SPECIAL eBULLETIN

JANUARY 2018

FIRST QUARTER 2018 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the First Quarter 2018 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 November 2017 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:

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

Febuxostat (Uloric): Drug Safety Communication - Increased Risk of Heart-Related Death and Death From All Causes

On November 15, 2017, the FDA announced that preliminary results from a clinical safety trial demonstrated an increase in heart-related deaths with febuxostat (Uloric) when compared to allopurinol. Healthcare professionals are urged to take this information into consideration when prescribing or continuing patients on febuxostat. Further updates will be given when final results are received from the trial. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Diphenoxylate Hydrochloride and Atropine Sulfate Tablets by Greenstone LLC: Recall – Possible Sub Potent and Super Potent Tablets

On November 16, 2017, Greenstone LLC announced a voluntary recall of multiples lots of diphenoxylate HCL and atropine sulfate tablets to the consumer level. Tablets may contain varying amounts of active ingredient causing them to be sub potent or super potent. The tablets are packaged in 100- and 1000-count bottles (NDC 59762-1061-1 and 59762- 1061-2) and were distributed from November 2016 through June 2017. Lot numbers available on the FDA website. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Riomet (Metformin HCl Oral Solution) by Sun Pharmaceuticals: Recall – Microbial Contamination

On November 24, 2017, Sun Pharmaceutical Industries issued a voluntary recall of two lots of Riomet 500 mg/5 mL to the retail level (Class II Recall). The oral solution was found to be contaminated with *Scopulariopsis brevicaulis*. The affected Riomet includes products with NDC Code 10631-206-01, Lot Number A160031A, Expiration Date 01/2018, and NDC 10631-206-02, Lot Number A160031B, Expiration Date 01/2018. This contamination can result in infection, particularly for the immunocompromised patient. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Prescription Opioid Cough and Cold Medicines: Drug Safety Communication – Limited to Use in Adults

On January 11, 2018, the FDA announced that it would now require safety labeling changes for prescription cough and cold medications containing codeine or hydrocodone. This would limit use to adults 18 years of age and older as risks outweigh the benefits in children less than 18. Additional safety information detailing risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing will be added to the Boxed Warning. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Long-acting Beta Agonists (LABAs) and Inhaled Corticosteroids (ICSs): Drug Safety Communication - No Significant Increase in Risk of Serious Asthma Outcomes

On December 20, 2017, the FDA announced that after review of four large clinical safety trials, use of a LABA with an ICS for the treatment of asthma does not appear to increase asthma-related side effects when compared to treatment with an ICS alone. The Boxed Warning concerning asthma-related death has been removed from labels of drugs containing an ICS and LABA. Adverse events or 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 2018

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 December 19, 2017, unless otherwise noted.)

Brand Name	Generic Name	Comments
Qvar Redihaler*	beclomethasone	New inhaler device of Qvar indicated for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.
Tracleer ODT	bosentan	New dosage form (oral dispersible tablet) and first pulmonary arterial hypertension drug approved for pediatric patients (aged 3 years and older).
Fiasp	faster-acting insulin aspart	First injectable, ultra-rapid-acting insulin product indicated for improve glycemic control in adults with diabetes mellitus.

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Carospir	spironolactone suspension	spironolactone
Duzallo	lesinurad; allopurinol	allopurinol
Lynparza tablets	olaparib	Provider discretion
Cyltezo*	adalimumab-adbm	Provider discretion

Brand Name	Generic Name	Preferred Alternatives
benznidazole	benznidazole	Provider discretion
Adzenys ER	amphetamine ER suspension	dextroamphetamine-amphetamine, methylphenidate ER
Solosec*	secnidazole	metronidazole gel, clindamycin cream
Xhance	fluticasone propionate	Provider discretion
Verzenio	abemaciclib	Provider discretion
Lyrica CR*	pregabalin extended-release	Provider discretion
Gocovri	amantadine ER	amantadine (immediate-release)
Calquence	acalabrutinib	Provider discretion
Bydureon BCise	exenatide ER	dulaglutide (Trulicity), liraglutide (Victoza)
Trelegy Ellipta	fluticasone furoate/umeclidinium/vilanterol	Provider discretion
Shingrix	herpes zoster vaccine	Provider discretion

* Effective date to be determined.

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 3. Additions to the Specialty Tier Copay Option

Note: The specialty tier does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy/Formulary Information** link for details on the formularies and formulary options that apply to Highmark Delaware members.

