SPECIAL eBULLETIN

FEBRUARY 2017

FIRST QUARTER 2017 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the First Quarter 2017 update to the Highmark Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the following changes reflect the decisions made in December 2016 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

Section I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform Formulary
B. Updates to the Pharmacy Utilization Management Programs
   1. Prior Authorization Program
   2. Managed Prescription Drug Coverage (MRxC) Program
   3. Quantity Level Limit (QLL) Programs

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the Pharmacy/Formulary Information link from the menu on the left.

Important Drug Safety Updates

Pioglitazone-containing Medicines: Drug Safety Communication – Updated FDA Review, Increased Risk of Bladder Cancer

On December 12, 2016, the FDA approved updates to the labeling for pioglitazone. The labels show warnings for bladder cancer, but the update will add further descriptions of the studies that correlate pioglitazone with an increased risk of bladder cancer. The FDA recommends against the use of pioglitazone in patients with active bladder cancer. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

General Anesthetic and Sedation Drugs: Drug Safety Communication – New Warnings for Young Children and Pregnant Women

On December 14, 2016, the FDA announced that it is requiring warnings to be added to the labels of general anesthetic and sedation drugs. The additions warn that the use of general anesthetic or sedation drugs for an extended period of time or in repetition during procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Health care professionals should consider the benefits vs. risks when sedation or anesthesia is needed. Health care professionals should pay particular attention to procedures that last more than 3 hours and to children under 3 that require more than one procedure. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Chantix (varenicline) and Zyban (bupropion): Drug Safety Communication – Mental Health Side Effects Revised

On December 16, 2016, the FDA removed the Boxed Warning of mental health side effects from Chantix and Zyban. The FDA found — based on review of a clinical trial — that mental health side effects on mood, behavior, and thinking are present but at a lower risk than presumed. The warning sections of each respective label will also be updated with the results from the FDA's review of the clinical trial. Health care professionals should encourage patients to quit smoking and weigh the benefits vs. risks of smoking cessation products. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Highmark Formulary Update — January 2017

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare 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 also added to the Open Formulary. These updates are effective on the dates noted throughout this document. For your convenience, you can search the following formularies online:

Highmark Comprehensive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=8103967260)
Highmark Comprehensive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4906449921)

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 to promote adherence to maintenance products and improve the overall health of our members.

Table 1. Products Added

(All products added to the formulary effective date to be determined in 1Q2017, unless otherwise noted)

Brand Name	Generic Name	Comments
Invokamet XR	canagliflozin/metformin ER	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate.
Selzentry	maraviroc	Indicated for combination antiretroviral treatment of adults infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.
Vemlidy	tenofovir alafenamide	Indicated for treatment of chronic hepatitis B virus infection in adults with compensated liver disease.
Technivie	ombitasvir/paritaprevir/ritonavir	Indicated in combination with ribavirin for the treatment of adults with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis.

		Effective date: 11/21/2016
Epclusa	sofosbuvir/velpatasvir	Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection: • Without cirrhosis or with compensated cirrhosis • With decompensated cirrhosis for use in combination with ribavirin *Effective date: 11/21/2016*
Xiidra*	lifitegrast ophthalmic solution	Indicated for the treatment of the signs and symptoms of dry eye disease (DED). *Effective date: 12/07/2016*

Coverage may be contingent upon plan benefits.
*Applicable only to the Commercial Comprehensive Line of Business.

Table 2. Products Not Added*

Brand Name	Generic Name	Preferred Alternatives
Erelzi (*Biosimilar to Enbrel*)	etanercept-szzs	Enbrel, Humira
Kyleena	levonorgestrel IUD	Provider discretion
Yosprala	enteric-coated aspirin and omeprazole	aspirin, omeprazole, pantoprazole
Amjevita (*Biosimilar to Humira*)	adalimumab-atto	Humira, Enbrel
Vermox	mebendazole	Provider discretion
Epaned	enalapril oral solution	Provider discretion
Bonjesta	doxylamine; pyridoxine	Provider discretion
Xultophy	insulin degludec/liraglutide	Lantus, Victoza, Bydureon
Soliqua	insulin glargine/lixisenatide	Lantus, Victoza, Bydureon
Intrarosa	prasterone	Premarin Vaginal Cream
Zepatier	elbasvir/grazoprevir	Provider discretion
Sovaldi	sofosbuvir	Provider discretion

