PR 14-46

SPECIAL BULLETIN

JULY 2014

CHANGES TO THE HIGHMARK DRUG FORMULARIES

2ND QUARTER UPDATE

The 2nd Quarter 2014 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 March 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 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

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**). 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.

(Continued on next page)

Highmark Delaware

FDA ISSUES WARNING ABOUT ESZOPICLONE CONTAINING PRODUCTS

The FDA has announced that it is requiring manufacturers of products containing eszopiclone (e.g., Lunesta®), a commonly-used medication for the treatment of insomnia, to lower the previously recommended starting dose of 2 mg to 1 mg immediately before bedtime. The recommendation is based on a clinical study of adults taking eszopiclone 3 mg for insomnia. The study found that eszopiclone 3 mg can cause impairment to driving skills, memory and coordination that can last more than 11 hours after receiving an evening dose.

As a result, the FDA has required manufacturers of eszopiclone products to lower the recommended initial dose for both men and women. The new dosing recommendations are shown in the following table:

Drug	**New Dosing Recommendation**	**Additional Information**
eszopiclone (e.g., Lunesta®)	**Men and Women:** 1 mg by mouth immediately before bedtime, with at least 7-8 hours remaining before the planned time of awakening. The 1 mg dose can be increased to 2 mg or 3 mg if needed, but the higher doses are more likely to impair next-day driving and other activities that require full alertness.	Women and men are equally susceptible to impairment from eszopiclone. Elderly patients and patients with severe liver disease should not take doses of more than 2 mg.

(continued)

Highmark Formulary Update – July 2014

Highmark Comprehensive and Health Care Reform Formularies

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

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Comprehensive Incentive and the Highmark Comprehensive Health Care Reform Formularies are a complete subset of the corresponding Open Formularies; therefore, all medications added to the Comprehensive Incentive and Comprehensive State Exchange Formularies are automatically added to the corresponding Open Formularies. 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 on the Provider Resource Center (accessible via NaviNet or our website, **www.highmarkbcbsde.com**). Click the *Pharmacy/Formulary Information* link from the menu on the left.

Table 1: Products Not Added*

(Effective upon completion of internal review and operationalization unless otherwise noted)

Brand Name	Generic Name	Preferred Alternative
Anoro™ Ellipta™	umeclidinium bromide and vilanterol	Advair Diskus®, Spiriva® HandiHaler, Symbicort®
Esomeprazole Strontium	esomeprazole strontium	omeprazole, pantoprazole
Farxiga™	dapaglifozin	metformin, glimepiride, glipizide, Invokana®
Isentress® oral solution	altegravir potassium	Tivicay®
Kuvan® oral powder	sapropterin dihydrochloride	Provider Discretion
Orenitram™	treprostinil	Provider Discretion
Pennsaid® 2% Topical solution	diclofenac sodium	diclofenac sodium tablet, meloxicam
Sovaldi™	sofosbuvir	Provider Discretion
Velphoro®	sucroferric oxyhydrochloride	calcium acetate

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online via the 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

(If approved, authorization may be granted for up to one year unless otherwise noted.)

Brand Name	Policy Effective Date	Approval Criteria
Acthar® HP	5/1/14	Acthar HP has been changed from MRxC to Prior Authorization. Approval criteria for H.P. Acthar® has been updated to be consistent with FDA-approved indication. Additional criteria will now require the intolerance of two corticosteroids (i.e. IV methylprednisolone, IV dexamethasone, or high-dose oral steroids).
Pulmonary Arterial	5/1/14	Orenitram™ has been added to this policy.

