SPECIAL eBULLETIN

JULY 2019

THIRD QUARTER 2019 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Third Quarter 2019 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 May 2019 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 Program/Formularies link from the menu on the left.

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Important Drug Safety Updates

Update Health Professional and Consumer on Recent Recalled Products Due to Detection of Probable Human Carcinogen Impurities and Increased Risk of Cancer

As part of an ongoing investigation into the voluntary recall of products due to the detection of probable human carcinogen impurities and increased risk of cancer, there were six additional voluntary recalls. Health care professionals should be aware that the recalled products pose an unnecessary risk to patients.

Pharmacists and physicians may direct patients to alternative treatment prior to returning to their medications. Physicians should evaluate the risk versus the benefit if treatment is stopped immediately, as stopping treatment immediately without alternative treatment may lead to a higher risk of harm to the patient's health.

The additional products that have been recalled due to the impurities are listed below. Not all products from all the manufacturers are recalled. Patients and physicians should check the FDA website to see if the lot number of their medication has been included in the recall.

Manufacturer	Recalled Drugs	Detected Impurity
Legacy Pharmaceutical Packaging, LLC 3	Losartan potassium tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)
Torrent Pharmaceuticals Limited	Losartan potassium tablets and Losartan potassium/HCTZ tablets	N-Methylnitrosobutyric acid (NMBA)
Teva Pharmaceuticals USA, Inc.	Losartan potassium tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)
Heritage Pharmaceuticals Inc.	Losartan potassium tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)

Uloric (febuxostat) Gout Medicine: Drug Safety Communication – Increased Risk of Death

On February 21, 2019, the FDA announced an increased risk of heart-related death with Uloric (febuxostat) compared to another gout medicine, allopurinol. As a result, the FDA is updating the Uloric prescribing information to require a *Boxed Warning* and a new patient Medication Guide, as well as limiting the approved use of Uloric to certain patients who are not treated effectively, or experience severe side effects, with allopurinol. Health care professionals should reserve Uloric for use only in patients who have failed or do not tolerate allopurinol, counsel patients about the cardiovascular risk with Uloric, and advise them to seek immediate medical attention if they experience heart-related symptoms while taking Uloric.

Higher Dose of Tofacitinib (Xeljanz, Xeljanz XR) in Rheumatoid Arthritis Patients: Drug Safety Communication - Increased Risk of Blood Clots

On February 25, 2019, the FDA announced that a safety clinical trial found an increased risk of blood clots in the lungs and death when a 10 mg twice daily dose of tofacitinib was used in patients with rheumatoid arthritis (RA). The FDA has not approved a 10 mg twice daily dose for RA. This dose is only approved in the dosing regimen for patients with ulcerative colitis. In the

ongoing safety trial, patients who were on the 10 mg twice daily dose are being transitioned to the currently approved dose of 5 mg twice daily. The trial is expected to be completed by the end of 2019. Health care professionals should follow the recommendations in the tofacitinib prescribing information for the specific condition they are treating, monitor patients for the signs and symptoms of pulmonary embolism, and advise them to seek immediate medical attention if they experience them.

Opioid Pain Medicines: Drug Safety Communication – Serious Patient Harm Due to Sudden Discontinuation of Medicine

On April 9, 2019, the FDA announced that serious harm, such as serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide, has been reported when patients who are physically dependent on opioid pain medicines suddenly have these medicines discontinued or their dose rapidly decreased. As a result, the FDA is requiring changes to the prescribing information for these medicines intended for use in an outpatient setting which will provide expanded guidance to health care professionals on how to safely decrease the dose in physically-dependent patients when the dose is to be decreased or the medicine is to be discontinued.

Fentanyl Transdermal System by Alvogen, Inc.: Recall – Product Mislabeling

On April 21, 2019, Alvogen, Inc., announced a voluntary recall of two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level. A small number of cartons labeled 12 mcg/h Fentanyl Transdermal System patches contained 50 mcg/h patches. The affected Fentanyl Transdermal System lots include Lot 180060 (expiration 05/2020) and Lot 180073 (expiration 06/2020). As a result of the mislabeled packages, application of a 50 mcg/h patch instead of a prescribed 12 mcg/h patch could result in serious, life threatening, or fatal respiratory depression.

Prescription Insomnia Medicines: Drug Safety Communication – Boxed Warning for Risk of Serious Injuries Caused by Sleepwalking

On April 30, 2019, the FDA advised that rare but serious injuries and deaths have occurred with certain common prescription insomnia medicines, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These behaviors appear to be more common with eszopiclone, zaleplon, and zolpidem. As a result, the FDA is requiring a *Boxed Warning* to be added to the prescribing information and the patient Medication Guides, along with a *Contraindication* to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem. Healthcare professionals should not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medicines. Patients should be told to discontinue taking these medicines if they experience an episode of complex sleep behavior.

Promacta 12.5 mg for Oral Suspension by Novartis: Recall – Potential Peanut Contamination

On May 11, 2019, Novartis issued a voluntary recall of three lots of Promacta (eltromobopag) 12.5 mg for oral suspension to the consumer level. The oral suspension lots are being recalled because of a risk of potential peanut flour contamination. The affected Promacta includes products with NDC Number 0078-0972-61 (carton) or 0078-0972-19 (packet), Lot Number 8H57901589 with Expiration Date 09/2020, Lot Number 9H57900189 with Expiration Date 12/2020, and Lot Number 9H57900289 with Expiration Date 12/2020. This contamination can result in hypersensitivity reaction in patients with a known or unknown sensitivity to peanut antigen, including a medically significant anaphylactic reaction, which can be fatal.

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 – July 2019

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 medication protocols and improve the overall health of our members.

Table 1. Products Added
(Effective date of products added to the formulary to be determined.)

Brand Name	Generic Name	Comments
Tremfya One-Press	guselkumab	New patient-controlled injector formulation of guselkumab for the treatment of adult patients with moderate-to-severe plaque psoriasis
Dovato	dolutegravir/lamivudine	Self-administered integrase inhibitor (INSTI)/nucleoside reverse transcriptase inhibitor (NRTI) given orally for treatment of human immunodeficiency virus type-1(HIV-1) infection in treatment naïve adults
Skyrizi	risankizumab-rzaa	Third FDA-approved IL-23 antagonist after Ilumya (tildrakizumab-asmn) and Tremfya (guselkumab) for the treatment of adult patients with moderate-to-severe plaque psoriasis
Aemcolo	rifamycin	Treatment of Travelers' Diarrhea caused by noninvasive strains of *E. coli* in adults

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Tosymra*	sumatriptan	sumatriptan nasal spray
Evekeo ODT*	amphetamine sulfate	methylphenidate oral solution, dextroamphetamine-amphetamine

Brand Name	Generic Name	Preferred Alternatives
Gloperba*	colchicine	Colcrys
Lotemax SM	loteprednol etabonate	dexamethasone eye drops, prednisolone eye drops
Adhansia XR*	methylphenidate ER	methylphenidate HCL ER, dextroamphetamine ER
Rocklatan	netarsudil/latanoprost	latanoprost 0.005% eye drops, timolol 0.25% eye drops
Zykadia tablets	ceritinib	Xalkori
Sunosi*	solriamfetol	modafinil
Mayzent	siponimod	glatiramer, Gilenya
Mavenclad	cladribine	glatiramer, Gilenya
Jatenzo*	testosterone undecanoate	testosterone gel in packet, testosterone cypionate, testosterone enanthate
Duaklir Pressair*	aclidinium/formoterol	Anoro Ellipta, Stiolto Respimat
Zelnorm*	tegaserod	Amitiza, Linzess
Avaclyr ophthalmic ointment*	acyclovir	trifluridine 1% eye drops
Welchol chewable bars*	colesevelam	cholestyramine, colestipol
Evenity	romosozumab-aqqg	Tymlos
Cablivi	caplacizumab-yhdp	Provider discretion
Egaten*	triclabendazole	Provider discretion
Balversa	erdafitinib	Provider discretion

Coverage may be contingent upon plan benefits.
*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 Healthcare Reform members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware Healthcare Reform members.