*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**.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
PCSK9 Inhibitors – Healthcare Reform	01/01/2017	New policy for Healthcare Reform (HCR) line of business. Revised lipid clinic requirement to include documentation of member undergoing lifestyle modifications. Clarified quantity limit for Repatha Pushtronex (1 pushtronex per 30 days) vs. Repatha (2 syringes per 28 days).
Yosprala (aspirin and omeprazole) – Commercial, Healthcare Reform and Medicare	03/20/2017	New policy was created to ensure patient is 18 years of age or older, has risk of developing aspirin associated gastric ulcers, and requires trial and failure of aspirin, generic omeprazole, and generic pantoprazole taken separately.
Amjevita (adalimumab-atto) Biosimilar – Commercial, Healthcare Reform	TBD	New policy created to ensure appropriate use of adalimumab-atto (Amjevita), a biosimilar to adalimumab (Humira) in patients with all of the same chronic inflammatory conditions in which Humira is approved for except pediatric Crohn's disease (CD), hidradenitis suppurativa, and uveitis. Policy step therapy criteria include an adequate trial of the following products for the respective indications: • Juvenille idiopathic arthritis (JIA), psoriatic arthritis (PsA), or rheumatoid arthritis (RA): An adequate trial of at least one non-biologic DMARD (e.g., methotrexate, lefluonide, etc.). • Ulcerative colitis (UC): An adequate trial of two immunosuppressants (e.g., corticosteroids, azathioprine, or 6-mercaptopurine). • CD: An adequate trial of two immunosuppressants or Remicade. • Chronic plaque psoriasis: An adequate trial of phototherapy or at least one systemic therapy (e.g., cyclosporine, methotrexate, etc.). • Ankylosing spondylitis: An adequate trial of at least one non-steroidal anti-inflammatory drug.
Erelzi (etanercept-szzs) – Biosimilar Commercial, Healthcare Reform	TBD	New policy created to ensure appropriate use of Erelzi, a biosimilar to Enbrel in patients with all of the same chronic inflammatory conditions in which Enbrel is currently approved. Policy step therapy criteria include an adequate trial of the following products for the respective indications: • Juvenille idiopathic arthritis (JIA), psoriatic arthritis (PsA), or rheumatoid arthritis (RA): At least one non-biologic DMARD (e.g., methotrexate, lefluonide, etc.). • Ulcerative colitis (UC): Two immunosuppressants (e.g.,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		corticosteroids, azathioprine, or 6-mercaptopurine). • Crohn's disease (CD): Two immunosuppressants or Remicade. • Chronic plaque psoriasis: Phototherapy or at least one systemic therapy (e.g., cyclosporine, methotrexate, etc.) • Ankylosing spondylitis: At least one non-steroidal anti-inflammatory drug.
West Virginia – Step Therapy Override Exception – Commercial, Healthcare Reform and Medicare	01/01/2017	New policy based on West Virginia House Bill 4040, to outline the expectation process made for West Virginia members to override step-therapy criteria.
Diclegis (doxylamine and pyridoxine) and Bonjesta (doxylamine and pyridoxine) – Commercial and Healthcare Reform	03/20/2017§	New policy created to ensure appropriate use in patients with pregnancy induced nausea and vomiting who have documented a trial of over-the-counter (OTC) doxylamine and pyridoxine (B6).
Xenazine (tetrabenazine) – Commercial	12/08/2016	New policy created to require step therapy with tetrabenazine, the generic equivalent of brand name Xenazine.
Kinase Inhibitors – Commercial, Healthcare Reform and Medicare	12/08/2016	Policy revised to capture expanded indications for lenvatinib (Lenvima) [renal cell carcinoma] and erlotinib (Tarceva) [non-small cell lung cancer (NSCLC)]. Additional changes include removal of language requiring FDA-approved tests for genetic mutations from the criteria and addition of applicable diagnosis codes.
Orkambi (lumacaftor-ivacaftor) – Commercial and Healthcare Reform	12/08/2016	Policy revised to add expanded indication for treatment of patients now as young as 6 years of age, where use was previously limited to patients 12 years of age and older. Reauthorization criteria were also clarified.
Immune Globulin (Medical Injectable Policy) – Commercial and Healthcare Reform	12/08/2016	Policy revised to include immune globulin subcutaneous (human) 20% (Cuvitru) and the applicable procedure code.
PCSK9 Inhibitors – Commercial	01/01/2017	Policy revised to include Commercial line of business only. Added step therapy language to require trial and failure of evolocumab (Repatha) prior to alirocumab (Praluent) for HeHF and ASCVD indications. Revised lipid clinic requirement to include documentation of member undergoing lifestyle modifications. Clarified quantity limit for Repatha Pushtronex (1 pushtronex per 30