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

Brand Name	Generic Name
Lynparza tablets	olaparib
Cyltezo	adalimumab-adbm
Tracleer ODT	bosentan
Verzenio	abemaciclib
Gocovri	amantadine ER
Calquence	acalabrutinib

B. Changes to the Highmark Progressive Formulary and the Highmark Progressive Healthcare Reform Formulary

Note: The Progressive Formulary does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy/Formulary Information** link for details on the formularies and formulary options that apply to Highmark Delaware members. For your convenience, you may search the following formularies online:

Highmark Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=1176922773)

Highmark Progressive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)

Table 1. Formulary Updates (All products added to the formulary effective December 19, 2017, unless otherwise noted.)

Brand Name	Generic Name	Tier*	Comments/Preferred Alternatives
Items listed below are preferred products			
Fiasp	faster-acting insulin aspart	2-Preferred Brand	First injectable, ultra-rapid-acting insulin product indicated for improve glycemic control in adults with diabetes mellitus.
Items listed below are non-preferred products			
Qvar Redihaler*	beclomethasone	3-Non-preferred Brand	Provider discretion
Carospir	spironolactone suspension	3-Non-preferred Brand	generic spironolactone
Duzallo	lesinurad; allopurinol	3-Non-preferred Brand	allopurinol
benznidazole	benznidazole	3-Non-preferred Brand	Provider discretion
Adzenys ER	amphetamine ER suspension	3-Non-preferred Brand	dextroamphetamine-amphetamine ER
Solosec*	secnidazole	3-Non-preferred Brand	metronidazole gel, clindamycin cream
Xhance	fluticasone propionate	3-Non-preferred Brand	mometasone furoate
Lyrica CR*	pregabalin extended-release	3-Non-preferred Brand	Provider discretion
Bydureon BCise	exenatide ER	3-Non-preferred Brand	dulaglutide (Trulicity), liraglutide (Victoza)
Trelegy Ellipta	fluticasone furoate/umeclidinium/ vilanterol	3-Non-preferred Brand	Provider discretion
Shingrix	herpes zoster vaccine	3-Non-preferred Brand	Provider discretion
Lynparza tablets	olaparib	4-Non-preferred Specialty	Provider discretion
Cyltezo*	adalimumab-adbm	4-Non-preferred Specialty	Provider discretion
Tracleer ODT	bosentan	4-Non-preferred Specialty	Provider discretion
Verzenio	abemaciclib	4-Non-preferred Specialty	Provider discretion
Gocovri	amantadine ER	4-Non-preferred Specialty	amantadine (immediate release)
Calquence	acalabrutinib	4-Non-preferred Specialty	Provider discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
****Tier 1:** Preferred generic drugs; **Tier 2:** Preferred brand drugs; **Tier 3:** Non-preferred generic drugs, non-preferred brand drugs, preferred specialty drugs; **Tier 4:** Non-preferred specialty drugs.

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans in Pennsylvania and West Virginia. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=6571849149.

Table 1. Formulary Updates
(All formulary changes effective date December 19, 2017, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Qvar Redihaler*	beclomethasone	2	Provider discretion
Fiasp	faster-acting insulin aspart	3	First injectable, ultra-rapid-acting insulin product indicated for improve glycemic control in adults with diabetes mellitus.
Lynparza tablets	olaparib	4	Provider discretion
Verzenio	abemaciclib	4	Provider discretion
Items listed below were not added to the formulary			
Cyltezo*	adalimumab-adbm	NF	Provider discretion
Tracleer ODT	bosentan	NF	Provider discretion
Gocovri	amantadine ER	NF	amantadine (immediate release)
Calquence	acalabrutinib	NF	ibrutinib (Imbruvica)
Carospir	spironolactone suspension	NF	spironolactone
Duzallo	lesinurad; allopurinol	NF	allopurinol
benznidazole	benznidazole	NF	Provider discretion
Adzenys ER	amphetamine ER suspension	NF	dextroamphetamine-amphetamine ER
Solosec*	secnidazole	NF	metronidazole gel, clindamycin cream
Xhance	fluticasone propionate	NF	Provider discretion
Lyrica CR*	pregabalin extended-release	NF	Provider discretion
Bydureon BCise	exenatide ER	NF	dulaglutide (Trulicity), liraglutide (Victoza)
Trelegy Ellipta	fluticasone furoate/umeclidinium/vilanterol	NF	Provider discretion
Shingrix	herpes zoster vaccine	NF	Provider discretion