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

Brand Name	Generic Name
Tremfya One-Press	guselkumab
Cablivi	caplacizumab-yhdp
Zykadia tablets	ceritinib
Mayzent	siponimod
Mavenclad	cladribine
Evenity	romosozumab-aqqg
Skyrizi	risankizumab-rzaa
Balversa	erdafitinib

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

Note: The Progressive Formulary does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** 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 Healthcare Reform Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)

Table 1. Formulary Updates (Effective date of products added to the formulary to be determined.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Dovato	dolutegravir/lamivudine	2 – Preferred brand	Self-administered INSTI/NRTI given orally for treatment of HIV-1 infection in treatment naïve adults
Aemcolo	rifamycin	2 – Preferred brand	Treatment of Travelers' Diarrhea caused by noninvasive strains of *E. coli* in adults
Tremfya One-Press	guselkumab	3 – Preferred specialty	New patient-controlled injector formulation of guselkumab for the treatment of adult patients with moderate-to-severe plaque psoriasis
Skyrizi	risankizumab-rzaa	3 – Preferred specialty	Third FDA-approved IL-23 antagonist after Ilumya (tildrakizumab-asmn) and Tremfya (guselkumab) for the treatment of adult patients with moderate-to-severe plaque psoriasis
Items listed below are non-preferred products			
Jatenzo*	testosterone undecanoate	3 – Non-preferred brand	testosterone gel in packet, testosterone cypionate, testosterone enanthate
Duaklir Pressair*	aclidinium/formoterol	3 – Non-preferred brand	Anoro Ellipta, Stiolto Respimat
Tosymra*	sumatriptan	3 – Non-preferred brand	sumatriptan nasal spray† rizatriptan ODT, sumatriptan tablet‡
Evekeo ODT*	amphetamine sulfate	3 – Non-preferred brand	methylphenidate oral solution, dexmethylphenidate
Gloperba*	colchicine	3 – Non-preferred brand	Colcrys
Avaclyr ophthalmic ointment*	acyclovir	3 – Non-preferred brand	trifluridine 1% eye drops

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Welchol chewable bars*	colesevelam	3 – Non-preferred brand	colestipol
Lotemax SM	loteprednol etabonate	3 – Non-preferred brand	dexamethasone eye drops, prednisolone eye drops
Adhansia XR*	methylphenidate ER	3 – Non-preferred brand	methylphenidate HCL ER, dextroamphetamine-amphetamine ER
Rocklatan	netarsudil/latanoprost	3 – Non-preferred brand	latanoprost 0.005% eye drops, timolol 0.25% eye drops
Sunosi*	solriamfetol	3 – Non-preferred brand	modafinil, armodafinil
Egaten*	triclabendazole	3 – Non-preferred brand	Provider discretion
Zelnorm*	tegaserod	3 – Non-preferred brand	Provider discretion
Mavenclad	cladribine	4 – Non-preferred specialty	glatiramer, Gilenya
Mayzent	siponimod	4 – Non-preferred specialty	glatiramer, Gilenya
Evenity	romosozumab-aqqg	4 – Non-preferred specialty	Tymlos
Zykadia tablets	ceritinib	4 – Non-preferred specialty	Xalkori
Cablivi	caplacizumab-yhdp	4 – Non-preferred specialty	Provider discretion
Balversa	erdafinitib	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.
† Preferred product for Commercial Progressive Formulary.
‡ Preferred product for Progressive Healthcare Reform Formulary.

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
(Effective date of formulary changes to be determined.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Dovato	dolutegravir/lamivudine	3	Self-administered INSTI/NRTI given orally for treatment of HIV-1 infection in treatment naïve adults
Aemcolo	rifamycin	3	Treatment of Travelers' Diarrhea caused by noninvasive strains of *E. coli* in adults
Tremfya One-Press	guselkumab	4	New patient-controlled injector formulation of guselkumab for the treatment of adult patients with moderate-to-severe plaque psoriasis
Zykadia tablets	ceritinib	4	New tablet form of Zykadia, indicated for the treatment of adults with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
Skyrizi	risankizumab-rzaa	4	Third FDA-approved IL-23 antagonist after Ilumya (tildrakizumab-asmn) and Tremfya (guselkumab) for the treatment of adult patients with moderate-to-severe plaque psoriasis
Items listed below were not added to the formulary			
Jatenzo*	testosterone undecanoate	NF	testosterone cypionate, testosterone enanthate, testosterone gel packet
Mavenclad	cladribine	NF	glatiramer, Gilenya
Duaklir Pressair*	aclidinium/formoterol	NF	Anoro Ellipta, Stiolto Respimat
Zelnorm*	tegaserod	NF	Amitiza, Linzess
Avaclyr ophthalmic ointment*	acyclovir	NF	trifluridine 1% eye drops
Welchol chewable bars*	colesevelam	NF	colesevelam, cholestyramine, colestipol
Evenity	romosozumab-aqqg	NF	Prolia, Tymlos
Sunosi*	solriamfetol	NF	modafinil, armodafinil
Mayzent	siponimod	NF	generic glatiramer, Gilenya
Tosymra*	sumatriptan	NF	zolmitriptan ODT, rizatriptan ODT, sumatriptan tablet
Evekeo ODT*	amphetamine sulfate	NF	dexmethylphenidate, methylphenidate oral solution
Gloperba*	colchicine	NF	colchicine tablets, colchicine capsules

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Lotemax SM	loteprednol etabonate	NF	dexamethasone eye drops, prednisolone eye drops
Adhansia XR*	methylphenidate ER	NF	methylphenidate HCl ER, dextroamphetamine-amphetamine ERr
Rocklatan	netarsudil/latanoprost	NF	latanoprost 0.005% eye drops, timolol 0.25% eye drops
Balversa	erdafitinib	NF	Provider discretion
Cablivi	caplacizumab-yhdp	NF	Provider discretion
Egaten*	triclabendazole	NF	Provider discretion

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

D. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=3442182690.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Cablivi	caplacizumab-yhdp	2	Adjunct to treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in adults
Lotemax SM	loteprednol etabonate	2	New gel formulation of loteprednol for the treatment of post-operative inflammation and pain following ocular surgery
Tremfya One-Press	guselkumab	2	New patient-controlled injector formulation of guselkumab for the treatment of adult patients with moderate-to-severe plaque psoriasis
Skyrizi	risankizumb-rzaa	2	Third FDA-approved IL-23 antagonist after Ilumya (tildrakizumab-asmn) and Tremfya (guselkumab) for the treatment of adult patients with moderate-to-severe plaque psoriasis
Zykadia tablets	ceritinib	2	New tablet form of Zykadia, indicated for the treatment of adults with metastatic NSCLC whose tumors are ALK-positive as detected by an FDA-approved test.
Dovato	dolutegravir/lamivudine	2	Self-administered INSTI/NRTI given orally for treatment of HIV-1 infection in treatment naïve adults
Balversa	erdafitinib	2	Provider discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (non-preferred)			
Evekeo ODT*	amphetamine sulfate	3	methylphenidate oral solution, dextroamphetamine-amphetamine
Evenity*	romosozumab-aqqg	3	Tymlos, Forteo
Mavenclad*	cladribine	3	glatiramer, Gilenya
Mayzent*	siponimod	3	glatiramer, Gilenya
Rocklatan*	netarsudil/latanoprost	3	latanoprost 0.005% eye drops, timolol 0.25% eye drops
Adhansia XR*	methylphenidate ER	3	methylphenidate HCL ER, dextroamphetamine ER
Avaclyr ophthalmic ointment*	acyclovir	3	trifluridine 1% eye drops
Duaklir Pressair*	aclidinium/formoterol	3	Anoro Ellipta, Bevespi Aerosphere
Egaten*	triclabendazole	3	Provider discretion
Gloperba*	colchicine	3	Colcrys
Jatenzo*	testosterone undecanoate	3	testosterone gel in packet, testosterone cypionate, testosterone enanthate
Sunosi*	solriamfetol	3	modafinil
Tosymra*	sumatriptan	3	sumatriptan nasal spray
Welchol chewable bars*	colesevelam	3	cholestyramine, colestipol
Zelnorm*	tegaserod	3	Amitiza, Linzess, Trulance

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

Table 2. Additions to the Specialty Tier Copay Option
(Effective upon completion of internal review and implementation, unless otherwise noted.)

Brand Name	Generic Name
Tremfya One-Press	guselkumab
Cablivi	caplacizumab-yhdp
Zykadia tablets	ceritinib
Mayzent	siponimod
Mavenclad	cladribine
Evenity	romosozumab-aqqg
Skyrizi	risankizumab-rzaa
Balversa	erdafitinib

