SPECIAL eBULLETIN

FEBRUARY 2015

1ST QUARTER 2015 UPDATE

CHANGES TO THE HIGHMARK MEDICARE-APPROVED DRUG FORMULARIES

The following is the 1st 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 December 2014 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)

HIGHMARK West Virginia

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Important Information Update Regarding Tecfidera (dimethyl fumarate)
On Nov. 25, 2014, the FDA issued a warning that a patient who was being treated for multiple sclerosis (MS) with Tecfidera (dimethyl fumarate) developed progressive multifocal leukoencephalopathy (PML) and then later died. This patient was not taking any medications thought to be associated with developing PML. As a result, information regarding this case has been added to the labeling for Tecfidera (dimethyl fumarate).

PML is a rare, but serious brain infection caused by the John Cunningham (JC) virus. This virus is common, and often harmless, but can cause PML in patients with a weakened immune system. Symptoms suggestive of PML may include progressive weakness on one side of the body or limbs, visual disturbances, changes in thinking, memory or orientation, confusion and personality changes.

FDA recommendations for health care professionals at this time include:

- Inform patients that take Tecfidera (dimethyl fumarate) about the signs and symptoms suggestive of PML and to contact their physician if they develop these symptoms.
- Discontinue use of Tecfidera (dimethyl fumarate) in patients who develop symptoms and perform diagnostic evaluation for PML.
- Perform appropriate monitoring of lymphocyte counts in patients who are being treated with Tecfidera (dimethyl fumarate), according to package labeling.

Highmark Medicare-approved Formulary Update, February 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 CMS approval and upon completion of internal review and operationalization, unless otherwise noted)

Brand Name	Generic Name	Alternatives/Comments
Tybost™	cobicistat	A boosting agent to increase exposure to antiretroviral therapy used to treat HIV.
Spiriva® Respimat®	tiotropium bromide	For treatment of bronchospasm and prevention of exacerbations in patients with COPD.
Trumenba™	meningococcal group B vaccine	For prevention of group B meningococcal meningitis.
Invokamet™	canagliflozin/metformin	For treatment of adult patients with Type II diabetes mellitus. *Effective: 12/1/2014*
Xarelto® Starter Pack	rivaroxaban	For prevention of embolus formation in high-risk patients. *Effective: 11/1/2014*
Novofine® Plus 32 Gauge x 1/6" Needle	insulin needle (disposable) 32 gauge x 1/6"	For administration of insulin. *Effective: 11/1/2014*

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
Movantik™	naloxegol	Amitiza
Trulicity™	dulaglutide	Victoza, Bydureon
Uceris® (rectal foam)	budesonide	hydrocortisone enema, mesalamine enema
Mitigare™	colchicine	allopurinol
Akynzeo®	netupitant/palonosetron	Provider Discretion
Sotylize™	sotalol HCl	sotalol, sotalol AF
Xigduo™ XR	dapagliflozin/metformin	Invokana, metformin, Invokamet
Hysingla™ ER	hydrocodone bitartrate ER	morphine sulfate ER, oxymorphone ER

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
Tybost™	cobicistat	A boosting agent to increase exposure to antiretroviral therapy used to treat HIV.
Spiriva® Respimat®	tiotropium bromide	For treatment of bronchospasm and prevention of exacerbations in patients with COPD.
Trumenba™	meningococcal group B vaccine	For prevention of group B meningococcal meningitis.
Xarelto® Starter Pack	rivaroxaban	For prevention of embolus formation in high-risk patients. *Effective: 11/1/2014*
Invokamet™	canagliflozin/metformin	For treatment of adult patients with Type II diabetes mellitus. Effective: 12/1/2014
Novofine® Plus 32 Gauge x 1/6" Needle	insulin needle (disposable) 32 gauge x 1/6"	For administration of insulin. *Effective: 11/1/2014*

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
Movantik™	naloxegol	Amitiza
Akynzeo®	netupitant/palonosetron	Provider Discretion
Sotylize™	sotalol HCl	sotalol, sotalol AF
Hysingla™ ER	hydrocodone bitartrate ER	morphine sulfate ER, oxymorphone ER

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
Trulicity™	dulaglutide	Victoza, Bydureon
Uceris® (rectal foam)	budesonide	hydrocortisone enema, mesalamine enema
Mitigare™	colchicine	allopurinol
Xigduo™ XR	dapagliflozin/metformin	Invokana, metformin