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).
*Effective date to be determined.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
benznidazole – Commercial and Healthcare Reform	12/21/2017	New policy created to ensure appropriate use in patients 2 to 12 years of age with Chagas disease.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Parathyroid Hormone Analogs – Commercial WVS***	01/01/2018	New policy created for the Commercial line of business, which was split from the initially combined Commercial and Healthcare Reform policy. Step through abaloparatide (Tymlos) before receiving teriparatide (Forteo) was also added.
Targretin (bexarotene) – Healthcare Reform WVS***	01/01/2018	New policy created for the Healthcare Reform line of business, which was split from the initially combined Commercial and Healthcare Reform policy. An additional step through generic bexarotene was also added.
CaroSpir (spironolactone) – Commercial and Healthcare Reform WVS***	12/21/2017	New policy created to require clinical documentation that patient is unable to swallow tablets in order to receive the suspension formulation of spironolactone.
Daraprim (pyrimethamine) – Commercial WVS***	TBD	New policy created to promote appropriate step with trimethoprim-sulfamethoxazole for prophylaxis and treatment of certain infections.
Delaware Cancer Chemotherapy Override Exception – Commercial and Healthcare Reform	11/15/2017	New policy created to include rationale and criteria for provisions of the new Delaware Oncology Chemotherapy Exception legislation. According to House Bill 120, coverage of cancer chemotherapy drugs cannot be limited or excluded due to failure to respond to a different agent when use of those drugs are supported by national clinical guidelines (NCCN Grade 1, 2A, or 2B) or by peer reviewed medical literature for the treatment of cancer. The following policies were modified to include provisions for the mandate: [J-24 Kinase Inhibitors], [J-101 Miscellaneous Immunomodulators], [J-107 Zolinza (vorinostat)], [J-127 Afinitor (everolimus)], [J-139 Zytiga (abiraterone acetate)], [J-183 Valchlor (mechlorethamine)], [J-479 Venclexta (venetoclax)], [J-610 Idhifa (enasidenib)], [J-611 Nerlynx (neratinib)], [J-639 Lonsurf (trifluridine-tipiracil)], J-156 Xtandi (enzalutamide)].
Doxycycline products – Commercial WVS***	TBD	New policy created to ensure brand name oral doxycycline therapies are used for severe acne vulgaris in patients who have tried and failed two different generic oral antibiotics, one of which must be doxycycline, and a different topical product.
Opioid Management – Commercial	TBD	To align with recommendations from CDC Safe Opioid Prescribing Guidelines, policy created to require prior authorization for first-time short acting opioids users with prescriptions for greater than a 7 day supply (>14 days/30) . Approval for additional days of therapy may

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		be granted for pain due to cancer or sickle cell anemia, patients in hospice, and in those with continued need for chronic opioid therapy. Policy also requires prior authorization on long acting opioids for opioid naive patients to ensure short-acting opioid therapies are optimized prior to transitioning to long-acting opioid therapy.
Oral Isotretinoin Therapy – Commercial WVS***	TBD	New policy created to ensure oral isotretinoin therapies are used for nodular acne in patients who have tried and failed two different generic oral antibiotics and one different topical product. Step through another isotreinoin agent required between Absorica (isotretinoin capsules) may be approved.
Spinraza (nusinersen) – Commercial and Healthcare Reform	12/21/2017	New policy created for Commercial and Healthcare Reform members to ensure appropriate utilization based on supporting clinical evidence (i.e. SMA type I). This policy will ensure the same criteria is applied across all lines of business.
Verzenio (abemaciclib) – Commercial and Healthcare Reform WVS***	11/15/2017	New policy created to ensure appropriate use in women with HR-positive, HER2 negative advanced breast cancer.
Calquence (acalabrutinib) - Commercial and Healthcare Reform WVS***	11/15/2017	Policy created to ensure acalabrutinib (Calquence) is used for adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
Gocovri (amantadine ER) – Commercial and Healthcare Reform WVS***	12/21/2017	New policy created to ensure amantadine ER (Gocovri) is used in patients with Parkinson's dyskinesia on concomitant levidopa-based therapy and after failure or intolerance to immediate release amantadine.
Targretin (bexarotene) – Commercial WVS***	11/15/2017	Policy revised to include additional step therapy through generic bexarotene for patients requesting the brand name Targretin and to remove the Healthcare Reform line of business.
Contraceptive Therapies – Commercial	11/15/2017	Policy revised to include ovarian cysts and Turner's Syndrome as approvable indications.
Tretinoin Therapy – Commercial and Health Care Reform	11/15/2017	Policy revised to include psoriasis as an approvable indication.
Increlex (mecasermin) – Commercial and Healthcare Reform	11/15/2017	Policy revised to remove Medicare line of business. Diagnostic criteria were also updated to reflect the most current guidance. Reauthorization criteria added requiring bone age < 14 years for females or < 16 years for males.
Xuriden (uridine triacetate) – Commercial and Healthcare Reform	11/15/2017	Policy enhanced to require the demonstration of megaloblastic anemia which is unresponsive to iron, folic acid, or Vitamin B-12 and that the member has

