SPECIAL eBULLETIN

AUGUST 2016

THIRD QUARTER 2016 UPDATE

CHANGES TO THE HIGHMARK MEDICARE PART D DRUG FORMULARIES

The following is the Third 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 June 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

Fluconazole (Diflucan) — FDA Evaluating Study Examining Use of Oral Fluconazole (Diflucan) in Pregnancy
On 04/26/2016 the FDA communicated a safety concern of possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections, based on a Danish study. Caution is advised when prescribing fluconazole in pregnancy, until a review by the FDA is complete and more is understood about this study and other available data. It should be noted that the Centers for Disease Control and Prevention guidelines recommend using only topical antifungal products to treat pregnant women with vulvovaginal yeast infections, including for longer periods than usual if these infections persist or recur. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Brintellix (vortioxetine) — Brand Name Change to Trintellix, to Avoid Confusion With Antiplatelet Drug Brilinta (ticagrelor)
On 05/02/2016 the FDA communicated the approval of a brand name change for the antidepressant Brintellic (vortioxetine to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinner Brillinta (ticagrelor). Trintellix is now available on the market, starting June 2016. This change was due to continued reports of name confusion between the two medications, which are used for very different purposes. Health care professionals are advised to take caution when prescribing these medications and include the generic name of the medication they are ordering, in addition to the brand name. Trintellix tablets will look the same as the Brintellix tablets. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Aripiprazole (Abilify, Abilify Maintena, Aristada) — FDA Warns About New Impulse-Control Problems On 05/03/2016 the FDA issued a warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada and generics). Though rare, these urges may result in harm to the patient and others if not recognized. Health care professionals are advised to inform their patients of this risk and closely monitor for new or worsening symptoms. Dose modification may be warranted for some patients. Abrupt discontinuation is not recommended without direct supervision under a health care professional. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Olanzapine — FDA Warns About Rare but Serious Skin Reactions
On 05/10/2016 the FDA issued a warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. Olanzapine is available under the brand names Zyprexa, Zyprexa Zydis, Zyprexa Relprevv and Symbyax, and also as generics. The FDA added a new warning to the drug label for all olanzapine-containing products that address this Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS may include fever and swollen lymph nodes and a swollen face; result in injury to organs, including the liver, kidneys, lungs, heart or pancreas; and can lead to death, with a 10% chance of mortality. Health care providers should advise their patients who are taking olanzapine-containing products to seek medical care right away if they develop a fever with a rash and swollen lymph glands, or swelling in the face. Abrupt

discontinuation is not recommended without direct supervision under a health care professional. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Fluoroquinolone Antibacterial Drugs — FDA Advises Restricting Use for Certain Uncomplicated Infections

On 05/12/2016 the FDA advised that serious side effects associated with use of fluoroquinolone antibiotics outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have alternative treatment options. Side effects can involve tendons, muscles, joints, nerves and the central nervous system, and can be disabling and potentially permanent, occurring alone or simultaneously. Drug labels and medication guides for all fluoroquinolone antibacterial drugs are to be updated with this safety information. Patients should be advised to contact a health care professional immediately if they experience any serious side effects while on therapy with agents containing this product. Therapy should be stopped by a health care professional immediately and switched to a non-fluoroquinolone antibacterial drug to complete treatment course. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Canagliflozin (Invokana, Invokamet) — Clinical Trial Results Find Increased Risk of Leg and Foot Amputations

On 05/18/2016 the FDA alerted the public about safety results from an ongoing clinical trial that found an increase in leg and foot amputations in patients treated with canagliflozin (Invokana, Invokamet), used for treatment of diabetes. Though the drug is under investigation, health care professionals should follow the recommendation in the canagliflozin drug labels and monitor patients for the signs and symptoms, such as pain or tenderness, sores or ulcers, or infections in their legs or feet. Patients should not stop or change their diabetes medications without first consulting a health care professional. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Over-the-Counter Antacid Products Containing Aspirin: FDA Drug Safety Communication — Serious Bleeding Risk

On 06/06/2016 the FDA issued a warning about the risk of serious bleeding when using over-the-counter (OTC) aspirin-containing antacid products to treat heartburn, sour stomach, acid indigestion, or upset stomach. Despite current warnings on the labels of these products, the FDA continues to receive reports. Multiple alternative products are available for these conditions that do not contain aspirin. Patients with the following risk factors may have a higher chance of serious bleeding when taking aspirin-containing antacid products: are 60 years of age or older; have history of stomach ulcers or bleeding problems; taking a blood-thinner or steroids; taking other NSAID-containing medications, such as ibuprofen or naproxen; or drink three or more alcoholic drinks per day. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Loperamide (Imodium) — Serious Heart Problems With High Doses From Abuse and Misuse

