezil	donepezil HCl tablet, rivastigmine capsule
Aricept® ODT	donepezil	donepezil HCl tablet, rivastigmine capsule
Atelvia®	risedronate sodium delayed-release	risedronate tablet, alendronate tablet
Avodart®	dutasteride	finasteride tablet, tamsulosin capsule

Betapace AF®	sotalol HCl	sotalol tablet, amiodarone tablet
Canasa®	mesalamine	mesalamine enema, hydrocortisone rectal suppository
Catapres-TTS®	clonidine	clonidine patch, clonidine HCl tablet
Delatestryl®	testosterone enanthate	testosterone enanthate injection, testosterone cypionate injection
Depo®-Testosterone	testosterone cypionate	testosterone cypionate injection, testosterone enanthate injection
Finacea®	azelaic acid	metronidazole gel, adapalene topical gel
Fioricet®	butalbital/acetaminophen/caffeine	butalbital-acetaminophen-caffeine capsules and tablets
Imdur® ER	isosorbide mononitrate	isosorbide mononitrate ER tablet, isosorbide dinitrate ER tablet
Imitrex® vial	sumatriptan succinate	sumatriptan solution for injection, rizatriptan
Iopidine®	apraclonidine	apraclonidine eye drops, brimonidine eye drops
Isochron™	isosorbide dinitrate, ISDN	isosorbide dinitrate ER tablet
Mepron® suspension	atovaquone	atovaquone oral suspension, sulfamethoxazole-trimethoprim oral suspension
Methergine®	methylergonovine maleate	methylergonovine tablet
Miacalcin®	calcitonin-salmon	calcitonin nasal spray
Namenda®	memantine	memantine tablet, donepezil HCl tablet
Nexium® oral capsules	esomeprazole	pantoprazole tablet, omeprazole capsule
Prevpac®	lansoprazole/amoxicillin/clarithromycin	lansoprazole, amoxicillin, clarithromycin
Rosula®	sodium sulfacetamide/sulfur	sulfacetamide sodium-sulfur topical cleanser, Cerisa topical cleanser
Rythmol®	propafenone	propafenone tablet, flecainide tablet
Suprax® oral suspension	cefixime	cefixime oral suspension, cefdinir oral suspension
Targretin®	bexarotene	bexarotene capsule, methotrexate tablet
Vfend®	voriconazole	voriconazole tablets
Vospire ER®	albuterol sulfate ER	albuterol sulfate ER tablet, metaproterenol tablet
Zyvox®	linezolid	linezolid tablets
Commercial Comprehensive Incentive Products		
Fuzeon®	enfuvirtide	Provider discretion
Commercial Comprehensive Closed Products		
venlafaxine ER tablets	venlafaxine HCl ER	venlafaxine ER capsules, duloxetine
All Commercial Comprehensive — HCR Products		
Accolate®	zafirlukast	montelukast sodium
Aldactazide®	spironolactone/hydrocholorothiazide	spironolactone/hydrochlorothiazide tablets
Avandamet®	rosiglitazone maleate/metformin HCl	pioglitazone-metformin tablet

Avandaryl®	rosiglitazone maleate/glimepiride	pioglitazone/glimepiride
Avandia®	rosiglitazone maleate	pioglitazone HCl tablet
Dibenzyline®	phenoxybenzamine	propranolol
Elixophyllin®	theophylline	theophylline ER tablets
Glyset®	miglitol	acarbose tablets
PrandiMet®	metformin/repaglinide	repaglinide tablets, metformin tablets
Surmontil®	trimipramine	desipramine tablets, imipramine HCl tablets

B. Updates to the Pharmacy Utilization Management Programs

1. Updates to the Prior Authorization Program

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
Entresto (sacubitril/valsartan) — Commercial and Medicare	10/15/2015	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	10/15/2015	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 reauthorization criteria showing minimal change in FEV_1 over baseline FEV_1.
Odomzo (sonidegib) — Commercial and Medicare	10/15/2015	New policy created to ensure appropriate use of sonidegib (Odomzo), indicated for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.
Viberzi (eluxadoline) — Commercial and Medicare	10/15/2015	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	10/15/2015	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.

