Formulary Updates

Published September 2, 2021

The formularies and pharmaceutical management procedures are updated on a bimonthly basis, and the following changes reflect the decisions made in **June 2021** 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:

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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

Metformin HCl Extended-Release Tablets, USP 750 mg by Viona Pharmaceuticals Inc.: Recall – Detection of N-Nitrosodimethylamine (NDMA) Impurity

On June 11th, 2021, Viona Pharmaceuticals Inc. recalled the above product. The affected product was recalled after being found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Patients who have received impacted lots of Metformin Hydrochloride Extended-Release Tablets, USP 750 mg are advised to continue taking their medication and contact their physician for advice regarding an alternative treatment. According to the FDA, it could be dangerous for patients with this serious condition to stop taking their Metformin without first talking to their healthcare professionals. To date, neither Viona Pharmaceuticals Inc., nor Cadila Healthcare Limited have received any reports of adverse events related to this recall.

07/20/2021 - FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins. Breastfeeding not recommended in patients who require statins.

The U.S. Food and Drug Administration (FDA) is requesting revisions regarding cholesterol-lowering statin use in pregnancy. Specifically, the FDA is removing the contraindication against using statin medications in all patients who are pregnant. While most pregnant patients should discontinue use of statins when they discover they are pregnant, the benefits of using a statin may outweigh the risk in very high-risk individuals, such as those who have homozygous familial hypercholesterolemia or who have established cardiovascular disease. Therefore, contraindicating statins in all pregnant patients is not appropriate.

Statin use in patients who may become pregnant is safe. However, it is recommended that patients do not breastfeed while taking a statin. Instead, they should use infant formula or other alternatives. Adverse events involving statins should be reported to the FDA MedWatch program.

05/26/2021 - Due to risk of serious liver injury, FDA restricts use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis. Adding and updating warnings.

The U.S. FDA has added a contraindication to the prescribing information and patient Medication Guide for Ocaliva (obeticholic acid) that restricts use of the liver disease medication in patients with primary biliary cholangitis (PBC) with advanced cirrhosis of the liver. The Boxed Warning for Ocaliva has also been revised to include this information along with related warnings about the risk.

Advanced cirrhosis is cirrhosis with current or prior evidence of liver decompensation or portal hypertension. Examples of liver decompensation include encephalopathy or coagulopathy, and examples of portal hypertension include ascites, gastroesophageal varices, or persistent

thrombocytopenia. Some PBC patients with cirrhosis, especially those with advanced cirrhosis, developed liver failure while taking Ocaliva. In certain cases, the liver failure required a liver transplant. Adverse events involving Ocaliva should be reported to the FDA MedWatch program.

02/04/2021 - Initial safety trial results find increased risk of serious heart-related problems and cancer with arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib). FDA will evaluate the trial results.

The FDA has stated that preliminary results from a safety clinical trial involving the arthritis and ulcerative colitis treatment Xeljanz, Xeljanz XR (tofacitinib) show an increased risk of serious heart-related problems and cancer compared to tumor necrosis factor (TNF) inhibitors, which are another type of treatment. Additional results from the trial are pending, after reviewing the results the FDA will share its final conclusions and recommendations. Until then, healthcare professionals should consider the benefits and risks of Xeljanz and Xeljanz XR as they determine whether to start or continue patients on the treatment. Adverse events involving Xeljanz or Xeljanz XR should be reported to the FDA MedWatch program.

Highmark Formulary Update – June 2021

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. 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
- Highmark Comprehensive Healthcare Reform Formulary

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes to promote adherence to medication protocols and improve the overall health of our members.

Table 1. Products Added

All products added to the formulary effective June 2021 unless otherwise noted.

Brand Name	Generic Name	Comments
Kloxxado 8 mg	naloxone 8 mg	Opioid Overdose

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Evekeo ODT 2.5 mg*	amphetamine ODT 2.5 mg	Dextroamphetamine-amphetamine, methylphenidate HCl tablet
Myrbetriq oral granules*	mirabegron oral granules	oxybutynin chloride tablet, oxybutynin chloride syrup, oxybutynin chloride ER
Nextstellis	drospirenone/estetrol	drospirenone-ethinyl estradiol
Qelbree	viloxazine	methylphenidate ER capsule, extended release biphasic 30-70, dextroamphetamine-amphetamine
Roszet	rosuvastatin/ezetimibe	atorvastatin calcium, rosuvastatin calcium, ezetimibe
Zegalogue	dasiglucagon	Glucagen 1 MG, Baqsimi, Gvoke Hypopen
Fotivda	tivozanib	Cabometyx, Nexavar

Brand Name	Generic Name	Preferred Alternatives
Ponvory 20 mg tablet	ponesimod 20 mg tablet	dimethyl fumarate capsule
Ponvory starter pack	ponesimod starter pack	dimethyl fumarate capsule
Xolair prefilled syringes	omalizumab prefilled syringes	Dupixent; Dupixent pen; fluticasone propionate spray, suspension