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		elevated urinary orotic acid levels. Duration of authorization has also been decreased to 12 months with reauthorization based on documentation that the condition is being stabilized.
Kalydeco (ivacaftor) – Commercial and Healthcare Reform	11/15/2017	Policy revised to move the Medicare line of business to its own policy and to include expanded indication of additional 5 splice mutation in the CFTR gene for the treatment of cystic fibrosis.
Nitisinone (Orfadin and Nityr) – Commercial WVS***	11/15/2017	Policy revised to require documentation of trial and failure of Nityr prior to receiving Orfadin. The duration of authorization was also modified from a lifetime authorization to 12 months.
Nitisinone (Orfadin and Nityr) – Healthcare Reform WVS***	11/15/2017	New policy created for the Healthcare Reform line of business, which was split from the initially combined Commercial and Healthcare Reform policy. Approval criteria remain the same.
PCSK9 Inhibitors – Commercial WVS***	12/01/2017	Policy revised to modify previous statin treatment requirements for heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease (ASCVD) indications to require trial and failure of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg). Baseline LDL requirement was also revised for HeFH and ASCVD indications to offer PCSK9 therapy for patients with LDL ≥70 mg/dL (previously ≥100 mg/dL). Language was also added to cover PCSK9 inhibitor monotherapy for patients who are determined to be statin intolerant.
PCSK9 Inhibitors – Healthcare Reform WVS***	12/01/2017	Policy revised to modify previous statin treatment requirements for heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease (ASCVD) indications to require trial and failure of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg). Baseline LDL requirement was revised for HeFH and ASCVD indications to offer PCSK9 therapy for patients with LDL ≥70 mg/dL (previously ≥100 mg/dL). Language was also added to cover PCSK9 inhibitor monotherapy for patients who are determined to be statin intolerant.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform WVS***	11/15/2017	Policy revised to add an expanded indication for ustekinumab (Stelara) subcutaneous in the treatment of adolescents 12 years and older with moderate to severe plaque psoriasis and to highlight the adolescent weight-based dosing regimen. The initial approval criteria for ustekinumab (Stelara) in Crohn's

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		disease was also revised to require Stelara intravenous induction therapy, trial and failure of two immunosuppressants, and trial and failure of the preferred biologic product for Crohn's Disease, adalimumab (Humira).
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial WVS***	11/15/2017	Policy revised to remove crisaborole (Eucrisa) to its own policy. Approval criteria remain the same.
Amjevita (adalimumab-atto) and Cyltezo (adalimumab-adbm) Biosimilar – Commercial and Healthcare Reform	TBD	Policy revised to include adalimumab-adbm (Cyltezo) for the treatment of • Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Adult Crohn's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)
Testosterone (Androgens) – Commercial WVS***	12/11/2017	Policy revised to include step requirement of all branded topical products. Requirement for transgender male patients to undergo reassignment surgery was removed. Approval criteria include: age > 16 years, diagnosis of gender identity disorder or gender dysphoria, and goal of therapy of female-to-male gender transition.
Testosterone (Androgens) – Healthcare Reform WVS***	12/11/2017	Policy revised to remove the requirement for transgender male patients to undergo reassignment surgery. Approval criteria include: age > 16 years, diagnosis of gender identity disorder or gender dysphoria, and goal of therapy of female-to-male gender transition.
Hepatitis C Oral Agents – Commercial WVS***	1/1/2018	Policy revised to include sofosbuvir/velpatasvir (Epclusa) as a preferred product for the treatment of Hepatitis C infection.
Pulmonary Hypertension – Commercial and Healthcare Reform WVS***	12/21/2017	Policy revised to change the title from Pulmonary Arterial Hypertension to Pulmonary Hypertension to be aligned with the Medicare policy, and for accuracy as the policy includes criteria for WHO group IV patients with chronic thromboembolic pulmonary hypertension (CTEPH). Additional policy changes include addition of criteria for newly approved bosentan (Tracleer) ODT tablets for the pediatric population, changes to the background section, including new safety considerations and prescribing considerations.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Benlysta (belimumab) – Commercial and Healthcare Reform WVS***	11/15/2017	Policy revised to align with Medical policy criteria for belimumab (Benlysta) IV. Criteria outline titer values for anti-nuclear antibody (ANA) (≥1:80) and anti-double-strand DNA antibody (≥30 IU/mL). Additionally, individuals should demonstrate insufficient response to two standard of care drug classes (corticosteroids, antimalarials, immunosuppressives), and continue to receive concomitant standard of care for the treatment of systemic lupus erythematosus (SLE) while utilizing belimumab (Benlysta).
Lyrica (pregabalin) & Lyrica CR (pregabalin ER) – Commercial and Healthcare Reform WVS***	TBD	Policy revised to add pregabalin ER (Lyrica CR) and required step through pregabalin (Lyrica) immediate release.

