

SPECIAL eBULLETIN

JUNE 2015

2ND QUARTER 2015 UPDATE CHANGES TO THE HIGHMARK MEDICARE- APPROVED DRUG FORMULARIES

The following is the 2nd 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 March 2015 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 eBulletin or our Medicare-approved Formularies, please contact your Provider Relations Representative.

(continued)



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Highmark Medicare-approved Formulary Update, June 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
Gardasil®9	Human Papillomavirus 9-valent Vaccine, Recombinant	Provider discretion
Bexsero®	meningococcal group B vaccine	Provider discretion
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

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
Savaysa™	edoxaban	Xarelto; Eliquis; Pradaxa
Xtoro™	finfloxacin otic suspension	Acetic acid, acetic acid/hydrocortisone, neomycin/polymyxin B/hydrocortisone, ofloxacin; Ciprodex
Soolantra™	ivermectin cream	metronidazole
Namzaric™	memantine HCl & donepezil HCl	donepezil, galantamine, Exelon patch
Dyloject®	diclofenac sodium injection	ketorolac
Rytary™	carbidopa/levodopa	carbidopa/levodopa IR and ER
Duopa™	carbidopa/levodopa	Provider discretion
Prestalia®	perindopril arginine & amlodipine besylate	perindopril, amlodipine
Glyxambi®	empagliflozin/linagliptin	Invokana, Tradjenta, Januvia

Brand Name	Generic Name	Alternatives/Comments
Pazeo™	olopatadine HCl	Pataday
Onexton™	benzoyl peroxide-clindamycin topical gel	clindamycin 1%-BP 5% gel; erythromycin-BP 3%-5% gel

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
Gardasil®9	Human Papillomavirus 9-valent Vaccine, Recombinant	Vaccine used to prevent infections/disease caused by 9 types of HPV
Bexsero	Meningococcal group B vaccine	Vaccine, indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B in patients 10-25 years of age
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

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
Savaysa™	edoxaban	Xarelto; Eliquis; Pradaxa
Xtoro™	finfloxacin otic suspension	Acetic acid, acetic acid/hydrocortisone, neomycin/polymyxin B/hydrocortisone, ofloxacin; Ciprodex
Duopa™	carbidopa/levodopa	carbidopa/levodopa IR and ER
Prestalia®	perindopril arginine & amlodipine besylate	perindopril, amlodipine

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
Soolantra™	ivermectin cream	Finacea, metronidazole
Namzaric™	memantine HCl & donepezil HCl	donepezil, Galantamine, Exelon patch
Dyloject®	diclofenac sodium injection	ketorolac
Rytary™	carbidopa/levodopa	carbidopa/levodopa IR and ER
Glyxambi®	empagliflozin/linagliptin	Invokana, Tradjenta, Januvia
Pazeo™	olopatadine HCl	Pataday
Onexton™	benzoyl peroxide-clindamycin topical gel	Clindamycin 1%-BP 5% gel; Erythromycin-BP 3%-5% 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*.

C. Additions to the Specialty Tier**(Effective immediately pending CMS approval and upon completion of internal review and operationalization)**

Brand Name	Generic Name
Blincyto™	blinatumomab
Lynparza™	olaparib
Rapivab™	peramivir
Opdivo®	nivolumab
Cosentyx™	secukinumab
Natpara®	parathyroid hormone
Signifor® LAR	pasireotide
Zerbaxa™	ceftolozane/tazobactam
Lenvima™	lenvatinib
Ibrance®	palbociclib
Farydak®	panobinostat

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

Policy Name	Policy Effective Date	Updates and Approval Criteria
Blincyto (blintumomab) — Medicare Only	TBD	A new policy was created to ensure appropriate utilization, for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
Gattex (teduglutide) — Medicare Only	01/01/2016	New separate policy from commercial, which includes updated criteria for documentation of dietary needs and goals, the ability to ingest solid food, and a pretreatment colonoscopy

Policy Name	Policy Effective Date	Updates and Approval Criteria
Tecfidera (dimethyl fumarate) — Medicare Only	01/01/2016	New separate policy from commercial, includes recommended baseline CBC with lymphocyte count or CBC with lymphocyte count within 6 months of starting therapy
Human Growth Hormone — Medicare Only	TBD	Updated to include FDA-approved indications and modified children’s growth velocity requirement for children less than 3 years of age
Acthar HP – Medicare Only	03/05/2015	Addition of new criteria to require failure for classes of medications other than corticosteroids for nephritic syndrome. Addition of new medically accepted indications with criteria for approval
Provigil (modafinil) & Nuvigil (armodafinil) – Medicare Only	03/05/2015	Updated to include International Classification of Sleep Disorders-Third Edition guidance on narcolepsy diagnosis criteria
Hepatitis C Oral Agents – Medicare Only	TBD	Removed creatinine clearance from approval criteria, included ledipasvir/sofosbuvir (Harvoni) management for treatment-naive members without cirrhosis pretreatment HCV RNA < 6 million IU mL (12-week treatment duration) and included sofosbuvir (Sovaldi) treatment for genotype 6 patients within approval criteria to be in line with CMS recommendations
Administrative Prior Auth for Medicare Part D Plans	TBD	Added a section with B vs D criteria for injectable osteoporosis agents. Expanded the section on B vs D criteria for drugs administered via infusion pump. Added a section about coverage of compound medications
C1 Esterase Inhibitors	TBD	Updated policy to include International Consensus Algorithm for the diagnosis criteria for hereditary angioedema (HAE)
Lynparza (olaparib)	05/05/2015	When a benefit, coverage of olaparib may be provided when the following criteria have been met: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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