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
Addyi (filbanserin) — Commercial and Medicare	10/15/2015	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.
Cerdelga (eliglustat) — Commercial Only	09/03/2015	Policy was revised to be in line with the FDA-approved indication and dosing for eliglustat (Cerdelga). Approval criteria were added to include CYP2D6 metabolizer status (extensive, intermediate or fast metabolizer) based on an FDA-cleared test. Policy was updated to include appropriate quantity limits based on type of metabolizer (once-daily versus twice-daily dosing of eliglustat for extensive compared to poor metabolizers, respectively).
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.
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	10/15/2015	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.
Pulmonary Arterial Hypertension— Commercial Only	TBD	Policy was revised to include step therapy criteria for trial and failure of sidenafil 20mg prior to Revatio® and Adcirca® use for new start members.
Humira (adalimumab) — Commercial Only	09/03/2015	Policy quantity limitations criteria were revised to include added approval criteria of weekly dosing for rheumatoid arthritis (RA)

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
		patients not receiving methotrexate.
Fertility— Commercial Only	09/03/2015	Policy was revised to remove language that male partners must be fertile and potent for certain fertility products indicated for the treatment of ovulatory failure in infertile women under the age of 35, unable to conceive after 12 months of regular unprotected intercourse (or 6 months for women over 35 years of age).
Fertility— Commercial Only ASO Groups	09/03/2015	Policy was updated to mirror policy for fully insured business, which will be utilized for all ASO groups.
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) — Commercial Only	10/15/2015	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.
Thrombopoiesis Stimulating Agents— Commercial and Medicare	10/15/2015	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— Commercial 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— Commercial 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	10/15/2015	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.

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

Policy Name	Policy Effective Date**	Updates and Automatic Approval Criteria*
Vimovo (Naproxen/esomeprazole) — Commercial Only	12/01/2015	New policy was created to promote the use of generic alternatives.
Duexis (Ibuprofen/famotidine) — Commercial Only	12/01/2015	New policy was created to promote the use of generic alternatives.
Cyclobenzaprine (Amrix, Fexmid) — Commercial Only	12/01/2015	New policy was created to promote the use of generic alternatives.
Rayos (Prednisone) — Commercial Only	12/01/2015	New policy was created to promote the use of generic alternatives.
Brand Metformin— Commercial Only	12/01/2015	New policy was created to promote the use of generic alternatives.
Atypical Antipsychotics — Commercial and Medicare	10/15/2015	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. Tesamorelin (Egrifta) is indicated for reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

*Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.
** The Commercial Health Care Reform Policy Effective Date for Vimovo, Duexis, Amrix, Fexmid and Rayos will be 01/01/2016.

3. Updates to the Quantity Level Limit (QLL) Program
(Effective immediately upon completion of internal review and operationalization, unless otherwise noted)*

Drug Name	Up to 34-Day Supply Limit (retail)	35- to 90-Day Supply Limit (retail or mail)
Adipx-P®	34 capsules/tablets	90 capsules/tablets
benzphetamine	102 tablets	270 tablets
Bontril® PDM	204 tablets	540 tablets
Daklinza™ [1] 30mg, 60mg	34 tablets	90 tablets
diethylpropion	102 tablets	270 tablets
diethylpropion ER	34 tablets	90 tablets
Egrifta®	60 vials	180 vials
Entresto™ 24mg/26mg, 49mg/51mg, 97mg/103mg	60 tablets	180 tablets
Iressa®	34 tablets	90 tablets
Keveyis™	136 tablets	360 tablets
Orkambi™	112 tablets	336 tablets
Praluent® 75mg/mL, 150mg/mL	2 pens/syringes	6 pens/syringes
Qsymia®	68 capsules	180 capsules
Repatha™ [1] 140mg/mL	2 syringes/auto-injectors	6 syringes/auto-injectors
Rexulti®	34 tablets	90 tablets
Ritalin® LA 60mg	34 capsules	90 capsules

Saxenda®	5 pens	15 pens
Suprenza™	34 disintegrating tablets	90 disintegrating tablets
Technivie™	68 tablets	180 tablets
Viberzi™	68 tablets	180 tablets
Xenical®	102 capsules	270 capsules

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

Maximum day's supply on certain medications may vary depending on member benefit design.

[1]Coverage for requests exceeding the defined quantity level limits can be submitted for clinical review. Examples of clinically appropriate reason: change in insulin dosing, change in medications, illness causing less stable blood glucose levels, pediatric patients testing in multiply locations and females with uncontrolled DM during pregnancy.