*All effective dates are tentative and subject to delay pending internal review or approval.
***WVS: West Virginia members may bypass any step therapy requirements outlined in the respective policies.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Interferon Beta- Select Healthcare Reform Plans WVS***	12/01/2017	New policy created for the Healthcare Reform line of business, which was split from the initially combined Commercial and Healthcare Reform policy. Authorization criteria remain the same.
Xhance (fluticasone propionate) – Commercial and Healthcare Reform WVS***	12/26/2017	New policy created for new medication fluticasone propionate (Xhance) to require confirmation of nasal polyps and trial and failure, or intolerance to generic mometasone furoate nasal spray.
Non-Preferred Glucagon-Like Peptide Receptor Agonists – Commercial and Healthcare Reform WVS***	01/01/2018	New policy created to promote use of preferred products, liraglutide (Victoza) and dulaglutide (Trulicity), prior to the approval of non-preferred GLP-1 receptor antagonists.
Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Healthcare Reform WVS***	01/01/2018	New policy created to promote use of preferred products, empagliflozin (Jardiance) and canagliflozin (Invokana), prior to the approval of non-preferred SGLT2 inhibitors.
Eucrisa (crisaborole) – Commercial WVS***	11/15/2017	New policy created to separate crisaborole (Eucrisa) to its own policy. Approval criteria remain the same.
glycopyrrolate – Commercial and Healthcare Reform WVS***	12/26/2017	New policy created to require trial of glycopyrrolate 1 mg prior to 1.5 mg for the treatment of peptic ulcer disease.
benzonatate – Commercial and Healthcare Reform WVS***	12/26/2017	New policy created to require trial of benzonatate 100 mg prior to 150 mg for the symptomatic relief of cough.

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Trulance (plecanatide) – Commercial WVS***	TBD	New policy created to require trial and failure of lubiprostone (Amitiza) and linaclotide (Linzess) prior to receiving plecanatide (Trulance) for the indication of chronic idiopathic constipation.
Solodyn and Ximino (minocycline ER) & Minocin (minocycline HCl) – Commercial WVS***	TBD	New policy created for the Commercial line of business, which was split from the initially combined Commercial and Healthcare Reform policy. Ximino and Minocin (both minocycline ER products) were also added to the new Commercial policy as targeted products.
Interferon Beta – Commercial WVS***	12/01/2017	Policy revised to move interferon beta-1b (Betaseron) from a non-preferred to preferred position. The Healthcare Reform component was also separated to its own policy.
Diabetic Test Strips Quantity Limitation – Commercial and Healthcare Reform	11/15/2017	Policy revised to reflect quantity limit of seven test strips daily for all covered test strips.
Azilect (rasagiline) – Healthcare Reform WVS***	01/01/2018	Policy revised to include step through generic selegiline for the treatment of Parkinson's Disease.
Gout Therapies - Commercial and Healthcare Reform WVS***	12/26/2017	Policy revised to include Duzallo (lesinurad/allopurinol) for the treatment of hyperuricemia due to gout in patients who have experienced failure with allopurinol alone.
Lorzone, Parafon Forte DCS (chlorzoxazone) – Commercial and Healthcare Reform WVS***	12/26/2017	Policy revised to include chlorzoxazone 250 mg and update step therapy requirement through chlorzoxazone 500 mg and one additional muscle relaxant for all targeted products.
Solodyn and Ximino (minocycline ER) – Healthcare Reform WVS***	12/26/2017	New policy created for the Healthcare Reform line of business, which was split from the initially combined Commercial and Healthcare Reform policy. Ximino (minocycline ER) was also added as a targeted product.
Xeloda (capecitabine)-- Commercial	11/15/2017	Policies were revised to include provisions for the Delaware Oncology Chemotherapy Exception mandate.
Branded Aromatase Inhibitors – Commercial	11/15/2017	
Branded Antiandrogen Therapy – Commercial	11/15/2017	

*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.
***WVS: West Virginia members may bypass any step therapy requirements outlined in the respective policies.

3. Formulary Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
General Non-Formulary Request Criteria – Commercial	TBD	Policy revised to add Lyrica CR as a non-covered extended release product with immediate release formulation covered on the formulary.

*All effective dates are tentative and subject to delay pending internal review or approval.

4. 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 and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Cyltezo prefilled syringe 40mg/0.8 ml	80 mg (2 syringes) per 28 days	240 mg (6 syringes) per 84 days
benznidazole 12.5 mg, 100 mg	60 days per 720 days	
Copaxone 20mg*	28 per 28 days	84/84 days
Glatopa 20mg*	28 per 28 days	84/84 days
glatiramer acetate 20mg*	28 per 28 days	84/84 days
Copaxone 40mg*	12 per 28 days	36/84 days
glatiramer acetate 40mg*	12 per 28 days	36/84 days
Bydureon BCise (exenatide ER) all strength	4 auto-injectors per 28 days	12 auto-injectors per 84 days

*Applicable to Commercial plans only. Effective date to be determined.