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		days) vs. Repatha (2 syringes per 28 days).
Sublingual Immunotherapy – Commercial, Healthcare Reform and Medicare	01/01/2017	Policy revised with the addition of immunologists to list of accepted prescribers.
Enbrel (etanercept) – Commercial, Healthcare Reform	12/08/2016	Policy revised to reflect updated indication, where plaque psoriasis is now approved for children 4 years of age and older.
Strensiq (asfotase alfa) – Commercial, Healthcare Reform and Medicare	TBD	Policy revised with the addition of criteria to substantiate the diagnosis of hypophosphatasia, including ALP and PLP lab values.
Stelara (ustekinumab) – Commercial	12/08/2016	Policy revised to reflect the new indication for Crohn's disease along with criteria used today for non-preferred biologics for this indication.
Diclofenac Containing Products – Commercial and Healthcare Reform	01/01/2017	Policy revised to remove Flector and Voltaren Gel. At this time, these drugs will only be managed under our quantity level limit program. Policy criteria for trial and failure of generic diclofenac will be applicable to Pennsaid, Zorvolex, and Zipsor.
Xiidra (Lifitegrast Ophthalmic Solution) – Healthcare Reform and Medicare	12/07/2016	Policy revised to remove the commercial line of business. Criteria now only impacts HCR and Medicare lines of business.
Pulmonary Arterial Hypertension – Commercial and Select Healthcare Reform	12/08/2016	Policy revised to add additional information under limitations of coverage to highlight key information from current guidance on appropriate diagnosis and use of advanced therapies. Additions to the limitations of coverage section include: • Recommendation of referral to high-volume specialized centers for pulmonary arterial hypertension (PAH) • Recommendations from guidelines for use of calcium-channel blockers (CCBs) for Idiopathic PAH (IPAH) patients after vasoreactivity testing. • Highlight of safety concerns to the fetus and the need to adhere to REMS associated with select products (bosentan, ambrisentan, macitentan, riociguat) per FDA-labeling. Policy criteria modifications include: • A requirement that advanced therapies are being prescribed by or in consultation with a cardiovascular or pulmonary specialist. • CTEPH criteria were modified to require a V/Q scan as the preferred diagnostic tool.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Hepatitis C – Commercial and Healthcare Reform	01/01/2017	Policy criteria revised to reflect guidance from most recent FDA-approved labeling and AASLD guidelines. Preferred products implemented. Non-preferred products will require contraindication to preferred products for patient characteristics. Please refer to policy for additional details.
Xenazine (tetrabenazine) – Healthcare Reform and Medicare	12/08/2016	Policy revised to remove the commercial line of business. Now only impacts HCR and Medicare lines of business.
Interleukin –1β blockers – Commercial, Healthcare Reform and Medicare	12/08/2016	Policy revised to add indications of Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome, Hyperimmonoglobulin D Syndrome/ Mevalonate Kinase Deficiency, and Familial Mediterranean Fever. Added a requirement for patients to be 28 days or older for these indications.