Brand Name	Policy Effective Date	Approval Criteria
Hypertension		
Hepatitis C Oral Agents	5/1/14	Sovaldi™ (sofosbuvir) is a new addition to the Hepatitis C Oral Agents policy. When a benefit, initial coverage for Sovaldi ™ will be approved if members meet the following criteria: Treatment with sofosbuvir for Genotype 1: a) Sofosbuvir is being used for the treatment of chronic hepatitis C genotype 1 infection or HIV/HCV co-infection in an adult patient (18 years and older) with compensated liver disease, including cirrhosis AND b) Sofosbuvir is being used in combination with peginterferon alfa and ribavirin for one of the following: OR i) Treatment-naïve patients ii) Non-responder patients with or without previous therapy with a protease inhibitor c) Sofosbuvir is being used in combination with simeprevir with or without ribavirin for one of the following: OR i) Documentation substantiating the treatment-naïve member is interferon ineligible ii) Non-responder patients without previous therapy with a protease inhibitor with documentation of a METAVIR score of F3 or greater iii) Documentation substantiating non-responder member is interferon ineligible and has not failed a protease inhibitor with documentation of a METAVIR score of F3 or greater d) Sofosbuvir is being used in combination with ribavirin for one of the following: AND i) Treatment-naïve or non-responder member without cirrhosis AND ii) For non-responder members: previous therapy was with or without a protease inhibitor AND iii) Documentation substantiating the member is interferon ineligible e) The patient has not previously failed a course of therapy that included sofosbuvir AND f) The prescribed dose of sofosbuvir is 400 mg (one 400 mg tablet) once daily OR g) The prescribed dose of simeprevir is 150 mg (one 150 mg capsule) once daily Genotype 2 and 3: a) Sofosbuvir is being used for the treatment of chronic

Brand Name	Policy Effective Date	Approval Criteria
		hepatitis C or HIV/HCV co-infection in genotype 2 or 3 infection in an adult patient (18 years and older) with compensated liver disease, including cirrhosis AND b) Sofosbuvir is being used in combination with ribavirin OR c) Sofosbuvir is being used in combination with peginterferon and ribavirin AND d) The patient has not previously failed a course of therapy that included sofosbuvir AND e) The prescribed dose is 400 mg (one 400 mg tablet) once daily Genotype 4: a) Sofosbuvir is being used for the treatment of chronic hepatitis C or HIV/HCV co-infection genotype 4 infection in an adult patient (18 years and older) with compensated liver disease, including cirrhosis AND b) Sofosbuvir is being used in combination with peginterferon alfa and ribavirin OR c) Sofosbuvir is being used in combination with ribavirin for members with documented interferon ineligibility AND d) Sofosbuvir is being used in combination with peginterferon alfa and ribavirin AND e) The patient has not previously failed a course of therapy that included sofosbuvir AND f) The prescribed dose is 400 mg (one 400 mg tablet) once daily Genotype 5 or 6 a) Sofosbuvir is being used for the treatment of chronic hepatitis C or HIV/HCV co-infection genotype 5 or 6 infection in an adult patient (18 years and older) with compensated liver disease, including cirrhosis AND b) Sofosbuvir is being used in combination with peginterferon alfa and ribavirin AND c) The patient has not previously failed a course of therapy that included sofosbuvir AND d) The prescribed dose is 400 mg (one 400 mg tablet) once daily

2. Updates to the Managed Prescription Drug Coverage (MRxC) Program
(If approved, authorization may be granted for up to one year unless otherwise noted.)

Brand Name	Policy Effective Date	Automatic Approval Criteria*
Extended Release Opioid Management - Commercial	6/4/14	Zohydro™ ER has been added to this policy. In the absence of a cancer qualifier, Zohydro™ ER has a retail pharmacy dispensing limit of 100 capsules in 25 days and a mail order dispensing limit of 300 capsules in 75 days.
Kuvan®	5/1/14	Kuvan® oral powder has been added to this policy.
Opioid Dependence Therapy	TBD	Criteria have been updated to include a limit on the amount of product that may be dispensed of buprenorphine-containing combination products. Suboxone and buprenorphine/naloxone will have automatic approval of up to 24 mg of the buprenorphine component per day. In addition, Zubsolv will have automatic approval of up to 17.1 mg of the buprenorphine component per day.
Generic Step Therapy Edit	6/4/14	Esomeprazole strontium (brand only) will be added as a brand Proton Pump Inhibitor (PPI) to the generic step therapy edit.

* 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.