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Cablivi (caplacizumab-yhdp) – Commercial and Healthcare Reform	06/10/19	New policy to ensure use of caplacizumab-yhdp (Cablivi) in adult patients with acquired thrombotic thrombocytopenic purpura, in conjunction with plasma exchange and immunosuppressive therapy.
CDKi Kinase Inhibitors – Commercial and Healthcare Reform	05/02/2019	Policy updated with expanded indications for palbociclib (Ibrance).
CDKi Kinase Inhibitors – Commercial and Healthcare Reform	TBD	Policy updated to implement preference of either abemaciclib (Verzenio) or palbociclib (Ibrance). Coverage of ribociclib (Kisqali) may be covered if the patient is not a candidate for therapy with abemaciclib (Verzenio) or palbociclib (Ibrance).
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	05/24/2019	• Policy revised to include newly FDA-approved agent of risankizumab (Skyrizi) as another preferred product for plaque psoriasis. • Policy revised to make guselkumab (Tremfya) a preferred product for plaque psoriasis and to include exception criteria for pregnant patients to ensure that pregnant patients are not required to step through two immunosuppressants for Crohn's disease or ulcerative colitis based on a guideline update. • Policy revised to include expanded indication of non-radiographic axial spondyloarthritis (nr-axSpA) for certolizumab (Cimzia) following failure of two nonsteroidal anti-inflammatory drugs (NSAIDs).
Coverage Outside Contract Parameters – Commercial and Healthcare Reform	05/02/2019	Policy revised to include additional drug/class and therapy exclusions.
Cuvposa (glycopyrrolate) oral solution – Commercial	TBD	New policy created to promote appropriate use in patients aged 3-16 years with neurologic conditions associated with problem drooling.
Dibenzyline (phenoxybenzamine) – Commercial	TBD	New policy created for phenoxybenzamine (Dibenzyline), mirroring Healthcare Reform (HCR) criteria. Requires a diagnosis of pheochromocytoma substantiated by lab values or computed tomography scan (CT scan), and trial and failure of alpha-adrenergic agonist (doxazosin, prazosin or terazosin).
Dibenzyline (phenoxybenzamine) – Healthcare Reform	05/31/2019	Updated approval criteria to include up to date diagnostic criteria and reauthorization criteria.
Dificid (fidaxomicin) – Commercial	TBD	Created new policy for commercial line of business.
Dupixent (dupilumab) – Commercial and Healthcare Reform	05/02/2019	Policy revised to cover members 12 years of age and older with atopic dermatitis.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Efudex, Zyclara, and Aldara – Commercial	TBD	• New policy created to ensure appropriate use of fluorouracil (Efudex), imiquimod (Zyclara and Aldara) in members who have actinic keratosis, external genital warts, or superficial basal cell carcinoma. • For actinic keratosis member must experience therapeutic failure to 2 of the following agents: generic imiquimod 5% cream, generic fluorouracil 5% topical cream, and generic fluorouracil topical solution. • For external genital warts, member must be 12 years of age or older and have experienced therapeutic failure to generic imiquimod cream. • For superficial basal cell carcinoma, member has experienced therapeutic failure to all of the following agents: generic imiquimod 5% cream and generic fluorouracil 5% topical cream or solution.
Efudex, Zyclara, and Aldara – Healthcare Reform	05/31/2019	Policy revised to include age criteria of 12 years of age or older for use in external genital warts. Addition of superficial basal cell carcinoma criteria to ensure appropriate use in members who have experienced therapeutic failure to generic imiquimod 5% cream and generic fluorouracil 5% topical cream or solution.
Egaten (triclabendazole) – Commercial and Healthcare Reform	Best Date	New policy created for triclabendazole (Egaten) which ensures appropriate age and diagnosis.
Evekeo (amphetamine sulfate) – Healthcare Reform	Best Date	Policy revised to add new formulation, orally disintegrating tablet (ODT tablets), under drug products as well as FDA-approved indication for ODT tablets, initial authorization and reauthorization criteria.
Evoxac (cevimeline) – Commercial	TBD	New policy created to ensure appropriate use of cevimeline (Evoxac) in members with dry mouth symptoms due to Sjogren's Syndrome. Step through generic cevimeline before obtaining cevimeline (Evoxac). Reauthorization criteria attesting clinical response to therapy.
Evoxac (cevimeline) – Healthcare Reform	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Fertility – Commercial	07/01/2019	Policy revised to remove criteria for Healthcare Reform plans from Commercial plans and to require trial and failure of follitropin beta (Follistim AQ) for approval of follitropin alfa (Gonal-F).
Fertility – Commercial NSF	07/01/2019	New policy created to separate National Select Formulary criteria from the criteria for the Commercial plans.
FGFR Kinase Inhibitors – Commercial and Healthcare Reform	06/10/2019	New Fibroblast Growth Factor Receptor-Targeting (FGFR) Kinase Inhibitor policy created for erdafitinib (Balversa) to be approved for locally advanced or metastatic urothelial carcinoma with FGFR3 or FGFR2 genetic mutation and disease progression during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Hepatitis C Oral Agents – Commercial and Healthcare Reform	07/01/2019	Policy revised to note excluding plans with the Commercial Core formulary.
Hepatitis C Oral Therapy – Commercial Core	07/01/2019	New policy created to prefer only ledipasvir/sofosbuvir (Harvoni AG), sofosbuvir/velpatasvir (Epclusa AG), and glecaprevir/pibrentasvir (Mavyret).
Hereditary Angioedema – Commercial and Healthcare Reform	05/31/2019	Policy revised to require trial and failure of antihistamines in patients with Hereditary angioedema (HAE) type III, to remove the requirement of having family history or a mutation for medications to be approved for HAE type III, and to remove the requirement for the documentation of weight in medications that do not require weight-based dosing. Reauthorization criteria were added to ensure that patients require additional therapy for Hereditary angioedema and that patients are not taking two acute medications simultaneously.
Human Growth Hormone – Commercial and Healthcare Reform, and Delaware Commercial and Healthcare Reform	05/02/2019	Policy revised to outline preferred growth hormone products by formulary in table 1. Documented trial and failure of all of the preferred growth hormone products is required prior to coverage of a non-preferred product. Policy revised to only require bone age for reauthorization in males greater than or equal to 16 years of age and females greater than or equal to 14 years of age.
Inbrija (levodopa) – Commercial and Healthcare Reform	05/31/2019	Policy revised to remove the requirement for members to try and fail two alternative therapies or be unable to swallow tablets. Members must be experiencing at least 2 hours of off episodes per day.
Hedgehog Pathway Inhibitors – Commercial and Healthcare Reform	05/02/2019	Policy revised to reflect 2 year authorization duration for all vismodegib (Erivedge), sonidegib (Odomzo), and glasdegib (Daurismo).
Lonsurf (trifluridine-tipiracil) – Commercial and Healthcare Reform	05/02/2019	Policy revised to include new indication of metastatic gastric or gastroesophageal junction adenocarcinoma.
Loprox (ciclopirox 1% shampoo) – Commercial	TBD	New policy created for ciclopirox 1% shampoo (Loprox), mirroring HCR criteria. Policy requires diagnosis of seborrheic dermatitis of the scalp and trial and failure of at least 2 generic topical antifungals. Policy includes reauthorization criteria that prescriber attests that the member has previously experienced a therapeutic response with ciclopirox 1% shampoo (Loprox) for the same condition.
Market Watch Programs – Delaware, PA, and WV	05/02/2019	Policy revised to include newly launched High Cost Low Value drugs itraconazole (Tolsura), meloxicam orally disintegrating tablet (Qmiiz ODT), cyclobenzaprine extended release (ER) and chlorzoxazone 375 & 750 mg with alternatives.
Mavenclad (cladribine) – Commercial and Healthcare Reform	05/15/2019	New policy created to ensure appropriate use of cladribine (Mavenclad) in members with a relapsing form of multiple sclerosis (MS) who have tried and failed at least one other therapy for the treatment of MS.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Mayzent (siponimod) – Commercial and Healthcare Reform	05/02/2019	New policy created to ensure appropriate use of siponimod (Mayzent) in members with a relapsing form of multiple sclerosis.
Naproxen and Fenoprofen Containing Products – Commercial and Healthcare Reform	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Nityr and Orfadin (nitisinone) – Commercial and Healthcare Reform	05/31/2019	• Policy revised to include diagnosis of hereditary tyrosinemia type I (HT-1) confirmed by biochemical and/or genetic testing. • The member is following a diet restricted in tyrosine and phenylalanine. • The member has experienced therapeutic failure or intolerance to nitisinone (Nityr) to receive nitisinone (Orfadin). • For nitisinone (Orfadin) suspension, the prescriber attests that the member has an inability to swallow tablets and capsules. • Reauthorization criteria attesting clinical response to therapy.
Nityr and Orfadin (nitisinone) – Commercial National Select	05/31/2019	Policy revised to include attestation that the member has an inability to swallow tablets and capsules. Reauthorization criteria attesting clinical response to therapy.
Nityr and Orfadin (nitisinone) – Healthcare Reform	05/02/2019	Policy terminated. Healthcare reform combined with Commercial policy J-478 as both policies contained the same criteria.
Noxafil (posaconazole) – Commercial	TBD	New policy created for posaconazole (Noxafil), mirroring HCR criteria. Policy requires use for an FDA approved diagnosis and trial and failure of at least 2 generic alternatives.
Parathyroid Hormone Analogs – Commercial, Commercial NSF, and Healthcare Reform	05/31/2019	Policy revised to categorize members with previous hip or vertebral fracture as high risk. Clarified that Fracture Risk Assessment Tool (FRAX) score can be interpreted in treated patients.
PCSK9 Inhibitors – Commercial and Healthcare Reform	05/02/2019	Policy revised to include expanded indication for alirocumab (Praluent) for prevention of cardiovascular events and treatment of primary hyperlipidemia. Included alirocumab (Praluent) in criteria for primary hyperlipidemia not associated with Atherosclerotic Cardiovascular Disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH).
Prolia (denosumab) and Evenity (romosozumab-aqqg) – Commercial and Healthcare Reform	06/10/2019	• Policy revised to include criteria for romosozumab-aqqg (Evenity) requiring the member to be a post-menopausal woman at high risk of fracture and to have tried and failed a bisphosphonate. • Policy revised to categorize members with previous hip or vertebral fracture as high risk. • Policy revised to categorize members age 50 years or older with osteopenia and history of 5 mg/day prednisone (or equivalent) as high risk.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		• Clarified that FRAX score can be interpreted in treated patients.
Pulmonary Hypertension – Commercial and Healthcare Reform	05/02/2019	Policy revised to move statement that other causes of pulmonary hypertension has been ruled out to limitations of coverage. Combined bosentan (Tracleer) tablets and ODT into one authorization criteria, and condensed reauthorization criteria to attesting clinical response to therapy.
Relistor (methylnaltrexone bromide) – Commercial	05/31/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy. Policy revised to include an additional step through naldemedine (Symproic).
Relistor (methylnaltrexone bromide) – Healthcare Reform	05/31/2019	• Policy revised to include the 2019 American Gastroenterological Association (AGA) Opioid-Induced Constipation (OIC) guidelines in the Background section. • Policy revised to include reauthorization criteria that prescriber attests the member has experienced positive clinical response to therapy. • Policy revised to include an additional step through naldemedine (Symproic).
Sabril and Vigadrone (vigabatrin) – Healthcare Reform	05/02/2019	Policy revised to include vigabatrin (Vigadrone). Additionally, members will be required to try and fail two alternative anticonvulsants for the treatment of complex partial seizures prior to approval.
Spleen Tyrosine Kinase Inhibitors – Commercial	05/31/2019	Policy revised to add reauthorization criteria.
Spleen Tyrosine Kinase Inhibitors – Healthcare Reform	05/31/2019	Policy revised to add reauthorization criteria.
Sucraid (sacrosidase) – Commercial	TBD	New policy created to ensure appropriate use of sacrosidase (Sucraid) in members 5 months of age or older with congenital sucrase-isomaltase deficiency (CSID) supported by one of the following: small bowel biopsy, stool pH, breath hydrogen, lactose breath test, or one week trial with improved clinical response. Reauthorization criteria attesting clinical response to therapy.
Sucraid (sacrosidase) – Healthcare Reform	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Sunosi (solriamfetol) – Commercial and Healthcare Reform	Best Date	Policy requires documentation of either narcolepsy or obstructive sleep apnea, if obstructive sleep apnea (OSA), requires continuous positive airway pressure (CPAP) use, and for both diagnoses, t/f of both modafinil and armodafinil.
Synarel (nafarelin) – Commercial	TBD	New policy created for nafarelin (Synarel), mirroring HCR criteria. Policy requires use in consultation with an endocrinologist, diagnosis of central precocious puberty substantiated by lab values and symptoms or diagnosis of endometriosis.
Tegsedi (inotersen) – Commercial and Healthcare Reform	03/22/2019	Policy revised to remove the requirement for completion of biopsy or electrophysiological tests to support the diagnosis of hereditary