*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
Viekira Pak™	ombitasvir/paritaprevir/ritonavir; dasabuvir
Harvoni®	ledipasvir/sofosbuvir
Keytruda®	pembrolizumab
Kabiven® and Perikabiven®	amino acids; electrolytes; dextrose; lipid
Auryxia®	ferric citrate
Vitekta™	elvitegravir
Fosrenol® (solution)	lanthanum carbonate
Iluvien™	fluocinolone intravitreal injection
Esbriet®	pirfenidone
Ofev®	nintedanib
Lemtrada™	alemtuzumab
HyQvia	IVIG 10% with recombinant hyaluronidase

D. Updates to the Pharmacy Utilization Management Programs
1. Updates to the Prior Authorization Program

Policy Name	Policy Effective Date	Updates and Approval Criteria
Hepatitis C Oral Agents	TBD	Addition of Harvoni (ledipasvir/sofosbuvir) and Viekira Pak™ to policy with criteria for use consistent with guidelines and prescribing information.
Movantik® (naloxegol)	TBD	When a benefit, Movantik may be covered when the following criterion is met: • Member has a diagnosis of opioid-induced constipation (OIC) in adult patients with chronic non-cancer related pain.
Idiopathic Pulmonary Fibrosis	TBD	When a benefit, Esbriet® or Ofev® may be covered when the following criteria are met: • The medication is being prescribed by a pulmonologist. • The member has a documented diagnosis of idiopathic pulmonary fibrosis (ICD-9 516.31, ICD-10 J84.112). • The member has a baseline forced vital capacity (FVC) of at least 50% and a percent predicted diffusing capacity of the lungs of carbon monoxide (DLCO) of at least 30%. • The member is not using pirfenidone and nintedanib in combination.
Keytruda®	TBD	When a benefit, pembrolizumab may be approved when the

Policy Name	Policy Effective Date	Updates and Approval Criteria
(pembrolizumab)		following criterion is met: • Pembrolizumab (Keytruda) is to be used for the treatment of unresectable or metastatic melanoma (ICD-9 172.0 - 172.9, ICD-10 C43-44) and disease progression following ipilimumab (Yervoy) and, if BRAF V600 mutation positive, a BRAF inhibitor.
Xtandi®	12/4/2014	Docetaxel failure has been removed from the policy to align with current FDA-approved indication. When a benefit, enzalutamide may be approved when the following criteria are met: • Enzalutamide is to be used for patients with metastatic castration-resistant prostate cancer (ICD-9 185.X, ICD-10 C61).
Humira®	12/4/2014	New indications have been added to the policy for pediatric Crohn's disease and juvenile idiopathic arthritis. Criteria have been updated to reflect current FDA approved indications. When a benefit, adalimumab may be approved when the following criteria are met: • Adalimumab is to be used in reducing the signs and symptoms of moderately to severely active polyarticular-course juvenile idiopathic arthritis (ICD-9 714.3X, ICD-10 M08.00) in patients 2 years of age and older who have had an inadequate response to one or more DMARDs OR • Adalimumab is to be used in reducing the signs and symptoms of pediatric patients > 6 years of age with moderate to severe Crohn's disease (ICD-9 555, ICD-10 K50.X) who have not responded to treatment with either a corticosteroid or immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate or monotherapy with Remicade.
Otezla	12/4/2014	Plaque psoriasis, with approval criteria, has been added as an indication to the policy. When a benefit, Otezla may be approved when all of the following criteria are met: 1. Apremilast is to be used for the treatment of moderate to severe psoriasis (ICD-9 696.1, ICD-10 L40.X) in patients ***AND***

Policy Name	Policy Effective Date	Updates and Approval Criteria
		2. The member has had an adequate trial or has experienced an intolerance to Humira and Enbrel, both of which are biologic agents indicated for the treatment of psoriasis. 3. Maintenance dose does not exceed 30 mg twice daily.
Administrative Prior Authorization for Part D Plans	TBD	Diagnosis codes for primary immunodeficiency have been added to the policy. **Immune Globulins (IG)** - Covered under Part B when administered in the home to a member with a diagnosis of primary immunodeficiency disease (PID). Applies to ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2 OR ICD-10-CM codes D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D83.0, D83.2, D83.8, or D83.9 if only an unspecified diagnosis is necessary. IG provided in the home for a diagnosis other than PID may be covered under the Part D benefit.
IG for Medicare Part D Only	TBD	Diagnosis codes for primary immunodeficiency have been added to the policy. **If a physician determines that the administration of IG in the patient's home is medically appropriate for a patient with a diagnosis of PID, coverage for IG is provided in the home setting under the member's Part B benefit. Part B coverage for PID applies to ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2 OR ICD-10-CM codes D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D83.0, D83.2, D83.8, or D83.9 if only an unspecified diagnosis is necessary. IG provided in the home for a diagnosis other than PID may be covered under the Part D benefit according to aforementioned criteria.** Payment is limited to that for the IG itself and does not cover items and services related to administration of the product. Administration and related Home Infusion Therapy services are reimbursed as a health service benefit.
Reduction of authorization period to 12 months	12/4/2014	Per CMS guidance, authorization duration was reduced to 12 months for 26 prior authorization policies. The affected policies are listed in the "**Authorization Duration Reduced to 12 Months**" table below.