*All effective dates are tentative and subject to delay pending internal review or approval.
§Effective Date reflects PA additions for Diclegis commercial lines of business only.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Extended-release Amphetamine/ Dextroamphetamine – Commercial and Healthcare Reform	TBD	New policy outlining criteria for coverage of twice daily dosing. Patients must be > than 16 years of age and weight >/= than or equal to 75 kg. Adult members (18 years or older) will receive twice daily dosing at Point of Service.
Migraine Therapies – Commercial and Healthcare Reform	12/08/2l016	Revised policy to clarify coverage for sumatriptan/naproxen sodium (Treximet) to align with FDA-approved maximum dosing.
Extended-release minocycline – Commercial and Healthcare Reform	12/08/2016	Policy revised to update duration of authorization from 1 year to 12 weeks.
Vimovo (naproxen/esomeprazole) – Commercial	12/08/2016	Policy revised to add claims history for generic NSAID (other than naproxen) to automatic approval criteria.
Lorzone-Parafon Forte DSC (chlorzoxazone) – Commercial	TBD	Policy revised to include change in criteria to try and fail two *generic* muscle relaxants, as opposed to two *formulary* muscle relaxants. Standard non-coverage and closed formulary

		verbiage were also added. The duration of authorization was condensed to 12 months as opposed to a lifetime authorization, as the indication noted in the policy is for acute, painful musculoskeletal conditions.
Oleptro ER (trazodone hydrochloride extended-release) – Commercial	TBD	Policy revised to include change in criteria to try and fail two generic antidepressants, as opposed to two other antidepressants. Added standard non-coverage and closed formulary verbiage and shortened the duration of authorization to 12 months as opposed to a lifetime authorization.
Vivlodex (meloxicam) – Commercial and Healthcare Reform	12/08/2016	Policy revised to add the following criteria: • Therapeutic failure or intolerance to generic meloxicam. • Therapeutic failure or intolerance to two other generic NSAIDs.
Combination Prescription Drug Safety – Commercial, Healthcare Reform and Medicare	TBD	Policy revised with the addition of multiple medications to the opiate agonists and benzodiazepines categories to ensure the safe use of the medications.
Buprenorphine (non-opioid dependence use) – Commercial, Healthcare Reform and Medicare	TBD	Policy revised with the addition of buprenorphine/ naloxone (Bunavail), and buprenorphine/naloxone (Zubsolv) to the medications indicated for the treatment of opioid-dependence that are not eligible for coverage when used for the treatment of chronic pain. A quantity limit of 2 filmstrips of buprenorphine (Belbuca) per day was added to the policy.
Qbrelis and Epaned Commercial and Healthcare Reform	02/10/2017	Policy revised to add enalapril oral solution (Epaned). The automatic approval criteria were revised to include members 1 month up to 11 years of age, as opposed to the previous criteria (1-11 years of age).

*All effective dates are tentative and subject to delay pending internal review or approval.
**Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Quantity Level Limit (QLL) Programs*
(Effective immediately upon completion of internal review and implementation, unless otherwise noted.)

Table 1. Quantity Level Limits – Quantity per Duration for Commercial Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Amjevita (adalimumab-atto)	2 syringes per 28 days	6 syringes per 84 days
Erelzi 25 mg (etanercept-szzs)	8 syringes per 28 days	24 syringes per 84 days
Erelzi 50 mg (etanercept-szzs)	4 syringes per 28 days	12 syringes per 84 days
Soliqua (insulin glargine/lixisenatide)	5 pens (15 mL) per 25 days	15 pens (45 mL) per 75 days
Xultophy (insulin degludec/liraglutide)	5 pens (15 mL) per 30 days	15 pens (45 mL) per 90 days

Quantity Level Limit Removals		
Xiidra (lifidegrast)	60 units/30 days	180 units/90 days

Requests for coverage of select medications exceeding the defined quantity limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on members benefit design.

Table 2. Quantity Level Limits – Quantity per Duration for Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Amjevita (adalimumab-atto)	2 syringes per 28 days	6 syringes per 84 days
Erelzi 25 mg (etanercept-szzs)	8 syringes per 28 days retail	24 syringes per 84 days
Erelzi 50 mg (etanercept-szzs)	4 syringes per 28 days retail	12 syringes per 84 days
Soliqua (insulin glargine/lixisenatide)	5 pens (15 mL) per 21 days	15 pens (45 mL) per 63 days
Xultophy (insulin degludec/liraglutide)	5 pens (15 mL) per 25 days	15 pens (45 mL) per 75 days

Maximum-day supply on certain medications may vary depending on member's benefit design.