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		transthyretin (TTR) amyloidosis and attestation that the member has not received a liver transplant.
Testosterone (Androgens) – Commercial	Best Date	Policy revised to include testosterone undecanoate (Jatenzo) to targeted drug list
Testosterone (Androgens) – Healthcare Reform	Best Date	Policy revised to remove testosterone products that are no longer on the market and to add testosterone undecanoate (Jatenzo) to targeted drug list.
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial and Healthcare Reform	05/31/2019	Policy revised to update the step through a "non-fluorinated topical corticosteroid" to a step through a "topical corticosteroid."
Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Commercial and Healthcare Reform	05/02/2019	Policy revised to remove the requirement for trial and failure of sodium polystyrene sulfonate for approval of patiromer (Veltassa) or sodium zirconium cyclosilicate (Lokelma). The criteria for serum potassium levels was updated from between 5.1 mmol/L and 6.4 mmol/L to between 5.1 mmol/L and 7.4 mmol/L.
Welchol (colesevelam) chewable bars – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of colesevelam (Welchol) chewable bars in members with hyperlipidemia, HeFH, or type 2 diabetes. The member must have experienced therapeutic failure or intolerance to generic colesevelam tablets. For hyperlipidemia the member has tried 1 other bile acid sequestrant and 1 other preferred generic statin. For HeFH the member has tried and failed 1 other preferred generic statin. For type 2 diabetes the member must have tried and failed 2 preferred antidiabetic agents. Reauthorization criteria attesting clinical response to therapy.
Mucosal Agents – Commercial	07/01/2019	New policy created to require prior authorization for all mucosal agents. For supersaturated calcium phosphate rinse (Neutrasal) and (SalivaMax), require failure of one product from at least 3 therapeutic categories, one of which must be (Caphosol).
Mucosal Agents – Healthcare Reform	07/01/2019	Policy revised to mirror new Commercial policy: added bioadhesive film spray (Episil), bioadherent oral rinse gel (GelX), supersaturated calcium phosphate rinse (SalivaMax) and oxygenated glycerol triesters (Xerostomia Relief). For supersaturated calcium phosphate rinse (Neutrasal) and (SalivaMax), require failure of one product from at least 3 therapeutic categories, one of which must be (Caphosol).

*For policies that require step therapy, an exception may be made for commercial and HCR members enrolled in a West Virginia plan. For additional details, refer to pharmacy policy bulletin J-513 (West Virginia – Step Therapy Override Exception).

**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
Absorica (isotretinoin) – Healthcare Reform	05/02/2019	Policy revised to include criteria that the member is 12 years of age or older.
Acute Migraine Therapies – Commercial	Best Date	Policy revised to include sumatriptan (Tosymra) nasal spray as a targeted drug.
Adhansia XR (methylphenidate hydrochloride) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of methylphenidate (Adhansia XR) for the treatment of attention deficit hyperactivity disorder (ADHD) in patients who are 6 years of age or older who have tried and failed at least 2 generic alternatives.
Antimalarial Agents – Healthcare Reform	05/31/2019	Policy revised to update approval criteria to require travel dates for malaria prophylaxis.
Azilect (rasagiline) – Commercial	TBD	New policy created for rasagiline (Azilect), mirroring HCR criteria. Policy requires diagnosis of Parkinson's disease and trial and failure of generic selegiline and one additional Parkinson's disease medication. Policy includes reauthorization criteria attesting clinical response to therapy.
Brand and Extended Release Metformin – Commercial and Healthcare Reform	05/02/2019	Policy revised to decrease authorization duration from lifetime to 12 months and to remove automatic approval criteria.
Briviact (brivaracetam) – Commercial and Healthcare Reform	TBD	New policy created for brivaracetam (Briviact) requiring trial and failure of two other anticonvulsants. Members requesting the oral solution must be unable to tolerate oral tablets.
Doxycycline Products – Commercial	05/31/2019	Policy revised to include reauthorization criteria for acne treatment requiring additional courses of therapy.
Epinephrine Auto-Injectors – Commercial and Healthcare Reform	05/31/2019	Policy revised to remove epinephrine (Adrenaclick) (discontinued) and add epinephrine (Symjepi) prefilled syringe as a preferred medication.
Eucrisa (crisaborole) – Commercial Core	07/01/2019	New policy created for Commercial Core formulary, requiring diagnosis of atopic dermatitis and trial and failure of generic topical tacrolimus or pimecrolimus.
Eucrisa (crisaborole) – Commercial	07/01/2019	Policy revised to note excluding plans with the Commercial Core formulary.
Evekeo (amphetamine sulfate) – Commercial	TBD	New policy created for amphetamine sulfate (Evekeo) tablets and new ODT formulation, mirroring Healthcare Reform (HCR) criteria. Policy requires trial and failure of 2 generic alternatives for diagnosis of narcolepsy or ADHD.
Extavia (interferon beta-1b) – Commercial	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy. Authorization duration updated from lifetime to 12 months. Policy also revised to note excluding plans with the Commercial Core formulary.
Gout Therapy – Commercial and Healthcare Reform	TBD	Policy revised to remove lesinurad (Zurampic) and lesinurad/allopurinol (Duzallo) (off market), and add a step through colchicine (Colcrys) tablets for other colchicine products. Colchicine (Gloperba) oral solution may be approved without trial of Colcrys if the member is unable to