Table 2. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Qvar Redihaler 40 mcg	One Inhaler	Three Inhalers
Qvar Redihaler 80 mcg	Two Inhalers	Six Inhalers
Adzenys ER 1.25 mg/mL	One bottle (450 mL)	Three bottles (1350 mL)
Xhance (fluticasone propionate) 93 mcg	One bottle (16ml)	Three bottles (48ml)
Solosec (secnidazole) 2 g	One granules packet	--
Trelegy Ellipta (all strengths)	One inhaler	Three inhalers

Quantity per dispensing event limits the quantity of medication that can be dispensed per each fill. If the submitted day supply on a claim is 34 days or less, the retail limit will apply. If the submitted day supply on a claim is greater than 34 days, the mail limit will apply.

Table 3. Maximum Daily Quantity Limits – Commercial and Healthcare Reform Plans

Drug Name	Daily Limit
Duzallo (all strengths)	1 tablet per day
Lynparza tablets 100, 150mg	4 tablets per day
Xuriden 2 g packets of granules	8 grams per day
Tracleer (bosentan) ODT 32mg oral dispersible tablets	4 tablets per day
Idhifa 50 mg	2 tablets per day
Gocovri (amantadine ER) 68.5 mg and 137 mg	2 capsules per day
Verzenio (abemaciclib) 50 mg, 100 mg, 150 mg, and 200 mg	2 tablets per day
Calquence (acalabrutinib)100mg	2 capsules per day
Uptravi (selexipag) 200 mcg	8 tablets per day

Members can receive up to the maximum day supply according to their benefits but the daily limit must not be exceeded for each individual 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.

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 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 Part D Formularies online at: https://medicare.highmark.com/#/resources

Table 1. Preferred Products*
(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Comments
Qvar Redihaler	beclomethasone	Provider discretion
Fiasp	faster-acting insulin aspart	Provider discretion
Shingrix	herpes zoster vaccine	Provider discretion

Table 2. Non-Preferred Products
(Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Carospir	spironolactone	spironolactone
Duzallo	lesinurad; allopurinol	Provider discretion
Kedrab	rabies immune globulin	Imogam Rabies-Ht (Tier 4); HyperRAB S/D (Tier 4)
Vabomere	meropenem/vaborbactam	Provider discretion
benznidazole	benznidazole	Provider discretion
Adzenys ER	amphetamine ER suspension	dextroamphetamine-amphet ER
Solosec	secnidazole	metronidazole gel, clindamycin cream
Xhance	fluticasone propionate	Provider discretion
Zilretta	triamcinolone acetonide extended-release	Provider discretion
Lyrica CR	pregabalin extended-release	Provider discretion
Bydureon BCise	exenatide ER	Provider discretion
Varubi	rolapitant	Provider discretion
Trelegy Ellipta	fluticasone furoate/ umeclidinium/vilanterol	Provider discretion

B. Changes to the Highmark Medicare Part D 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 Part D Formularies online at: https://medicare.highmark.com/#/resources

Effective Jan. 1, 2018, Highmark will offer three close formulary options (Performance, Choice and Venture), which will coincide with select available Medicare Advantage plans, in all regions where plans are available. The updates noted below are applicable to all three formularies, unless otherwise specified. A list of drugs included on the formulary, listed by therapeutic class, is available at: https://medicare.highmark.com/#/resources

Table 1. Preferred Products

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Comments
Qvar Redihaler	beclomethasone	Provider discretion
Fiasp	faster-acting insulin aspart	Provider discretion
Shingrix	herpes zoster vaccine	Provider discretion

Table 2. Products Not Added*

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Carospir	spironolactone suspension	generic spironolactone
Duzallo	lesinurad; allopurinol	Provider discretion
Cyltezo	adalimumab-adbm	Provider discretion
Kedrab	rabies immune globulin	Imogam Rabies-Ht (Tier 4); HyperRAB S/D (Tier 4)
Vabomere	meropenem/valorbactam	Provider discretion
benznidazole	benznidazole	Provider discretion
Adzenys ER	amphetamine ER suspension	dextroamphetamine-amphetamine ER
Mvasi	bevacizumab-awwb	Provider discretion
Solosec	secnidazole	metronidazole gel clindamycin cream
Xhance	fluticasone propionate	Provider discretion
Zilretta	triamcinolone acetonide extended-release	Provider discretion
Lyrica CR	pregabalin extended-release	Provider discretion
Gocovri	amantadine ER	Provider discretion
Bydureon BCise	exenatide ER	Provider discretion
Varubi	rolapitant	Provider discretion
Trelegy Ellipta	fluticasone furoate/ umeclidinium/vilanterol	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**.