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

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
Extended Release Opioid Management - Commercial Only	TBD	Hysingla ER has been added to this policy. A maximum of 30 tablets will be dispensed per month without an authorization. For claims exceeding this amount, a prior authorization will be required.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
Leukotriene Modifiers	1/1/2015	Singulair (montelukast) has been removed from this policy and no longer requires prior authorization.
Namenda XR	12/4/2014	When a benefit, Namenda and Namenda XR may be approved if members meet the following criteria: • Namenda or Namenda XR is being used for an FDA-approved or medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).
Reduction of authorization period to 12 months	12/4/2014	Per CMS guidance, authorization duration was reduced to 12 months for 4 managed prescription drug coverage policies. The affected policies are listed in the "**Authorization Duration Reduced to 12 Months"** table below.

3. Updates to the Nonformulary Program

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
General Nonformulary Request Criteria	TBD	Addition of definitions regarding supporting statements, adequate therapeutic trial. Addition of criteria requiring the prescriber to submit a supporting statement with the nonformulary request. Addition of provision for prevention of interruption of therapy for patients stable on a nonformulary protected class drug, as defined by CMS.

Tiering Exception	TBD	Addition of definitions regarding supporting statements, adequate therapeutic trial. Addition of criteria requiring the prescriber to submit a supporting statement with the tiering exception request. Addition of criteria clarifying that medications requested will only be compared against the immediate lower preferred tier.
		
		Requests for tiering exceptions will be approved when below criteria 1, 2, and 3 along with 4 or 5:
		
		1. The medication requested is being used to treat a medically accepted indication.
		2. There is at least 1 agent in the immediate lower preferred tier to review against the requested higher cost-share medication available for the treatment of the member's condition.
		  1. Tier 4 agents can only be reviewed against Tier 3 agents
		  2. Tier 2 agents can only be reviewed against Tier 1 agents
		3. The prescribing physician or other prescriber provides an explicit oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's conditions –
		  1. Would not be as effective for the enrollee as the requested drug OR
		  2. Would have adverse effects for the enrollee.
		4. The member had an adequate trial and/or failed three preferred agents on the immediate lower tier within the same therapeutic class (when alternatives are available), *or* category (when alternatives are not available in the same class) OR
		5. The member had an adequate trial and/or failed all preferred alternatives if less than 3 are present on the immediate lower tier.

Authorization Duration Reduced to 12 Months (effective 1/1/2015)

Program	Policy Name	Program	Policy Name
PA	Acthar HP	PA	Korlym (mifepristone)
PA	Afinitor (everolimus) – Medicare Only	PA	MAP Kinase Inhibitors
PA	Aubagio (teriflunomide)	PA	Myalept (metreleptin)
PA	Bosulif (bosutinib)	PA	Miscellaneous Immunomodulators
MRxC	Buprenorphine (non-opioid dependence use)	MRxC	Selective Serotonin-Norepinephrine Reuptake Inhibitors
PA	Cometriq (cabozantinib)	PA	Provigil (modafinil) & Nuvigil (armodafinil) – Medicare Only
PA	EGFR Tyrosine Kinase Inhibitors	PA	Savella (milnacipran)
PA	Forteo (teriparatide)	PA	Signifor (pasireotide) – Medicare Only

PA	Gattex (teduglutide)	PA	Simponi (golimumab) – Medicare Only
PA	Growth Hormone – Medicare Only	PA	Stivarga (regorafenib)
MRxC	High Risk Medications in the Elderly	PA	Sylvant (siltuximab) – Medicare Only
PA	Homozygous Familial Hypercholesterolemia	PA	Testosterone (Androgens) – Medicare Only
PA	Horizant (gabapentin enacarbil)	PA	Urea Cycle Disorder Medications
PA	IG for Medicare Part D Only	MRxC	Viibryd (vilazodone) and Brintellix (vortioxetine)
PA	Immediate Release Fentanyl Citrate – Medicare Only	PA	Xeljanz (tofacitinib) – Medicare Only

4. 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)*
Viekira Pak™	112 tablets	336 tablets
Harvoni®	28 tablets	84 tablets
Sovaldi®	28 tablets	84 tablets
Olysio®	28 capsules	84 capsules
Esbriet®	306 capsules	810 capsules
Ofev®	68 capsules	180 capsules
Mitigare™	68 capsules	180 capsules
Sivextro™ (tablets only)	6 tablets	6 tablets

* Unless noted.
**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.