SPECIAL eBULLETIN

June 2015

CHANGES TO THE HIGHMARK DRUG FORMULARIES

2ND QUARTER UPDATE

The 2nd 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 March 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 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 Drug Safety Updates

Use of Testosterone Products

On March 3, 2015, the FDA required a change in labeling to inform the public of possible increased risk for heart attack and stroke with use of testosterone products for low testosterone due to aging, as the benefits and safety of these drugs have not been established in this population. The FDA recommends only utilizing testosterone for labeled approved uses, and for health care professionals to only prescribe testosterone therapy for men with low testosterone levels caused by approved conditions that have been verified by laboratory tests and studies (i.e. hypogonadism in men with disorders of the testicles, pituitary gland or brain).

Use of Amiodarone with Select Hepatitis C Agents

On March 24, 2015, the FDA issued a warning of serious slowing of the heart rate when the antiarrhythmic agent amiodarone is used with hepatitis C treatments containing sofosbuvir (Sovaldi or Harvoni) in combination with another direct-acting antiviral drug. Based on post-marketing adverse event reports, the FDA recommends against the addition of Sovaldi or Harvoni combined with another direct-acting antiviral (e.g. Olysio), with amiodarone. If alternatives are not available, heart monitoring is recommended in an inpatient setting for the first 48 hours of therapy, followed by daily self-monitoring for at least two weeks.

Highmark Formulary Update – June 2015

SECTION I. Highmark Comprehensive Formulary

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
Prezcobix™	darunavir/cobicistat	For the treatment of HIV-1 infection in combination with other antiretroviral agents for treatment-naïve and treatment-experienced adults
Evotaz™	atazanavir/cobicistat	For the treatment of HIV-1 infection in combination with other antiretroviral agents for treatment-naïve and treatment-experienced adults
Dutrebis™	lamivudine/raltegravir	For the treatment of HIV-1 infection
Gilenya®	fingolimod	For the treatment of multiple sclerosis *Effective Date: 04/01/2015*
Linzess®	linalotide	For the treatment of irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC) *Effective Date: 04/01/2015*

Table 2: Products Not Added*

Brand Name	Generic Name	Preferred Alternatives
Lynparza™	olaparib	Provider discretion
Savaysa™	edoxaban	Xarelto®, Eliquis®, Pradaxa®
Cosentyx™	secukinumab	Humira®, Enbrel®
Natpara®	parathyroid hormone	Provider discretion
Xtoro™	finfloxacin otic suspension	acetic acid, acetic acid/hydorcort, oflaxacin, neomycin/poly/hydrocort
Soolantra™	Ivermectin cream	Finacea® gel, metronidazole
Saxenda®	liraglutide (rDNA origin) injection	Provider discretion
Namzaric™	memantine HCl & donepezil HCl	donepezil, Exelon® Patch
Rytary™	carbidopa/levodopa	carbidopa/levodopa IR and ER

Duopa™	carbidopa/levodopa	carbidopa/levodopa IR and ER
Prestalia®	perindopril arginine & amlodipine besylate	perindopril, amlodipine
Glyxambi®	empagliflozin/linagliptin	Invokana®, Tradjenta®, Januvia®
Lenvima™	lenvatinib	Provider discretion
Ibrance®	palbociclib	anastrazole, letrozole, tamoxifen
Farydak®	panobinostat	Revlimid®
Pazeo™	olopatadine HCl	Pataday™
Onexton™	benzoyl peroxide-clindamycin topical gel	clindamycin topical gel, erythromycin-benzoyl peroxide 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 4: Products To Be Removed – effective July 1, 2015

Product Name	Generic Name	Preferred Alternatives
Actonel®	risedronate	ibandronate, risedronate
Celebrex®	celecoxib	celecoxib, ibuprofen
Oxsoralen-Ultra®	methoxsalen	methoxsalen
Enjuvia®	synthetic conjugated estrogens	estradiol, Premarin
Rapamune®	sirolimus	sirolimus
Niaspan®	niacin ER	niacin ER
Xenical®	orlistat	Provider discretion

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
Lynparza (olaparib)	05/05/2015	When a benefit, coverage of olaparib may be provided when the following criteria have been met: • Olaparib is being used as monotherapy in patients with a BRCA mutation as detected by an FDA-approved test in advanced ovarian cancer (ICD 10 C56.9) who have been treated with three or more prior lines of chemotherapy
Cosentyx (secukinumab)	05/05/2015	When a benefit, coverage of secukinumab may be provided when all of the following criteria are met: • Secukinumab is to be used for the treatment of moderate to severe psoriasis (ICD-9 696.1, ICD-10 L40.X) AND • The member had an inadequate response to systemic (e.g. methotrexate, cyclosporine) therapy OR phototherapy (e.g. PUVA, UVB) AND • The member has had an adequate trial or experienced intolerance to the preferred biologic products (Enbrel and Humira)
Gattex (teduglutide) — Commercial Only	03/05/2015	Updated approval criteria to include documentation of dietary needs and goals, the ability to ingest solid food, and a pretreatment colonoscopy