On 06/07/2016 the FDA issued a warning that taking higher than recommended doses of OTC or prescription loperamide (Imodium) used for diarrhea can cause serious heart problems that may lead to death. The risk for heart problems, including abnormal heart rhythm may increase when taking high

doses of loperamide with several kinds of medications that may interact with loperamide (e.g., cimetidine, ranitidine, clarithromycin, gemfibrozil, ketoconazole, etc.). Patients should be advised to take loperamide in the dose recommended by their health care provider or according the OTC drug fact label. If diarrhea lasts more than two days, patients should stop taking loperamide and contact their health care professional. Immediate medical attention is warranted for individuals experiencing fainting, rapid heartbeat or irregular heart rhythm, or who are unresponsive. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Zecuity (sumatriptan) Migraine Patch — FDA Evaluating Risk of Burns and Scars

On 06/13/2016 the FDA provided an update to a previous drug safety communication regarding use of Zecuity migraine patches. Teva Pharmaceuticals, the manufacturer for Zecuity, has temporarily suspended sales, marketing and distribution of these patches to investigate the cause of burns and scars. Health care professionals should discontinue prescribing Zecuity, and patients should stop using any remaining patches and contact their prescribers to obtain an alternative migraine therapy. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR) — Strengthened Kidney Warnings

On 06/14/2016 provided a drug safety communication regarding strengthened the existing warning about the risk of acute kidney injury for canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR) for the treatment of type 2 diabetes. Risk factors that predispose patients to acute kidney injury should be assessed prior to initiating therapy with these agents, including decreased blood volume, chronic kidney insufficiency and congestive heart failure and taking other medications, such as diuretics, ACE-inhibitors or ARBs, and NSAIDs. Kidney function should be assessed prior to starting these agents. Should kidney injury occur, these agents should promptly be discontinued and treat the kidney impairment. Signs and symptoms of acute kidney injury include decreased urine or swelling in the legs or feet and should be reported immediately. Patients should not stop taking their medicine without first talking to their health care professionals. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Highmark Formulary Update — August 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 Part D 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
BromSite™	bromfenac	bromfenac, diclofenac sodium
Otovel Otic Solution	ciprofloxacin/fluocinolone acetonide	Ciprodex, ofloxacin otic suspension
Bevespi Aerosphere™	glycopyrrolate/formoterol fumarate	provider discretion
Acticlate® CAP	doxycycline hyclate	doxycycline hyclate, minocycline
Fycompa® oral suspension	perampanel	lamotrigine, levetiracetam
Xtampza® ER	oxycodone ER	oxymorphone ER, morphine sulfate ER
Generic simvastatin oral suspension	simvastatin	simvastatin

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
Fycompa® oral suspension	perampanel	lamotrigine, levetiracetam
Xtampza® ER	oxycodone ER	oxymorphone ER, morphine sulfate ER

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
BromSite™	bromfenac	bromfenac, diclofenac sodium
Otovel Otic Solution	ciprofloxacin/fluocinolone acetonide	Ciprodex, ofloxacin otic suspension
Bevespi Aerosphere™	glycopyrrolate/formoterol fumarate	Provider discretion
Acticlate® CAP	doxycycline hyclate	doxycycline hyclate, minocycline
Generic simvastatin oral suspension	simvastatin	simvastatin

*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
Odefsey®	emtricitabine/rilpivirine/tenofovir alafenamide
Cinqair®	reslizumab
Descovy®	emtricitabine/tenofovir alafenamide
Provayblue	methylene blue
Taltz®	ixekizumab
Photrexa® Viscous	riboflavin 5′-phosphate in 20% dextran ophthalmic solution 0.146%
Photrexa®	riboflavin 5′-phosphate ophthalmic solution 0.146%
Venclexta™	venetoclax
Cabometyx™	cabozantinib
Orfadin® Oral Suspension	nitisinone
Evomela™	melphalan, captisol-enabled
Defitelio®	defibrotide sodium
Ameluz® 10% Gel	aminolevulinic acid HCl
Tecentriq™	atezolizumab
Nuplazid™	pimavanserin

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and Approval Criteria
Taltz (ixekizumab) — Commercial, Healthcare Reform	07/01/2016	New policy for moderate to severe psoriasis. Criteria include therapeutic failure, intolerance or contraindication to systemic therapy (e.g., methotrexate, cyclosporine), or phototherapy, as well