Policy Name	Policy Effective Date	Updates and Approval Criteria
		and Humira)
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
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	<p>When a benefit, palbociclib (Ibrance) may be covered when the following criteria are met:</p> <ul style="list-style-type: none"> • 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)
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
New to Market Drug Policy	TBD	<p>Policy created for new to market drugs which have not been reviewed by the P&T committee. The criteria follow the FDA-approved indication and medically accepted indications for Part D.</p> <p>When a benefit, requests may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> • Drug is considered medically necessary when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS)
Horizant (gabapentin enacarbil)	05/05/2015	Added a generic gabapentin step prior to use of Horizant for the treatment of PHN

Policy Name	Policy Effective Date	Updates and Approval Criteria
Natpara (parathyroid hormone)	05/05/2015	When a benefit, parathyroid hormone may be covered when the following criteria are met: <ul style="list-style-type: none"> 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

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
High-Risk Medications in the Elderly – Medicare Only	03/05/2015	Addition of Soma (carisoprodol) to the policy
Lidoderm (lidocaine patch) — Medicare Only	01/01/2016	Cancer pain was added as a medically accepted indication
Opioid Dependence Therapy — Medicare Only	TBD	Updated policy to include FDA-approved labeling for recommended maximum daily dose. Differentiated maximum quantity per prescription limits for the agents included in policy: <ul style="list-style-type: none"> Buprenorphine monotherapy Buprenorphine/naloxone combination therapy Suboxone & buprenorphine/naloxone sublingual tablets/films Bunavail buccal films Zubsolv sublingual tablets Updated policy to comply with CMS recommendation for maximum daily dosing of Zubsolv 5.7mg/1.4mg and Zubsolv 1.4mg/0.36mg
Extended-Release Venlafaxine	01/01/2016	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: <ul style="list-style-type: none"> 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 <i>Effective Date: 1/1/2016</i>
Atypical Antipsychotics	03/05/2015	Policy was updated to include Abilify's new FDA-approved indication of Gilles de la Tourette's and FDA-approved age restrictions for pediatric patients
Proton Pump	01/01/2016	When a benefit, proton pump inhibitors exceeding the quantity

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria*
Inhibitors (PPI)		per prescription retail fill or prescription mail order fill may be approved when the following criteria are met: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 PHN

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	93 capsules	279 capsules
AcipHex® 10mg	31 capsules	93 capsules
AcipHex® 20mg	62 tablets	186 tablets
Adderall XR®	31 tablets	93 tablets
Avalide®	31 tablets	93 tablets
Avapro®	31 tablets	90 tablets
Azor®	34 tablets	93 tablets
Benicar® 5mg	93 tablets	279 tablets
Benicar® 20mg, 40mg	31 tablets	93 tablets
Benicar® HCT	31 tablets	93 tablets
Concerta®	31 tablets	93 tablets
Cozaar® 25mg	93 tablets	279 tablets
Cozaar® 50mg	62 tablets	186 tablets
Cozaar® 100mg	31 tablets	93 tablets
Cymbalta® 20mg, 60mg	62 capsules	186 capsules
Cymbalta® 30mg	31 capsules	93 capsules
Dexilant 30mg	31 capsules	93 capsules
Dexilant 60mg	62 capsules	186 capsules
Diovan® 40mg, 80mg, 160mg	62 tablets	186 tablets
Diovan 320mg	31 tablets	93 tablets
Diovan® HCT	31 tablets	93 tablets
Effexor XR®	31 tablets	93 tablets
Eliquis® 2.5mg	62 tablets	186 tablets
Eliquis® 5mg	64 tablets	191 tablets

Esbriet®	279 capsules	837 capsules
Esomeprazole strontium 24.65mg	31 capsules	93 capsules
Esomeprazole strontium 49.3mg	62 capsules	186 capsules
Exforge®	31 tablets	93 tablets
Harvoni®	28 tablets per 28 days	84 tablets per 84 days
Lexapro® solution	620 mL	1,860 mL
Lexapro® 5mg, 20mg	31 tablets	93 tablets
Lexapro® 10mg	47 tablets	140 tablets
Lumigan® 0.01%	2.5 mL	7.5 mL
Metadate CD™	31 capsules	93 capsules
Methylin®	465 mL	1,395 mL
Nexium® 20mg	31 capsules	93 capsules
Nexium® 40mg	62 capsules	186 capsules
Olysio®	28 capsules per 28 days	84 capsules per 84 days
Pradaxa®	62 tablets	186 tablets
Prevacid® 15mg	31 capsules/tablets	93 capsules/tablets
Prevacid® 30mg	62 capsules/tablets	186 capsules/tablets
Prilosec®	31 capsules/tablets	93 capsules/tablets
Protonix® 20mg, 40mg	31 tablets	93 tablets
Ritalin®	93 tablets	279 tablets
Ritalin LA® 10mg, 20mg, 40mg	31 capsules	93 capsules
Ritalin LA® 30mg	62 capsules	186 capsules
Ritalin SR®	93 tablets	279 tablets
Sovaldi®	28 tablets per 28 days	84 tablets per 84 days
Victralis®	336 capsules per 28 days	1,008 capsules per 84 days
Viekira Pak™	112 tablets per 28 days	336 tablets per 84 days
Vyvanse®	31 capsules	93 capsules
Wellbutrin SR®	62 tablets	186 tablets
Wellbutrin XL® 150mg	93 tablets	279 tablets
Wellbutrin XL® 300mg	31 tablets	93 tablets
Xarelto® 10mg, 20mg	31 tablets	93 tablets
Xarelto® 15mg	44 tablets	131 tablets
Zegerid®	31 capsules	93 capsules

* 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.