C. Additions to the Specialty Tier

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name
Besponsa	inotuzumab ozogamicin
Lynparza tablets	olaparib
Cyltezo	adalimumab-adbm
Mylotarg	gemtuzumab ozogamicin
Tracleer ODT	bosentan
Mvasi	bevacizumab-awwb
Vyxeos	daunorubicin and cytarabine
Kymriah	tisagenlecleucel
Prolastin-C Liquid	alpha-1-proteinase inhibitor
Aliqopa	copanlisib
Yescarta	axicabtagene
Gocovri	amantadine ER
Calquence	acalabrutinib

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
benznidazole - Medicare	TBD	New policy created to ensure appropriate use in patients 2 to 12 years of age with Chagas disease.
Eucrisa (crisaborole) – Medicare	07/01/2017	New policy created to ensure appropriate use in patients with mild to moderate atopic dermatitis after a trial of corticosteroids.
Vyxeos (daunorubicin; cytarabine) – Medicare	11/01/2017	New policy created to ensure daunorubicin/cytarabine (Vyxeos) is used for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)
Chimeric Antigen Receptor T-Cell Therapy – Medicare	TBD	New policy created for (Kymriah) and axicabtagene ciloleucel (Yescarta). Tisagenlecleucel (Kymriah) approval criteria consists of alignment with FDA approved indication, CD19 tumor expression, mutation status, trial/failure of 2 tyrosine kinase inhibitor medications (when applicable), absence of active infection, prior therapy, and manufacturer acceptance of apheresis.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Axicabtagene ciloleucel (Yescarta) approval criteria consists of alignment with FDA approved indication, CD19 tumor expression, mutation status, ECOG status score, absence of active infection, prior therapy, and manufacturer acceptance of apheresis.
Mylotarg (gemtuzumab ozogamicin)	TBD	New policy created to ensure appropriate use of gemtuzumab (Mylotarg) for CD33-positive acute myeloid leukemia (AML) and relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years of age and older.
Verzenio (abemaciclib) – Medicare	TBD	New policy created to ensure appropriate use in women with HR-positive, HER2-negative advanced breast cancer.
Calquence (acalabrutinib) – Medicare	TBD	New policy created to ensure acalabrutinib (Calquence) is used for adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
Gocovri (amantadine ER) – Medicare	TBD	New policy created to ensure appropriate use in patients with Parkinson's dyskinesia who are on concomitant levidopa-based therapy, and require demonstration of trial and failure, or intolerance, to immediate release amantadine
Lyrica CR (pregabalin ER) – Medicare	TBD	Policy revised to add pregabalin (Lyrica) CR and require step through pregabalin (Lyrica) immediate release for the treatment of diabetic peripheral neuropathy or post-herpetic neuralgia.
Xuriden (uridine triacetate) – Medicare	11/15/2017	The policy was enhanced to require the demonstration of megaloblastic anemia which is unresponsive to iron, folic acid, or Vitamin B-12, and to show that the member has elevated urinary orotic acid levels.
Kalydeco (ivacaftor) – Medicare	11/15/2017	Policy revised to include the expanded indication of additional 5 splice mutation in the CFTR gene for the treatment of cystic fibrosis. Commercial and Healthcare Reform lines of business were removed to their own policy.
Exondys 51 (eteplirsen) – Medicare	01/01/2018	Policy revised to meet CMS requirement to remove upper limit age restriction of 18 years.
Ingrezza (valbenazine) – Medicare	01/01/2018	Policy revised to remove provider restriction of neurologist.
Natpara (parathyroid hormone) – Medicare	01/01/2018	Policy revised to meet CMS requirement to remove non-Medicare Part D requirements of adjunctive treatment with Calcium and Vitamin D in patients with hypoparathyroidism.
Regranex (becaplermin) – Medicare	01/01/2018	Policy revised to clarify language with respect to provision of a wound care plan. Language updated from "documentation of" to "attestation of."
Kuvan (sapropterin) – Medicare	01/01/2018	Policy revised to lessen restrictions on reauthorization criteria. Authorization of maintenance therapy only requires attestation supporting improvement in blood phenylalanine (Phe) levels from baseline.
PCSK9 Inhibitors –Medicare	TBD	Policy revised to enhance statin intolerance language to permit coverage for patients experiencing a serious statin-associated