Policy Name	Policy Effective Date*	Updates and Approval Criteria
and Medicare		as therapeutic failure, intolerance or contraindication to preferred biologic product Humira. Policy also outlines appropriate induction as well as maintenance therapy quantity limits.
Cystic Fibrosis Inhaled Antibiotics —Medicare	06/02/2016	New policy created that captures prior authorization criteria formerly captured in administrative prior authorization policy J-30. Approval criteria include: • If the member is requesting a nebulizer solution, per policy J-30, the product has been determined to be eligible for coverage under Part D. • The member has a diagnosis of cystic fibrosis. • If the member is requesting Bethkis, the member has experienced therapeutic failure, intolerance or contraindication to generic tobramycin solution.
Orfadin (nitisinone) — Commercial, Healthcare Reform and Medicare	TBD	New policy to ensure appropriate utilization based on labeled indication of hereditary tyrosinemia type I (HT-1). Criteria also include the requirement to follow a diet restricted in tyrosine and phenylalanine.
Venclexta (venetoclax) — Commercial, Healthcare Reform and Medicare	07/01/2016	New policy to ensure appropriate utilization based on labeled indication of chronic lymphocytic leukemia (CLL) for patients with a 17p genetic mutation, as detected by an FDA-approved test, who have received at least one prior therapy.
Veltassa (Patiromer) — Medicare	TBD	New policy for hyperkalemia for patients unable to tolerate or who have a contraindication to sodium polystyrene sulfonate.
Nuplazid (pimavanserin) — Commercial, Healthcare Reform and Medicare	08/01/2016	New policy for new starts to ensure appropriate utilization based on labeled indication: treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
Korlym (mifepristone) — Commercial, Healthcare Reform and Medicare	06/02/2016	Policy revised with addition to Limitation of Coverage which states that Korlym should not be used in members who are pregnant.
Xeljanz (tofacitinib) —Medicare	06/01/2016	Policy revised and updated to include new formulation - Xeljanz XR
Viberzi (eluxadoline) — Healthcare Reform and Medicare	06/02/2016	Policy revised to add criterion about moderate to severe hepatic failure to limitations of coverage. Other safety-related limitations were added based on labeling.

Policy Name	Policy Effective Date*	Updates and Approval Criteria
Provigil (modafinil) & Nuvigil (armodafinil) — Medicare	06/02/2016	Policy revised with updated narcolepsy criteria to align with current guidelines. Criteria require either low CSF hypocretin-1 or sleep study testing to confirm a diagnosis of narcolepsy.
Cosentyx (secukinumab) — Medicare	TBD	Policy revised with added language requiring therapeutic failure, intolerance or contraindication to an NSAID for ankylosing spondylitis.
EGFR Kinase Inhibitors — Commercial, Healthcare Reform and Medicare	06/02/2016†	Policy revised with added criteria from policies J-14 [Gleevec (imatinib)], J-103 [Sutent (sunitinib)], J-104 [Nexavar (sorafenib)], J-106 [Sprycel (dasatinib), J-110 [Tykerb (lapatinib)], J-113 [Tasigna (nilotinib)], J-131 [Votrient (pazopanib)], J-144 [Xalkori (crizotinib)], J-145 [(MAP Kinase Inhibitors)], J-148 [Jakafi (ruxolitinib)], J-152 [Erivedge (vismodegib)], J-153 [Inlyta (axitinib)], J-165 [Bosulif (bosutinib), J-166 [Tyrosine Kinase Inhibitors for Thyroid Cancer], J-167 [Stivarga (regorafenib)], J-173 [Iclusig (ponatinib)], J-186 [Imbruvica (ibrutinib)], J-401 [ALK Inhibitors for NSCLC], J-412 [Olaparib (lynparza)], J-418 [Ibrance (palbociclib)], J-438 [Odomzo (sonidegib)], J-467 [Ninlaro (ixazomib)]. Added new indications for Gilotrif (squamous NSCLC), Lenvima (RCC), Xalkori (NSCLC ROS1+) and Imbruvica (SLL, updated CLL). Addition of criteria for new product Cabometyx (RCC) in alignment with FDA-approved indications. Please refer to policy for details of coverage criteria.
Afinitor (everolimus) — Medicare	TBD	Policy revised to include clarifications in the FDA-approved indications. Medically accepted indications were also updated to include relapsed or refractory Waldenström macroglobulinemia. Criteria also include double step therapy requirements for advanced renal cell carcinoma to align with NCCN guideline recommendations.
Xyrem (sodium oxybate) — Commercial, Healthcare Reform and Medicare	06/02/2016	Policy revised with updated narcolepsy criteria to align with current guidelines. Policy criteria require either low CSF hypocretin-1 or sleep study testing to confirm a diagnosis of narcolepsy.
Hepatitis C — Medicare	TBD	Policy revised to include new regimens recommended by AASLD guidelines. Please refer to policy for additional details. Policy also updated to include criteria for Epclusa (sofosbuvir/ velpatasvir) per FDA-approved labeling.
Eosinophilic Severe Asthma — Medicare	TBD	Policy revised to include the newly approved Cinqair (reslizumab) which is an IV infusion therapy for the same indicated phenotype of severe asthma as Nucala (mepolizumab). This policy was originally created to authorize appropriate utilization of Nucala, a subcutaneous therapy for severe asthma of an eosinophilic phenotype.