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		swallow. Policy revised to ensure colchicine (Mitigare) capsules, colchicine tablets, and colchicine (Gloperba) oral solution will be used in combination with or following failure of allopurinol for prophylaxis. Revised step for febuxostat (Uloric) to allopurinol only.
Gloperba (colchicine) oral solution – Commercial and Healthcare Reform	Best Date	New policy created for colchicine oral solution (Gloperba) to be approved for prophylaxis of gout flares. Policy requires colchicine oral solution (Gloperba) to be used in combination with or following failure of allopurinol. Policy requires trial and failure of colchicine (Colcrys) tablets. Colchicine (Gloperba) oral solution may be approved without trial of colchicine (Colcrys) if the member is unable to swallow.
Herpetic Keratitis – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of acyclovir (Avaclyr) ophthalmic ointment for the treatment of acute herpetic keratitis in patients who have tried and failed trifluridine 1% eye drops.
Insomnia Medications – Healthcare Reform	05/31/2019	Policy revised to add zolpidem tartrate oral spray (Zolpimist) for 1/2020, also corrected indication for doxepin (Silenor) as well as added to FDA approved indications and revised doxepin (Silenor) criteria. Added generic names for zolpidem (Ambien), zolpidem, extended-release (Ambien CR), zolpidem tartrate sublingual tablets (Edluar) and eszopiclone (Lunesta). Specified brand only for zolpidem (Ambien), zolpidem, extended-release (Ambien CR) and eszopiclone (Lunesta). Additional information added to background for eszopiclone (Lunesta).
Lidoderm (lidocaine patch) and ZTLido (lidocaine 1.8% topical system) – Commercial and Healthcare Reform	Best Date	Policy revised to require therapeutic failure or intolerance to lidocaine patch 5% (Lidoderm) for approval and automatic approval of lidocaine patch 5% (Lidoderm) or lidocaine 1.8% topical system (ZTLido). Policy combined criteria for lidocaine patch 5% (Lidoderm) and lidocaine 1.8% topical system (ZTLido) into one policy instead of separate policies.
Lorzone (chlorzoxazone) – Commercial and Healthcare Reform	Best Date	Policy revised to add 375 mg and 750 mg generic chlorzoxazone (Lorzone) as a target. Authorization duration revised from lifetime to 6 months.
Minocin (minocycline HCl) – Commercial National Select	05/31/2019	Policy revised to ensure appropriate use of minocycline HCl (Minocin) in members with bacterial infections. Reauthorization criteria attesting the member has a bacterial infection for minocycline HCl (Minocin) or the member's acne requires additional courses of treatment.
Minocycline Products – Commercial and Healthcare Reform	05/31/2019	Policy revised to ensure appropriate use of minocycline (Minocin) in members with bacterial infections. Reauthorization criteria added to ensure that the member has a bacterial infection for minocycline (Minocin) or the member's acne requires additional courses of treatment.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Non-Preferred Benign Prostatic Hyperplasia Therapy – Commercial	Best Date	Policy revised to include dutasteride/tamsulosin (Jalyn) in the policy as a non-preferred and reauthorization criteria attesting clinical response to therapy.
Non-Preferred Benign Prostatic Hyperplasia Therapy – Healthcare Reform	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Non-Preferred Bupropion Therapy – Healthcare Reform	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Non-Preferred Erectile Dysfunction Therapy – Commercial and Healthcare Reform	05/31/2019	Policy revised to include a trial of 2 preferred erectile dysfunction medications.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists – Commercial and Healthcare Reform	07/01/2019	Policy revised to note excluding plans with the Commercial Core formulary.
Non-Preferred Nasal Steroids – Commercial	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Opioid Dependence Therapy – Commercial and Healthcare Reform	05/02/2019	Clarified that authorizations are for quantities exceeding current quantity limits (QLs).
Opioid Management – Commercial and Healthcare Reform	05/02/2019	Policy revised to add benzhydrocodone/apap under Short-Acting Opioid analgesic examples
Oral Isotretinoin Therapy – Healthcare Reform Essential	05/02/2019	Policy terminated to be combined with Policy J-374 isotretinoin (Absorica) - Healthcare Reform.
Preferred Blood Glucose Testing Products – Commercial and Select Healthcare Reform	07/01/2019	Policy revised to note excluding plans with the Commercial Core formulary.
Proton Pump Inhibitors (PPIs) – Commercial	05/02/2019	Policy revised to update authorization duration from lifetime to 12 months and include reauthorization criteria that prescriber attests the member has experienced clinical improvement or response to therapy. Policy revised to include additional background information to explain the step through 80 mg daily dosing of both preferred proton pump inhibitors.
Proton Pump Inhibitors (PPIs) – Commercial NSF and Healthcare Reform	05/02/2019	Policy revised to update authorization duration from lifetime to 12 months and include reauthorization attesting clinical response to therapy.
Pulmicort (budesonide) nebulizer suspension – Commercial	TBD	New policy created to ensure appropriate use of budesonide (Pulmicort) nebulizer suspension in members with asthma 8 years of age or younger. Reauthorization criteria attesting clinical response to therapy.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Pulmicort (budesonide) nebulizer suspension – Healthcare Reform	05/02/2019	Policy revised to include reauthorization criteria attesting clinical response to therapy.
Ranexa (ranolazine) – Commercial and Healthcare Reform	07/01/2019	New policy created to ensure appropriate use of ranolazine (Ranexa) for the treatment of chronic angina in patients who have tried and failed a beta blocker and either a calcium channel blocker or nitrate agent.
Rhopressa (netarsudil) – Commercial and Healthcare Reform	04/01/2019	Policy revised to remove double step through latanoprost and an additional ophthalmic product to single step through generic latanoprost. Policy also revised to note excluding plans with the Commercial Core formulary.
Rhopressa (netarsudil) – Commercial NSF	04/01/2019	Policy terminated. Commercial NSF criteria included in Commercial netarsudil (Rhopressa) policy.
Rhopressa (netarsudil) – Commercial Core	07/01/2019	New policy created for Commercial Core formulary, requiring diagnosis of open-angle glaucoma or ocular hypertension and trial and failure of two ophthalmic alternatives, one of which must be generic latanoprost.
Rocklatan (netarsudil and latanoprost) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of netarsudil and latanoprost (Rocklatan) for the treatment of open-angle glaucoma or ocular hypertension in patients who have tried and failed at least 2 generic alternatives one of which must be generic latanoprost.
Selective Serotonin-Norepinephrine Reuptake Inhibitors – Commercial and Healthcare Reform and Commercial National Select	05/02/2019	Policy revised to change authorization duration to two years.
Tirosint-SOL – Commercial and Healthcare Reform	Best Date	Policy revised to require step through two levothryoxine tablet products prior to approval. Reauthorization criteria were also added to ensure the member still requires the solution.
Topical Antifungals – Commercial and Healthcare Reform and Commercial National Select	05/02/2019	Policy revised to include reauthorization criteria, 1 year authorization duration, and remove prescriber limitations of coverage.
Topical Rosacea Treatments – Commercial and Healthcare Reform	Best Date	Policy revised to add a step through generic azelaic acid for metronidazole (MetroCream), (MetroGel, (MetroLotion), (Noritate), (Rosadan) or ivermectin (Soolantra) for the treatment of rosacea.
Viibryd (vilazodone) and Trintellix (vortioxetine) – Commercial	05/02/2019	Policy revised from to require prior use of one antidepressant rather than two.
Zelnorm (tegaserod) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of tegaserod maleate (Zelnorm) for the treatment of irritable bowel syndrome with constipation (IBS-C) in female patients between 18 and 65 years of age who have tried and failed linaclotide (Linzess) and lubiprostone (Amitiza).

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
ZTLido (lidocaine 1.8% topical system) – Commercial and Healthcare Reform	TBD	Policy terminated to be combined with policy Commercial lidocaine topical patch (Lidoderm) policy.
Zyban (buproprion) and Chantix (varenicline) – Commercial and Healthcare Reform	03/28/2019	Policy terminated as benefit is no longer being offered.
Topical Corticosteroids – Commercial	07/01/2019	New policy created to step expensive (majority brand) topical corticosteroids through lower cost alternative topical corticosteroids. To receive a non-preferred low to medium potency topical corticosteroid, a member must try and fail two preferred low to medium potency topical corticosteroids. To receive a non-preferred high potency topical corticosteroid, a member must try and fail two preferred high potency topical corticosteroids.
Acute Migraine Therapies – Commercial	07/01/2019	Policy revised to require non-preferred nasal sprays to step through sumatriptan nasal spray. Prescriber attestation of nausea and vomiting is required for a non-oral medication to be approved. Diclofenac (Cambia) and sumatriptan (Tosymra) added as targeted drugs.
Migraine Therapies Step Therapy – Healthcare Reform	07/01/2019	Policy revised to require non-preferred nasal sprays to step through sumatriptan nasal spray. Prescriber attestation of nausea and vomiting is required for a non-oral medication to be approved. Diclofenac (Cambia) and sumatriptan (Tosymra) added as targeted drugs.
Fibrates – Commercial and Healthcare Reform	07/01/2019	New policy created to have members step through low cost fibrate medications before using high cost fibrate medications.
Vancocin (vancomycin) and Zyvox (linezolid) – Commercial and Healthcare Reform	07/01/2019	Policy revised to include the commercial line of business which allows additional quantities of vancomycin (Vancocin) or linezolid (Zyvox) for members with recurring or drug-resistant infection.
Topical Acne Medications – Commercial	07/01/2019	New policy created to ensure appropriate use in members with acne vulgaris. Members must step through the generic of the brand requested, if applicable, and two other formulary topical acne agents.
Tivorbex (indomethacin) – Commercial	07/01/2019	New policy created to ensure appropriate use of indomethacin (Tivorbex) in adults with mild to moderate pain who have had therapeutic failure or intolerance to generic oral indomethacin and two other formulary oral generic NSAIDs.
Brand Statins – Commercial	07/01/2019	Policy revised to include brand rosuvastatin (Crestor) as a target for step through trial and failure of at least one generic statin alternative.
Brand Statins – Healthcare Reform	07/01/2019	Policy revised for stand-alone Healthcare Reform version.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Generic Step Therapy Edit – Commercial	07/01/2019	Policy revised to include brand Crestor as a target for step through, requiring trial and failure of at least one generic statin alternative.
Generic Step Therapy Edit – Healthcare Reform	07/01/2019	Policy revised for stand-alone Healthcare Reform version.