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		adverse event during any course of statin therapy. The baseline requirement for LDL in atherosclerotic cardiovascular disease (ASCVD) was lowered to ≥70 mg/dL (previously ≥100 mg/dL) after the patient has attempted previous statin therapy.
Administrative Prior Authorization for Medicare Part D Plans	01/01/2018	Policy revised to add cinacalcet (Sensipar) to the Part B versus Part D review list for members with active ESRD status.
Amjevita (adalimumab-atto) and Cyltezo (adalimumab-adbm) Biosimilar – Medicare	TBD	Policy revised to include adalimumab-adbm (Cyltezo) for the treatment of: • Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Adult Crohn's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)
Pulmonary Hypertension – Medicare Only	01/01/2018	Policy revised to include additional criteria for newly approved bosentan (Tracleer) oral dispersible tablets for the pediatric population. Changes to the background section, including new safety considerations and prescribing considerations were also made. Lastly, WHO/NYHA functional classifications were removed based on feedback from CMS.
Benlysta (belimumab) – Medicare	TBD	Policy revised to align with Medical policy criteria for belimumab (Benlysta) IV. Criteria outline titer values for anti-nuclear antibody (ANA) (≥1:80) and anti-double-strand DNA antibody (≥30 IU/mL). Additionally, individuals should demonstrate insufficient response to two standard of care drug classes (corticosteroids, antimalarials, immunosuppressives), and continue to receive concomitant standard of care for the treatment of systemic lupus erythematosus (SLE) while utilizing belimumab (Benlysta).
Programmed Death Receptor Therapies – Medicare	TBD	Policy revised to include coverage for expanded indications of pembrolizumab (Keytruda) and nivolumab (Opdivo).

*All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program *

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
None		

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

3. Formulary Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
General Non-Formulary Request Criteria	01/01/2018	Addition of language clarifying that payer edits (i.e. BvD and AvD) should be resolved as part of Approval Criteria applying to the definition of a Part D drug.

*All effective dates are tentative and subject to delay pending internal review or approval.

4. Quantity Level Limit (QLL) Program*

(Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.)

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Qvar Redihaler 40 mcg	10.6 gm per 30 days	31.8 gm per 90 days
Qvar Redihaler 80 mcg	21.2 gm per 30 days	63.6 gm per 90 days
Duzallo all strengths	31 tablets per 31 days	93 tablets per 93 days
Lynparza tablets 100, 150 mg	124 tablets per 31 days	372 tablets per 93 days
Cyltezo prefilled syringe 40 mg/0.8ml	2 syringes per 28 days	6 syringes per 84 days
Xuriden 2g	248 gm per 31 days	720 gm per 90 days
Tracleer (bosentan) ODT 32mg	120 oral dispersible tablets per 30 days	360 oral dispersible tablets per 90 days
Xhance (fluticasone propionate) 93 mcg	16 ml per 30 days	48 ml per 90 days
Solosec (secnidazole) 2 g	2 g per 30 days	--
Zilretta (triamcinolone extended release) 32 mg/5 ml	2 syringes (1 injection/knee) per 30 days	--
Trelegy Ellipta all strengths	60 blisters per 30 days	180 blisters per 90 days
Gocovri (amantadine ER) 68.5 mg and 137 mg	60 capsules per 30 days	180 capsules per 90 days
Verzenio (abemaciclib) 50 mg, 100 mg, 150 mg, and 200 mg	56 tablets per 28 days	168 tablets per 84 days
Calquence (acalabrutinib) 100 mg	56 tablets per 28 days	168 tablets per 84 days
Uptravi (selexipag) 200 mcg	240 tablets per 30 days	720 tablets per 90 days
Bydureon BCise (exenatide ER) all strengths	4 auto-injectors per 28 days	12 auto-injectors per 84 days
Zytiga 500 mg*	62 tablets per 31 days	186 tablets per 93 days
Rayaldee 300 mcg*	31 extended release 24hr capsules per 31 days	93 extended release 24hr capsules per 93 days
Idhifa 100 mg*	31 tablets per 31 days	93 tablets per 93 days
Idhifa 50 mg*	62 tablets per 31 days	186 tablets per 93 days
Armonair Respiclick 113 mcg*	1 aerosol powder, breath activated (EA) per 30 days	3 aerosol powder, breath activated (EA) per 90 days
Armonair Respiclick 232 mcg*	1 aerosol powder, breath activated (EA) per 30 days	3 aerosol powder, breath activated (EA) per 90 days
Armonair Respiclick 55 mcg*	1 aerosol powder, breath activated (EA) per 30 days	3 aerosol powder, breath activated (EA) per 90 days
Mavyret 100mg-40mg*	84 tablets per 28 days	252 tablets per 84 days

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Nerlynx 40 mg*	186 tablets per 31 days	558 tablets per 93 days
Lynparza 100 mg*	124 tablets per 31 days	372 tablets per 31 days
Lynparza 150 mg*	124 tablets per 31 days	372 tablets per 31 days
Vosevi 400-100 mg*	28 tablets per 28 days	84 tablets per 84 days

All products listed Effective 1Q2018; *Effective November 1, 2017.

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