Table 3. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Selzentry (maraviroc) oral solution	4 bottles	12 bottles
Vermox (mebendazole)	1 tablet	3 tablets
Relenza (zanamivir)*	1 inhaler and 5 Rotadisks	1 inhaler and 5 Rotadisks

*Quantity limit was previously for patients 7 years of age and older but is now for patients 5 years of age and older.

Table 4. Maximum Daily Quantity Limits – Commercial Plans

Drug Name	Daily Limit
Epaned (enalapril oral solution)	40 mL per day
Invokamet XR (canagliflozin/metformin ER)	2 tablets per day
Vemlidy (tenofovir alafenamide)	1 tablet per day
Yosprala (enteric-coated aspirin and omeprazole)	1 tablet per day
Zubsolv (0.7mg/0.18mg) (buprenorphine and naloxone)	3 sublingual tablets per day
Adderall XR (amphetamine/dextroamphetamine ER)*	2 tablets per day
Januvia(sitagliptin)	1 tablet per day
Onglyza (saxagliptin)	1 tablet per day
Tradjenta (linagliptin)	1 tablet per day
Nesina (alogliptin)	1 tablet per day
Janumet (sitagliptin/metformin)	2 tablets per day
Janumet XR 50/1000 mg (sitagliptin/metformin)	2 tablets per day
Janumet XR 50/500 mg and 100/1000 mg (sitagliptin/metformin)	1 tablet per day
Jentadueto (linagliptin/metformin)	2 tablets per day
Jentadueto XR 2.5/1000 mg (linagliptin/metformin)	2 tablets per day
Jentadueto XR 5/1000 mg (linagliptin/metformin)	1 tablet per day
Kombiglyze 2.5/1000 mg (saxagliptin/metformin)	2 tablets per day

Kombiglyze 5/500 mg and 5/1000 mg (saxagliptin/metformin)	1 tablet per day
Oseni (alogliptin and pioglitazone)	1 tablet per day
Kazano (alogliptin/metformin)	2 tablets per day
Farxiga (dapagliflozin)	1 tablet per day
Jardiance (empagliflozin)	1 tablet per day
Invokana (canagliflozin)	1 tablet per day
Xigduo XR 5/1000 mg (dapagliflozin and metformin)	2 tablets per day
Xigduo XR 5/500 mg, 10/500 mg, 10/1000 mg (dapagliflozin and metformin)	1 tablet per day
Glyxambi (empagliflozin and linagliptin)	1 tablet per day
Synjardy (empagliflozin and metformin)	2 tablets per day
Invokamet (canagliflozin and metformin)	2 tablets per day
Intrarosa (prasterone)	1 one vaginal insert per day
Belbuca (buprenorphine)	2 tablets per day

Requests for coverage of select medications exceeding the defined quantity level limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on member's benefit design.
* Adderall XR: 2 tablets per day limit for patients 18 years of age or older; 1 tablet per day limit for patients younger than 18 years of age.

Table 5. Maximum Daily Quantity Limits – Healthcare Reform Plans

Brand Name	Generic Name	Daily Limit
Epaned	enalapril oral solution	40 mL per day
Invokamet XR	canagliflozin/metformin ER	2 tablets per day
Vemlidy	tenofovir alafenamide	1 tablet per day
Yosprala	enteric-coated aspirin and omeprazole	1 tablet per day
Zubsolv (0.7mg/0.18mg)	buprenorphine and naloxone	3 sublingual tablets per day
Adderall XR*	amphetamine/dextroamphetamine ER	2 tablets per day
Intrarosa	prasterone	1 one vaginal insert per day
Belbuca	buprenorphine	2 tablets per day

Maximum day supply on certain medications may vary depending on member's benefit design.
* Adderall XR: 2 tablets per day limit for patients 18 years of age or older; 1 tablet per day limit for patients younger than 18 years of age.

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