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
Tecfidera (dimethyl fumarate) — Commercial Only	03/05/2015	Update to include recommended baseline CBC with lymphocyte count or CBC with lymphocyte count within 6 months of starting therapy
Human Growth Hormone — Commercial Only	TBD	Updated to include FDA-approved indications, limitations of coverage and modified children's growth velocity requirement for children less than 3 years of age. Limitations of coverage include: • Coverage for growth hormone is determined according to individual or group customer benefits • Recombinant DNA growth hormone drugs should be prescribed under the supervision of an endocrinologist
Wellbutrin (bupropion)	TBD	Criteria updated to reflect any "FDA-approved indication" instead of any "medical condition"
Kalydeco (ivacaftor)	03/05/2015	Updated to include the extra genetic mutation, R117H, which was recently FDA approved.
Jakafi (ruxolitinib)	03/05/2015	Updated to include the expanded indication of polycythemia vera in patients who have had an inadequate response to or are intolerant of hydroxyurea
Immediate Release Fentanyl Citrate	TBD	Criteria were updated to include the requirement of the inability to swallow or the trial of at least one short-acting opioid
Tyrosine Kinase Inhibitors for Thyroid Cancer	TBD	Merged criteria from Caprelsa policy (J-138) and added criteria for Lenvima to align with FDA-approved indication
Imbruvica (ibrutinib)	03/05/2015	Updated policy to reflect new indication of Waldenstrom's macroglobulinemia (WM)
Miscellaneous Immunomodulators	TBD	Added Farydak to this policy with criteria based on FDA-approved indication. Updated policy to be aligned with new FDA indication for use of Revlimid in combination with dexamethasone for the treatment of Multiple Myeloma (MM)
Ibrance (palbociclib)	05/05/2015	When a benefit, palbociclib may be covered when the following criteria are met: • For ER-positive, HER2-negative metastatic breast cancer in postmenopausal women AND • Being used as initial endocrine-based therapy for the member's metastatic disease AND • Being used concomitantly with letrozole (Femara)
Provigil (modafinil) & Nuvigil (armodafinil)	03/05/2015	Updated to include International Classification of Sleep Disorders-Third Edition guidance on narcolepsy diagnosis criteria
Xyrem (sodium oxybate)	03/05/2015	Updated to include International Classification of Sleep Disorders-Third Edition guidance on narcolepsy diagnosis criteria
Firazyr (icatibant)	TBD	Updated policy to include International Consensus Algorithm for the diagnosis criteria for hereditary angioedema (HAE) and quantity level management criteria
C1 Esterase Inhibitors	TBD	Updated policy to include International Consensus Algorithm for the diagnosis criteria for HAE
New to Market Drug Policy	TBD	Policy created for new to market drugs which have not been reviewed by the P&T committee. The criteria follow the FDA-

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
		approved indication and medically accepted indications for Part D. When a benefit, requests may be approved if the following criteria are met: • Drug is considered medically necessary when used for an FDA-approved indication
Topical Patches/Gels (containing capsaicin, menthol and/or lidocaine)	05/31/2015	Excluding coverage of certain DESI (Drug Efficacy Study Implementation) topical patches as their efficacy has not been proven
Horizant (gabapentin enacarbil)	05/05/2015	Added a generic gabapentin step prior to use of Horizant for the treatment of PHN
Saxenda (liraglutide) — Commercial Only	05/05/2015	When a benefit, liraglutide may be covered when the following criteria are met: • Approved for members 18 years and older with BMI > 30 (obese) OR overweight (BMI ≥27) with at least one weight-related comorbidity • Reauthorization requires weight loss of 4% or more from starting weight
Natpara (parathyroid hormone)	05/05/2015	When a benefit, parathyroid hormone may be covered when the following criteria are met: • It is being used as adjunct therapy to calcium and vitamin D in patients with hypocalcemia associated with hypoparathyroidism