For policies that require step therapy, an exception may be made for Commercial and HCR members enrolled in a West Virginia plan. For additional details, refer to pharmacy policy bulletin J-513 (West Virginia – Step Therapy Override Exception).
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. Formulary Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
General Non-formulary Criteria – Commercial	07/01/2019	Policy terminated. Commercial Comprehensive Closed incorporated with Commercial Core into new General NF Criteria Policy PA & WV.
General Non-Formulary Request Criteria – PA and WV Commercial	07/01/2019	New policy created outlining coverage for non-formulary medications on the Commercial Core and Comprehensive Closed formularies.
General Non-Formulary Request Criteria – Delaware Commercial	07/01/2019	New policy created outlining coverage for non-formulary medications on the Commercial Core formulary.
General Non-Formulary Request Criteria – Delaware NSF	05/02/2019	Policy revised to include National Select formulary (NSF) exclusions with appropriate alternatives through April 2019. Policy updated on a continual basis as new products come to market and onto the exclusion list.
General Non-Formulary Request Criteria – PA and WV NSF	05/02/2019	Policy revised to include NSF exclusions with appropriate alternatives through April 2019. Policy updated on a continual basis as new products come to market and onto the exclusion list.

*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
Abacavir (abacavir sulfate) 20 mg/mL solution	4 bottles per 30 days	12 bottles per 90 days
Apadaz (benzhydrocodone/ acetaminophen)	120 grams acetaminophen in 25 days	360 grams acetaminophen in 75 days
Aptivus (tipranavir/vitamin E tpgs) 100 mg/mL solution	4 bottles per 30 days	12 bottles per 90 days
Emtriva (emtricitabine) 10 mg/mL solution	5 bottles per 30 days	15 bottles per 90 days
Epivir (lamivudine) 10 mg/mL oral solution	4 bottles per 30 days	12 bottles per 90 days
Evenity (romosozumab-aqqg)	2 syringes per 30 days	6 syringes per 90 days
Firvanq 25 mg/mL*	1,200 mL per 180 days	1,200 mL per 180 days
Firvanq 50 mg/mL*	600 mL per 180 days	600 mL per 180 days
Isentress (raltegravir potassium) 100 mg powder packet	1 box (60 packets) per 30 days	3 boxes (180 packets) per 90 days
Kaletra (lopinavir-ritonavir) 80 mg-20 mg/mL solution	2 bottles per 30 days	6 bottles per 90 days
lamivudine 10 mg/mL oral solution	4 bottles per 30 days	12 bottles per 90 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Lexiva (fosamprenavir calcium) 50 mg/mL suspension	8 bottles per 30 days	24 bottles per 90 days
linezolid tablets*	28 tablets per 180 days	28 tablets per 180 days
linezolid oral suspension*	900 mL per 180 days	900 mL per 180 days
lopinavir-ritonavir 80-20 mg/mL	2 bottles per 30 days	6 bottles per 90 days
Mavenclad (cladribine)	20 tablets per 365 days	20 tablets per 365 days
Methergine (methylergonovine)†	28 tablets per 180 days	28 tablets per 180 days
nevirapine 50 mg/5 mL suspension	5 bottles per 30 days	15 bottles per 90 days
Norvir (ritonavir) 100 mg powder packet	60 packets per 30 days	180 packets per 90 days
Norvir (ritonavir) 80 mg/mL solution	2 bottles per 30 days	6 bottles per 90 days
Prezista (darunavir/cobicistat) 100 mg/mL suspension	2 bottles per 30 days	6 bottles per 90 days
Retrovir (zidovudine) 10 mg/mL syrup	8 bottles per 30 days	24 bottles per 90 days
Skyrizi (risankizumab-rzaa)	2 syringes per 84 days	2 syringes per 84 days
Tosymra (sumatriptan)	120 mg per 25 days	360 mg per 75 days
Tremfya One-Press (guselkumab)	1 injector per 56 days	1 injector per 56 days
vancomycin 125 mg, 250 mg capsules*	112 capsules per 180 days	112 capsules per 180 days
Videx (didanosine) 2 gm pediatric solution	6 bottles per 30 days	18 bottles per 90 days
Viramune (nevirapine) 50 mg/5 mL suspension	5 bottles per 30 days	15 bottles per 90 days
Viread (tenofovir disoproxil fumarate) powder	4 bottles per 30 days	12 bottles per 90 days
Ziagen (avacavir sulfate) 20 mg/mL solution	4 bottles per 30 days	12 bottles per 90 days
zidovudine 50 mg/5 mL syrup	8 bottles per 30 days	24 bottles per 90 days

*QLLs have already been in effect for HCR Plans and are added here for only Commercial Plans.
†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
Avaclyr (acyclovir) ophthalmic ointment	1 tube	1 tube
Cambia (diclofenac) powder for oral suspension	1 box (9 packets)	3 boxes (27 packets)
Cordran (flurandrenolide) cream and ointment*	1 tube	1 tube
Duaklir Pressair (aclidinium/formoterol)	1 inhaler	3 inhalers
Egaten (triclabendazole)	8 tablets	8 tablets
Kenalog (triamcinolone acetonide) spray 63 gm*	3 cans	3 cans
Kenalog (triamcinolone acetonide) spray 100 gm*	2 cans	2 cans
Lotemax SM (loteprednol etabonate)	1 bottle (10 mL)	1 bottle (10 mL)
Nolix (flurandrenolide) cream*	1 tube	1 tube
Rocklatan (netarsudil/latanoprost)	1 bottle (2.5 mL)	3 bottles (7.5 mL)

*Effective date to be determined.
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
abacavir 300 mg tablet	2 tablets per day
abacavir-lamivudine 600-300 mg	1 tablet per day
abacavir-lamivudine-zidovudine tablet	2 tablets per day
Adhansia XR (methylphenidate ER) 25 mg	3 tablets per day
Adhansia XR (methylphenidate ER) 35 mg	2 tablets per day
Adhansia XR (methylphenidate ER) 45 mg, 55 mg, 70 mg, 85 mg	1 tablet per day
Aptivus 250 mg capsule	4 capsules per day
atazanavir sulfate 150 mg capsule	1 capsule per day
atazanavir sulfate 200 mg capsule	2 capsules per day
atazanavir sulfate 300 mg capsule	1 capsule per day
Atripla (efavirenz/emtricitabine/tenofovir disoproxil) tablet	1 tablet per day
Balversa (erdafitinib) 3 mg	3 tablets per day
Balversa (erdafitinib) 4 mg	2 tablets per day
Balversa (erdafitinib) 5 mg	1 tablet per day
Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) 50-200-25 mg tablet	1 tablet per day
Combivir (lamivudine/zidovudine) tablet	2 tablets per day
Complera (emtricitabine/rilpivirine/tenofovir disoproxil) tablet	1 tablet per day
Crixivan (indinavir) 200 mg capsule	3 capsules per day

Drug Name	Daily Limit
Crixivan (indinavir) 400 mg capsule	6 capsules per day
didanosine DR 125 mg, 200 mg, 250 mg, 400 mg capsules	1 capsule per day
Dovato (dolutegravir/lamivudine)	1 tablet per day
Edurant (rilpivirine) mg tablet	2 tablets per day
efavirenz 200 mg capsule	3 capsules per day
efavirenz 50 mg capsule	3 capsules per day
efavirenz 600 mg tablet	1 tablet per day
Emtriva (emtricitabine) 200 mg capsule	1 capsule per day
Epivir (lamivudine) 150 mg tablet	2 tablets per day
Epivir (lamivudine) 300 mg tablet	1 tablet per day
Epzicom (abacavir/lamivudine) tablet	1 tablet per day
Evekeo ODT (amphetamine sulfate) 5 mg, 10 mg	3 tablets per day
Evekeo ODT (amphetamine sulfate) 15 mg, 20 mg	2 tablets per day
Evotaz (atazanavir/cobicistat) 300 mg-150 mg tablet	1 tablet per day
fosamprenavir 700 mg tablet	4 tablets per day
Fuzeon (enfuvirtide) 90 mg vial	2 vials per day
Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) tablet	1 tablet per day
Gloperba (colchicine)	10 mL
Intelence (etravirine) 100 mg, 200 mg tablets	2 tablets per day
Intelence (etravirine) 25 mg tablet	4 tablets per day
Invirase (saquinavir) 500 mg tablet	4 tablets per day
Isentress (raltegravir) 25 mg, 100 mg tablet chew	6 tablets per day
Isentress (raltegravir) 400 mg tablet	4 tablets per day
Isentress HD (raltegravir) 600 mg tablet	2 tablets per day
Jatenzo (testosterone undecanoate) 158 mg	2 capsules per day
Jatenzo (testosterone undecanoate) 237 mg	2 capsules per day
Jatenzo (testosterone undecanoate)198 mg	4 capsules per day
Kaletra (lopinavir/ritonavir) 100-25 mg tablet	2 tablets per day
Kaletra (lopinavir/ritonavir) 200-50 mg tablet	4 tablets per day
lamivudine 150 mg tablet	2 tablets per day
lamivudine 300 mg tablet	1 tablet per day
lamivudine-zidovudine tablet	2 tablets per day
Lexiva (fosamprenavir) 700 mg tablet	4 tablets per day
Mayzent (siponimod) 0.25 mg	4 tablets per day
Mayzent (siponimod) 2 mg	1 tablet per day
nevirapine 200 mg tablet	2 tablets per day
nevirapine ER 100 mg tablet	3 tablets per day
nevirapine ER 400 mg tablet	1 tablet per day
Norvir (ritonavir) 100 mg softgel capsule	12 capsules per day