Policy Name	Policy Effective Date*	Updates and Approval Criteria
Administrative Prior Authorization for Medicare Part D Plans — Medicare	06/02/2016	Policy revised to align with CMS Chapter 6 guidance.
Entresto (sacubitril/valsarta) — Medicare	06/02/2016	Policy revised to remove the requirement for concomitant beta blocker use or intolerance.
Pulmonary Hypertension — Medicare	06/02/2016	Policy revised to remove functional class requirements that were not part of FDA-approved indications.

*All effective dates are tentative and subject to delay pending internal review or approval.
† Cabometyx criteria effective 08/01/2016.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
Extended release opioid management — Medicare	08/01/2016	Policy revised with the addition of new products: Xtampza ER, oxycodone HCL 15mg, 30mg and 60mg.
Migraine Therapies — Medicare	06/01/2016	Policy revised with the addition of new products: dihydroergotamine mesylate and frovatriptan.

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

3. Formulary Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
General Non-formulary Criteria — Medicare	06/02/2016	Policy revised with updated criteria to be in alignment with guidance from CMS and Government Compliance Department (GCD).

4. Quantity Level Limit (QLL) Program*

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Vraylar 1.5mg-3mg	14 capsules/ 365 days	14 capsules/365 days
Vraylar all strengths (except dose pack)	31 capsules/ 31 days	93 capsules/ 93 days
Allzital 25mg-325mg	372 tablets/ 31 days	1116 tablets/ 93 days
Frovatriptan Succinate 2.5mg	12 tablets/ 31 days	36 tablets/ 93 days
oxycodone ER 15mg, 30mg	100 tablets/ 31 days	300 tablets/ 93 days
oxycodone ER 60mg	69 tablets/ 31 days	207 tablets/ 93 days
Zembrace symtouch 3mg/0.5mL	8mL / 31 days	24mL/ 93 days
Xeljanz XR 11mg	31 tablets/ 31 days	93 tablets/ 93 days

butalbital compound with codeine 30-50-325mg-40mg (codeine-butalbital-asa-caffeine)	372 capsules/ 31 days	1116 capsules/ 93 days
Taltz autoinjector, Taltz syringe 80mg/mL	1 pen or syringe/ 28 days	3 pens or syringes/ 84 days
Onzetra Xsail 11mg/nosepiece	176 mg (16 nosepieces)/ 31 days	528 mg (48 nosepieces)/ 93 days
Kineret 100mg/0.67mL	18.76mL/ 28 days	56.28mL/ 84 days
Breo Ellipta 100-25mcg, 200-25 mcg	60 blisters/ 30 days	180 blisters/ 90 days
Cabometyx 20mg, 40mg, 60mg	31 tablets/ 31 days	93 tablets/ 93 days
Xtampza ER 9mg, 13.5mg, 18mg, 27mg, 36mg	62 capsules/ 31 days	186 capsules/ 93 days
Humira Pen 40mg/0.8mL	1.6 mL/ 28 days	4.8 mL/ 84 days
Humira Pediatric Crohn's 40mg/0.8mL	2.4 mL/ 28 days	2.4mL/ 84 days
Humira Pediatric Crohn's 40mg/0.8mL	4.8mL/ 28 days	4.8 mL/ 84 days
Dulera 200 mcg-5mcg/actuation, 100 mcg-5mcg/actuation	13 grams/ 30 days	39 grams/ 90 days
Odefsey all strengths†	31 tablets/ 31 days	93 tablets/ 93 days
BromSite all strengths†	10mL/ 31 days	10mL/ 93 days
Descovy all strengths†	31 tablets/ 31 days	93 tablets/ 93 days
Vistogard 10 gm packets†	20 packets/ 31 days	20 packets/ 93 days
Fycompa 0.5mg/mL†	680mL/ 28 days	2040mL/ 93 days
Bevespi Aerosphere all strengths†	1 canister/ 30 days	3 canisters/ 90 days
Taltz all strengths†	1 pen or syringe/ 31 days	3 pens or syringes/ 93 days
Otovel all strengths†	2 cartons (28 vials)/ 31 days	2 cartons (28 vials) / 93 days
Nuplazid 17mg†	62 tablets/ 31 days	186 tablets/ 93 days

*Requests for coverage exceeding the defined quantity level limits can be submitted for clinical review.
†Pending CMS approval.

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