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

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

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
Nuedexta (dextromethorphan/quinidine)	03/05/2015	Policy updated with current indication for Nuedexta – to be used for pseudobulbar affect (PBA), regardless of cause
Proton Pump Inhibitors (PPI)	07/14/2015	When a benefit, proton pump inhibitors exceeding the quantity limit may be approved when the following criteria are met: • Clinical documentation of Zollinger-Ellison syndrome (ZES)
Combination Prescription Drug Safety	06/01/2015	New policy was developed to ensure safe use of the following medications in combination: • Opiate agonists • Benzodiazepines • Centrally acting skeletal muscle relaxants
Gralise (gabapentin)	05/05/2015	Added a generic gabapentin step prior to use of Gralise for the treatment of post herpetic neuralgia (PHN)
DPP-IV Inhibitors – Commercial Only	05/05/2015	Addition of Glyxambi as a non-preferred product, requiring trial and failure of two preferred DPP-IV inhibitor-containing products
Extended-Release Venlafaxine	07/14/2015	When a benefit, coverage for additional quantities of extended-release venlafaxine 150mg, up to two units per day, may be

		covered if the following criteria is met: • The member has a diagnosis of major depressive disorder (MDD) and has tried and failed the maximum tolerable dose of at least two other antidepressants (e.g., SSRI, TCA, MAOI) AND • The member has tried and failed venlafaxine ER 225mg
Atypical Antipsychotics	03/05/2015	Policy updated to include FDA-approved indication of Gilles de la Tourette's and FDA-approved age restrictions for pediatric members
Lidoderm (lidocaine patch) – Commercial Only	03/30/2015	The Commercial policy has been updated to require use of any oral agent first for the treatment of PHN and to allow for the treatment of cancer pain if used as adjunctive therapy or for patients unable to swallow
Leukotriene Modifiers — Commercial Only	11/15/2014	Removed Singulair from policy. Removed coverage criteria for indications that are not FDA approved for Accolate and Zyflo
Terminated Policies		
Cymbalta (duloxetine) – Commercial Only	02/20/2015	Removed policy so members have access to quality generic medications to treat conditions such as diabetic peripheral neuropathy and fibromyalgia

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)
AcipHex® 5mg	102 capsules	270 capsules
AcipHex® 10mg	34 capsules	90 capsules
AcipHex® 20mg	68 tablets	180 tablets
Adderall XR®	34 tablets	90 tablets
Avalide®	34 tablets	90 tablets
Avapro®	34 tablets	90 tablets
Azor®	34 tablets	90 tablets
Benicar® 5mg	102 tablets	270 tablets
Benicar® 20mg, 40mg	34 tablets	90 tablets
Benicar® HCT	34 tablets	90 tablets
Concerta®	34 tablets	90 tablets
Cozaar® 25mg	102 tablets	270 tablets
Cozaar® 50mg	68 tablets	180 tablets
Cozaar® 100mg	34 tablets	90 tablets
Cymbalta® 20mg, 60mg	68 capsules	180 capsules
Cymbalta® 30mg	34 capsules	90 capsules
Dexilant 30mg	34 capsules	90 capsules
Dexilant 60mg	68 capsules	180 capsules
Diovan® 40mg, 80mg, 160mg	68 tablets	180 tablets
Diovan® 320mg	34 tablets	90 tablets
Diovan® HCT	34 tablets	90 tablets
Effexor XR®	34 tablets	90 tablets
Eliquis® 2.5mg	68 tablets	180 tablets
Eliquis® 5mg	70 tablets	210 tablets
Esomeprazole strontium	34 capsules	90 capsules

24.65mg		
Esomeprazole strontium 49.3mg	68 capsules	180 capsules
Exforge®	34 tablets	90 tablets
Lexapro® solution	680 mL	1,800 mL
Lexapro® 5mg, 20mg	34 tablets	90 tablets
Lexapro® 10mg	51 tablets	135 tablets
Lumigan®	2.5 mL	7.5 mL
Metadate CD™	34 capsules	90 capsules
Methylin®	510 mL	1,350 mL
Nexium® 20mg	34 capsules	90 capsules
Nexium® 40mg	68 capsules	180 capsules
Prilosec®	34 capsules/tablets	90 capsules/tablets
Protonix®	34 tablets	90 tablets
Pradaxa®	68 tablets	180 tablets
Prevacid® 15mg	34 capsules/tablets	90 capsules/tablets
Prevacid® 30mg	68 capsules/tablets	180 capsules/tablets
Ritalin®	102 tablets	270 tablets
Ritalin LA® 10mg, 20mg, 40mg	34 capsules	90 capsules
Ritalin LA® 30mg	68 capsules	180 capsules
Ritalin SR®	102 tablets	270 tablets
Vyvanse®	34 capsules	90 capsules
Wellbutrin SR®	68 tablets	180 tablets
Wellbutrin XL® 150mg	102 tablets	270 tablets
Wellbutrin XL® 300mg	34 tablets	90 tablets
Xarelto® 10mg, 20mg	34 tablets	90 tablets
Xarelto® 15mg	48 tablets	126 tablets
Zegerid®	34 capsules	90 capsules

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