Drug Name	Daily Limit
Norvir (ritonavir) 100 mg tablet	12 tablets per day
Plenity (superabsorbent hydrogel particles) [DEVICE]	6 capsules per day
Prezcobix (darunavir/cobicistat) 800 mg-150 mg tablet	1 tablet per day
Prezista (darunavir) 150 mg tablet	6 tablets per day
Prezista (darunavir) 600 mg tablet	2 tablets per day
Prezista (darunavir) 75 mg tablet	1 tablet per day
Prezista (darunavir) 800 mg tablet	1 tablet per day
Rescriptor (delavirdine) 100 mg tablet	12 tablets per day
Rescriptor (delavirdine) 200 mg tablet	6 tablets per day
Retrovir (zidovudine) 100 mg capsule	6 capsules per day
Reyataz (atazanavir) 150 mg capsule	1 capsule per day
Reyataz (atazanavir) 200 mg capsule	2 capsules per day
Reyataz (atazanavir) 300 mg capsule	1 capsule per day
ritonavir 100 mg tablet	12 tablets per day
Selzentry (maraviroc) 25 mg, 75 mg, 150 mg tablets	2 tablets per day
Selzentry (maraviroc) 300 mg tablet	4 tablets per day
stavudine 15 mg, 20 mg, 30 mg, 40 mg capsules	2 capsules per day
Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil) tablet	1 tablet per day
Sunosi (solriamfetol)	1 tablet per day
Sustiva (efavirenz) 200 mg capsule	3 capsules per day
Sustiva (efavirenz) 50 mg capsule	3 capsules per day
Sustiva (efavirenz) 600 mg tablet	1 tablet per day
Symfi (efavirenz/lamivudine/tenofovir disoproxil) 600-300-300 mg tablet	1 tablet per day
Tenofovir disoproxil fumarate 300 mg tablets	1 tablet per day
Tivicay (dolutegravir) 20 mg, 25 mg, 50 mg tablets	2 tablets per day
Triumeq (dolutegravir/abacavir/lamivudine) 600-50-300 mg tablet	1 tablet per day
Trizivir (abacavir/lamivudine/zidovudine) tablet	2 tablets per day
Truvada (emtricitabine/tenofovir disoproxil) 100mg-150mg, 133mg-200mg, 167mg-250mg, 200mg-300mg tablets	1 tablet per day
Tybost (cobicistat) 15 mg tablet	1 tablet per day
Videx EC (didanosine) 125mg, 200 mg, 250mg, 400 mg capsules	1 capsule per day
Viracept (nelfinavir) 250 mg tablet	9 tablets per day
Viracept (nelfinavir) 625 mg tablet	4 tablets per day
Viramune (nevirapine) 200 mg tablet	2 tablets per day
Viramune (nevirapine) XR 100 mg tablet	3 tablets per day
Viramune (nevirapine) XR 400 mg tablet	1 tablet per day
Viread (tenofovir disoproxil fumarate) 150 mg, 200 mg, 250 mg, 300 mg tablet	1 tablet per day
Welchol (colesevelam) chewable bars	1 chewable bar per day
Zelnorm (tegaserod)	2 tablets per day

Drug Name	Daily Limit
Ziagen (abacavir) 300 mg tablet	2 tablets per day
zidovudine 100 mg capsule	6 capsules per day
zidovudine 300 mg tablet	2 tablets per day
Zykadia (ceritinib) 150 mg capsules	3 capsules per day
Zykadia (ceritinib) 150 mg tablets	3 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:

Performance Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1349658900
Venture Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1347236614
Incentive Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1344627998

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

No changes at this time.

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
Tosymra	sumatriptan	sumatriptan nasal spray
Evekeo ODT	amphetamine sulfate	amphetamine sulfate, methylphenidate chewable tablet or oral solution
Gloperba	colchicine	colchicine tablets
Lotemax SM	loteprednol etabonate	dexamethasone eye drops, prednisolone eye drops
Adhansia XR	methylphenidate ER	methylphenidate HCL ER, dextroamphetamine-amphetamine ER
Rocklatan	netarsudil/latanoprost	latanoprost 0.005% eye drops, timolol 0.25% eye drops
Sunosi	solriamfetol	modafinil, armodafinil
Jatenzo	testosterone undecanoate	testosterone cypionate, testosterone gel pump, testosterone gel packet
Duaklir Pressair	aclidinium/formoterol	Anoro Ellipta, Stiolto Respimat
Zelnorm	tegaserod	Amitiza, Linzess
Avaclyr ophthalmic ointment	acyclovir	trifluridine 1% eye drops
Welchol chewable bars	colesevelam	colesevelam, cholestyramine, colestipol
Egaten	triclabendazole	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:

Performance Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1349658900
Venture Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1347236614
Incentive Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1344627998

Table 1. Preferred Products

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

No changes at this time.

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Gloperba	colchicine	colchicine tablets
Egaten	triclabendazole	Provider discretion
Sunosi	solriamfetol	modafinil, armodafinil

Table 3. Products Not Added*

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

Brand Name	Generic Name	Preferred Alternatives
Tosymra	sumatriptan	generic sumatriptan nasal spray
Evekeo ODT	amphetamine sulfate	amphetamine sulfate, methylphenidate chewable tablet or oral solution
Lotemax SM	loteprednol etabonate	dexamethasone eye drops, prednisolone eye drops
Adhansia XR	methylphenidate ER	methylphenidate HCL ER, dextroamphetamine-amphetamine ER
Rocklatan	netarsudil/latanoprost	latanoprost 0.005% eye drops, timolol 0.25% eye drops
Jatenzo	testosterone undecanoate	testosterone cypionate, testosterone gel pump, testosterone gel packet
Duaklir Pressair	aclidinium/formoterol	Anoro Ellipta, Stiolto Respimat
Zelnorm	tegaserod	Amitiza, Linzess
Avaclyr ophthalmic ointment	acyclovir	trifluridine 1% eye drops
Welchol chewable bars	colesevelam	colesevelam, cholestyramine, colestipol

*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 **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
Tremfya One-Press	guselkumab
Cablivi	caplacizumab-yhdp
Herceptin Hylecta	trastuzumab/hyaluronidase-oysk
Spravato	esketamine
Trazimera	trastuzumab-qyyp
Zykadia tablets	ceritinib
Zulresso	brexanolone
Mayzent	siponimod
Mavenclad	cladribine
Asceniv	immune globulin (human)-slra
Dovato	dolutegravir/lamivudine
Evenity	romosozumab-aqqg
Balversa	erdafitinib
Balversa 3 mg	erdafitinib
Balversa 4 mg	erdafitinib
Balversa 5 mg	erdafitinib
Skyrizi	risankizumab-rzaa

