SPECIAL eBULLETIN

February 2015

CHANGES TO THE HIGHMARK DRUG FORMULARIES

1ST QUARTER UPDATE

The 1st 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 December 2014 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 Health Care Reform Comprehensive Formularies

A. Changes to the Highmark Comprehensive and the Highmark Comprehensive Health Care Reform Formularies
B. Updates to the Pharmacy Utilization Management Programs
    1. Updates to the Prior Authorization Program
    2. Updates to the Managed Prescription Drug Coverage (MRxC) Program
    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, **www.highmarkbcbsde.com**). In the Provider Resource Center, click the *Pharmacy/Formulary Information* link in 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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Highmark Delaware

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 Formulary Update – February 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 this will 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
Vitekta™	elvitegravir	For the treatment of HIV in treatment-experienced adult patients.
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.
Invokamet™	canagliflozin/metformin	For treatment of adult patients with Type II diabetes mellitus. *Effective: 11/1/2014*
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*
Humira® Pediatric	adalimumab	For treatment of Crohn's disease and juvenile idiopathic arthritis in pediatric patients *Effective: 12/5/2014*
Crestor®	rosuvastatin	For treatment of dyslipidemia *Effective: 1/15/2015*
Sovaldi®	sofosbuvir	For treatment of chronic hepatitis C virus (HCV). *Effective: 2/3/2015*
Harvoni®	ledipasvir/sofosbuvir	For treatment of chronic hepatitis C virus (HCV) genotype 1. *Effective: 2/3/2015*
Viekira Pak™	ombitasvir/paritaprevir/ritonavir; dasabuvir	For treatment of chronic hepatitis C virus (HCV) genotype 1. *Effective: 2/3/2015*

Table 2: Products Not Added*

Brand Name	Generic Name	Preferred Alternatives
Movantik™	naloxegol	Amitiza
Trulicity™	dulaglutide	Victoza, Bydureon
Auryxia®	ferric citrate	calcium acetate
Contrave®	naltrexone/bupropion	Provider Discretion
Uceris® (rectal foam)	budesonide	hydrocortisone enema, mesalamine enema
Fosrenol® (solution)	lanthanum carbonate	calcium acetate
Mitigare™	colchicine	allopurinol
Akynzeo®	netupitant/palonosetron	Provider Discretion
Esbriet®	pirfenidone	Provider Discretion
Ofev®	nintedanib	Provider Discretion
Sotylize™	sotalol HCl	sotalol, sotalol AF
Xigduo™ XR	dapagliflozin/metformin	Invokana, metformin, Invokamet
Obredon	hydrocodone bitartrate/guaifenesin	benzonatate, Cheratussin DAC, codeine/guaifenesin
Hysingla™ ER	hydrocodone bitartrate ER	morphine sulfate ER, oxymorphone ER

*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*.

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
Hepatitis C Oral Agents	12/10/2014	Addition of Harvoni (ledipasvir/sofosbuvir) to policy for patients with chronic hepatitis C infection, genotype 1, and an estimate GFR > 30 mL/min. Additionally, all direct-acting agents will only be covered for patients who have a documented METAVIR score of F3 or F4, and documented abstinence from alcohol and illicit drugs.
Hepatitis C Oral Agents	1/19/2015	Addition of Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir) to the policy for patients with chronic hepatitis C infection, genotype 1, without renal or hepatic dysfunction and a documented METAVIR score of F3 or F4. Members must also have documented abstinence from alcohol and illicit drugs.
Movantik (naloxegol)	TBD	When a benefit, Movantik may be covered when the following criterion is met: 1. The member has a diagnosis of opioid-induced constipation (OIC) in adult patients with chronic non-cancer related pain.
Anti-Obesity	2/16/2015	Contrave has been added to this policy. When a benefit, Contrave® may be covered when the following criteria is met: 1. The member is ≥18 years of age and is obese, with a documented BMI ≥30 kg/m2 OR 2. The member is ≥18 years of age and is overweight, with a documented BMI ≥27 kg/m2 AND at least one weight-

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
		related comorbidity (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, symptomatic osteoarthritis of lower extremities, gastroesophageal reflux, coronary heart disease).
Idiopathic Pulmonary Fibrosis	2/16/2015	When a benefit, Esbriet® or Ofev® may be covered when the following criteria is met: 1. The medication is being prescribed by a pulmonologist. 2. The member has a documented diagnosis of idiopathic pulmonary fibrosis (ICD-9 516.31, ICD-10 J84.112). 3. 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%. 4. The member is not using pirfenidone and nintedanib in combination.
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

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
		AND 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.
Stelara	TBD	Approval criteria have been added to the policy to ensure use of the 90 mg dose in the appropriate population. **Approval Criteria:** When a benefit, Stelara may be approved when all of the following criteria are met: 1. Stelara is to be used for the treatment of moderate to severe plaque psoriasis (ICD-9 696.1, ICD-10 L40.X) in adult patients (> 18 years) who have previously received systemic therapy (e.g. methotrexate, cyclosporine) or phototherapy AND 2. The member has had an adequate trial or has experienced an intolerance to Humira, a biologic product indicated for the treatment of psoriasis OR 3. Stelara is to be used for the treatment of psoriatic arthritis (ICD-9 696.0, ICD-10 L40.52) AND 4. The member has failed to respond to, is intolerant of, or has a medical contraindication to one or more nonbiologic DMARDs AND 5. The member has had an adequate trial or has experienced intolerance to both preferred biologic products, Enbrel and Humira, indicated for the treatment of psoriatic arthritis. AND 6. Documentation of member weight and prescribed Stelara dose **Dosing:** **Psoriasis** • For patients weighing ≤100 kg (220 lbs.), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients weighing >100 kg (220 lbs.), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. **Psoriatic Arthritis** • The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs.), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

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	2/16/2015	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.
Extended Release Opioid Management – Commercial Only	TBD	MS Contin, Kadian, Avinza, Duragesic, levorphanol tartrate, Nucynta ER Dolophine and methadone have been added to this policy. Maximum quantities are based on dosing frequency for each individual agent. For claims exceeding the amount, a prior authorization will be required.
Therapy for Gout	2/16/2015	When a benefit, Mitigare™ may be covered when the following criterion is met: • Mitigare (colchicine) is to be used for prophylaxis of gout attacks (ICD-9 274.X, ICD-10 M10-X) following an adequate trial of allopurinol or other accepted gout treatment.
Immediate Release Opioid Management – Commercial Only	TBD	Dilaudid, hydromorphone, Demerol, meperidine, morphine sulfate, codeine sulfate and Nucynta have been added to this policy. Maximum quantities are based on dosing frequency for each individual agent. For claims exceeding the amount, a prior authorization will be required.

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

3. 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
Akynzeo®	1 capsule	1 capsule
Belsomra®	34 tablets	90 tablets
Esbriet®	306 capsules	810 capsules
Ofev®	68 capsules	180 capsules
Mitigare™	68 capsules	180 capsules
Sivextro™ (tablets only)	6 tablets	6 tablets

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