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Afinitor (everolimus) – Medicare	TBD	Policy revised to remove criteria for advanced non clear cell renal carcinoma, as this is not an FDA-labeled indication.
Anabolic Steroids – Medicare	TBD	Policy revised to include myelofibrosis as an approvable condition for treatment with oxymetholone (Anadrol-50).
Austedo (deutetrabenazine) – Medicare	TBD - Already posted	Policy revised to remove neurologist prescriber requirement.
Cablivi (caplacizumab-yhdp) – Medicare	06/01/2019	New policy to ensure use of caplacizumab-yhdp (Cablivi) in adult patients with acquired thrombotic thrombocytopenic purpura, in conjunction with plasma exchange and immunosuppressive therapy.
CDKi Inhibitors – Medicare	05/02/2019	Policy updated with expanded indications for palbociclib (Ibrance).
Cerdelga (eliglustat) – Medicare	TBD	Policy terminated to be combined with policy J-722.
Chronic Inflammatory Diseases – Medicare	05/02/2019	Policy revised to include expanded indication of nr-axSpA for certolizumab (Cimzia) following failure of two NSAIDs.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Dupixent (dupilumab) – Medicare	05/02/2019	Policy revised to cover members 12 years of age and older with atopic dermatitis.
Egaten (triclabendazole) – Medicare	Best Date	New policy created for triclabendazole (Egaten) which ensures appropriate age and diagnosis.
Evenity (romosozumab-aqqg) – Medicare	TBD	New policy created for romosozumab-aqqg (Evenity) requiring the member to be a post-menopausal woman at high risk of fracture and to have tried and failed a bisphosphonate.
FGFR Kinase Inhibitors – Medicare	TBD	New FGFR Kinase Inhibitor policy created for erdafitinib (Balversa) to be approved for locally advanced or metastatic urothelial carcinoma with FGFR3 or FGFR2 genetic mutation and disease progression during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
Flector (diclofenac epolamine) – Medicare	05/02/2019	Policy revised to cover members 6 years of age and older.
Gaucher Disease – Medicare	TBD	Policy revised to combine criteria for miglustat (Zavesca) and eliglustat (Cerdelga), require therapeutic failure, contraindication, or intolerance to generic miglustat for miglustat (Zavesca) to be approved and allow glucocerebrosidase activity or genetic testing as criteria for documenting type 1 Gaucher disease.
Human Growth Hormone – Medicare	05/02/2019	Policy revised to only require bone age for reauthorization in males greater than or equal to 16 years of age and females greater than or equal to 14 years of age.
Lonsurf (trifluridine-tipiracil) – Medicare	05/02/2019	Policy revised to include new indication of metastatic gastric or gastroesophageal junction adenocarcinoma.
Mavenclad (cladribine) – Medicare	TBD	New policy created to ensure appropriate use of cladribine (Mavenclad) in members with a relapsing form of MS who have tried and failed at least one other therapy for the treatment of MS.
Mayzent (siponimod) – Medicare	TBD	New policy created to ensure appropriate use of siponimod (Mayzent) in members with a relapsing form of multiple sclerosis.
Nuplazid (pimavanserin) – Medicare	05/02/2019	Policy revised to include age requirement of 18 years or older.
Parathyroid Hormone Analogs – Medicare	TBD	Policy revised to categorize members with previous hip or vertebral fracture as high risk. Policy revised to categorize members aged 50 years or older with osteopenia and history of 5 mg/day prednisone (or equivalent) as high risk. Clarified that FRAX score can be interpreted in treated patients.
PCSK9 Inhibitors – Medicare	05/02/2019	Policy revised to include expanded indication for alirocumab (Praluent)) for prevention of cardiovascular events and treatment of primary hyperlipidemia. Included alirocumab (Praluent) in criteria for primary hyperlipidemia not associated with ASCVD, HeFH, or HoFH.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Programmed Death Receptor Therapies – Medicare	TBD	Policy revised to remove BRAF V600 status, squamous-type NSCLC, and unresectable or metastatic criteria detail from nivolumab (Opdivo) criteria, due to absence of respective detail within the package insert. Policy revised to add expanded indication criteria detail for pembrolizumab (Keytruda) in melanoma, non-small cell lung cancer, hepatocellular carcinoma, Merkel cell carcinoma, and renal cell carcinoma.
Prolia (denosumab) – Medicare	TBD	Policy revised to categorize members with previous hip or vertebral fracture as high risk. Policy revised to categorize members aged 50 years or older with osteopenia and history of 5 mg/day prednisone (or equivalent) as high risk. Clarified that FRAX score can be interpreted in treated patients.
Sunosi (solriamfetol) – Medicare	TBD	Policy requires documentation of either narcolepsy or obstructive sleep apnea, and t/f of both modafinil and armodafinil
Tecentriq (atezolizumab) – Medicare	05/31/2019	Policy revised to add new indication for breast cancer (triple-negative), locally advanced or metastatic.
Tegsedi (inotersen) – Medicare	Already posted	Policy revised to remove the requirement for completion of biopsy or electrophysiological tests to support the diagnosis of hereditary TTR amyloidosis.
Testosterone (Androgens) – Medicare	TBD	Policy revised to include testosterone undecanoate (Jatenzo) to targeted drug list
Uloric (febuxostat) – Medicare	06/01/2019	Policy created due to new box warning of cardiovascular death risk. Criteria are to confirm diagnosis and failure, intolerance or contraindication to allopurinol.
Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Medicare	TBD	Policy revised to remove the requirement for trial and failure of sodium polystyrene sulfonate for approval of patiromer (Veltassa) or sodium zirconium cyclosilicate (Lokelma).The criteria for serum potassium levels was updated from between 5.1 mmol/L and 6.4 mmol/L to between 5.1 mmol/L and 7.4 mmol/L.
Verzenio (abemaciclib) – Medicare	05/02/2019	Policy revised to reflect package insert that abemaciclib (Verzenio) is being used in advanced disease.
Welchol (colesevelam) chewable bars – Medicare	TBD	New policy created to ensure appropriate use of colesevelam (Welchol) chewable bars in members with HeFH, or type 2 diabetes. The member must have experienced therapeutic failure or intolerance to generic colesevelam tablets. For hyperlipidemia the member has tried 1 other bile acid sequestrant and 1 other preferred generic statin. For HeFH the member has tried and failed 1 other preferred generic statin. For type 2 diabetes the member must have tried and failed 2 preferred antidiabetic agents. Reauthorization criteria attesting clinical response to therapy.

*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
Adhansia XR (methylphenidate hydrochloride) – Medicare	TBD	New policy created to ensure appropriate use of methylphenidate (Adhansia XR) for the treatment of ADHD in patients who are 6 years of age or older who have tried and failed at least 2 generic alternatives.
Herpetic Keratitis – Medicare	TBD	New policy created to ensure appropriate use of acyclovir (Avaclyr) ophthalmic ointment, trifluridine (Viroptic) ophthalmic solution, and ganciclovir (Zirgan) ophthalmic gel for the treatment of acute herpetic keratitis in patients who have tried and failed trifluridine 1% eye drops.
Rocklatan (netarsudil and latanoprost) – Medicare	TBD	New policy created to ensure appropriate use of netarsudil and latanoprost (Rocklatan) for the treatment of open-angle glaucoma or ocular hypertension in patients who have tried and failed at least 2 generic alternatives one of which must be generic latanoprost.
Zelnorm (tegaserod) – Medicare	TBD	New policy created to ensure appropriate use of tegaserod maleate (Zelnorm) for the treatment of IBS-C in female patients between 18 and 65 years of age who have tried and failed linaclotide (Linzess) and lubiprostone (Amitiza).
ZTLido (lidocaine 1.8% topical system) – Medicare	Best Date	Policy revised to change categorization from MRxC to Prior Authorization. In addition, added some background information about lidocaine 1.8% topical system (ZTLido) and deleted all references to automatic approval criteria.

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

3. Quantity Level Limit (QLL) Program*

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

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Adhansia 45 mg, 55 mg, 70 mg, 85 mg	31 tablets	90 tablets
Adhansia XR 25 mg	93 tablets	270 tablets
Adhansia XR 35 mg	62 tablets	180 tablets
Aimovig autoinjector 14 mg/mL	1 mL injector	3 mL injectors
albuterol sulfate HFA 90 mcg	2 inhalers	6 inhalers
Avaclyr (acyclovir) ophthalmic ointment	1 tube	1 tube
Balversa (erdafitinib) 3 mg	93 tablets	270 tablets
Balversa (erdafitinib) 4 mg	62 tablets	180 tablets
Balversa (erdafitinib) 5 mg	31 tablets	90 tablets
Buprenorphine-naloxone 12mg-3mg	62 films	180 films
Buprenorphine-naloxone 2mg-0.5mg	93 films	90 films
Buprenorphine-naloxone 4mg-1mg	93 films	90 films
Buprenorphine-naloxone 8mg-2mg	93 films	90 films
Diclofenacepolamine 1.3%	62 patches	180 patches

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Dovato (dolutegravir/lamivudine)	31 tablets	90 tablets
Duaklir Pressair (aclidinium/formoterol)	1 inhaler	3 inhalers
Dvorah (acetaminophen/caffeine/ dihydrocodeine) 325-30-16	372 tablets	372 tablets
Escitalopram oxalate 10 mg	45 tablets	135 tablets
Evekeo (amphetamine sulfate) ODT 15 mg, 20 mg	62 tablets	180 tablets
Evekeo (amphetamine sulfate) ODT 5 mg, 10 mg	93 tablets	270 tablets
Evenity (romosozumab-aqqg)	2 syringes	6 syringes
Fluticason-salmeterol	60 (blister pack with inhalation device)	180 (blister pack with inhalation device)
Gloperba (colchicine)	310 mL	900 mL
Glumetza (metformin HCL) 1000 mg	62 tablets	180 tablets
Jatenzo (testosterone undecanoate) 158 mg	62 capsules	180 capsules
Jatenzo (testosterone undecanoate) 237 mg	62 capsules	180 capsules
Jatenzo (testosterone undecanoate) 198 mg	124 capsules	360 capsules
Levorphanol tartrate 3 mg	186 tablets	540 tablets
Lotemax SM (loteprednol etabonate) 10 mL	1 bottle	1 bottle
Mavenclad (cladribine)	20 tablets per 365 days	--
Mayzent (siponimod) 0.25 mg	124 tablets	360 tablets
Mayzent (siponimod) 2 mg	31 tablets	90 tablets
Motegrity 1 mg, 2 mg	31 tablets	90 tablets
Ranolazine ER 500 mg, 1000 mg	62 tablets	180 tablets
Seebri neohaler (glycopyrrolate) 15.6 mcg	60 capsules with inhalation device per 30 days	180 capsules with inhalation device
Skyrizi (risankizumab-rzaa)	2 syringes	2 syringes
Sunosi (solriamfetol)	31 tablets	90 tablets
Tremfya One-Press (guselkumab) 100 mg/mL	1 injector	1 injector
Utibron neohaler (indacaterol/ glycopyrrolate) 27.5-15.6	60 capsules with inhalation device per 30 days	180 capsules with inhalation device
Venlafaxine HCL ER 75 mg	93 capsules	270 capsules
Welchol (colesevelam) chewable bars	31 chewable bars	90 chewable bars
Wixela Inhub 100-50mcg, 250-50mcg, 500-50mcg	60 (blister pack with inhalation device) per 30 days	180 (blister pack with inhalation device)
Zelnorm (tegaserod)	62 tablets	180 tablets
Zykadia (ceritinib) tablets	93 tablets	270 tablets

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