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

**Physicians may request coverage of these products using the Request for Non-Formulary Drug Coverage.

Table 3. Additions to the Specialty Tier Copay Option

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
Fotivda	tivozanib
Ponvory 20 mg tablet	ponesimod 20 mg tablet
Ponvory starter pack	ponesimod starter pack
Xolair prefilled syringes	omalizumab prefilled syringes

B. Changes to the Healthcare Reform Progressive Formulary

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 Healthcare Reform Progressive Formulary

Table 1. Formulary Updates

All products added to the formulary effective June 2021 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Kloxxado 8 mg	naloxone 8 mg	2 - Preferred Brand	Opioid Overdose
Items listed below are non-preferred products			

Evekeo ODT 2.5 mg*	amphetamine ODT 2.5 mg	3 - Nonpreferred Brand	methylphenidate HCL tablet, dextroamphetamine-amphetamine
Myrbetriq oral granules*	mirabegron oral granules	3 - Nonpreferred Brand	oxybutynin chloride tablet, oxybutynin chloride syrup, oxybutynin chloride ER
Nextstellis	drospirenone/estetrol	3 - Nonpreferred Brand	drospirenone-ethinyl estradiol
Qelbree	viloxazine	3 - Nonpreferred Brand	methylphenidate HCL tablet
Roszet	rosuvastatin/ezetimibe	3 - Nonpreferred Brand	atorvastatin calcium, rosuvastatin calcium, ezetimibe-simvastatin
Zegalogue	dasiglucagon	3 - Nonpreferred Brand	Baqsimi, Glucagen 1 MG, Gvoke Hypopen
Fotivda	tivozanib	4 - Nonpreferred Specialty	Cabometyx, Nexavar
Ponvory 20 mg tablet	ponesimod 20 mg tablet	4 - Nonpreferred Specialty	dimethyl fumarate capsule
Ponvory starter pack	ponesimod starter pack	4 - Nonpreferred Specialty	dimethyl fumarate capsule
Xolair prefilled syringes	omalizumab prefilled syringes	4 - Nonpreferred Specialty	Dupixent; Dupixent pen; fluticasone propionate spray, suspension

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. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

All formulary changes effective June 2021 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Kloxxado 8 mg	naloxone 8 mg	2	Opioid Overdose
Items listed below were not added to the formulary			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Evekeo ODT 2.5 mg*	amphetamine ODT 2.5 mg	NF	dextroamphetamine-amphetamine, methylphenidate HCL tablet
Fotivda	tivozanib	NF	Cabometyx, Nexavar
Myrbetriq oral granules*	mirabegron oral granules	NF	oxybutynin chloride tablet, oxybutynin chloride syrup, oxybutynin chloride ER
Nextstellis	drospirenone/estetrol	NF	drospirenone-ethinyl estradiol
Ponvory 20 mg tablet	ponesimod 20 mg tablet	NF	dimethyl fumarate capsule
Ponvory starter pack	ponesimod starter pack	NF	dimethyl fumarate capsule
Qelbree	viloxazine	NF	atomoxetine HCL, guanfacine HCL ER
Roszet	rosuvastatin/ezetimibe	NF	atorvastatin calcium, rosuvastatin calcium, ezetimibe
Xolair prefilled syringes	omalizumab prefilled syringes	NF	Dupixent; Dupixent pen; fluticasone propionate spray, suspension
Zegalogue	dasiglucagon	NF	Baqsimi, Glucagen 1 mg, Gvoke Hypopen

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).

*Effective date to be determined.

D. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial Individual plans. A list of drugs included on the Core Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

All formulary changes effective June 2021 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Kloxxado 8 mg	naloxone 8 mg	3	Opioid Overdose
Items listed below were not added to the formulary			
Evekeo ODT 2.5 mg*	amphetamine ODT 2.5 mg	NF	methylphenidate HCL tablet, dexmethylphenidate HCL
Fotivda	tivozanib	NF	Cabometyx, Nexavar
Myrbetriq oral granules*	mirabegron oral granules	NF	oxybutynin chloride tablet, oxybutynin chloride syrup, oxybutynin chloride er
Nextstellis	drospirenone/estetrol	NF	drospirenone-ethinyl estradiol, drospirenone-eth estra-levomef
Ponvory 20 mg tablet	ponesimod 20 mg tablet	NF	dimethyl fumarate capsule

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Ponvory starter pack	ponesimod starter pack	NF	dimethyl fumarate capsule
Qelbree	viloxazine	NF	atomoxetine HCL, guanfacine HCL ER
Roszet	rosuvastatin/ezetimibe	NF	atorvastatin calcium, rosuvastatin calcium, ezetimibe
Xolair prefilled syringes	omalizumab prefilled syringes	NF	Dupixent; Dupixent pen; fluticasone propionate spray, suspension
Zegalogue	dasiglucagon	NF	Baqsimi, Gvoke Hypopen

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).

*Effective date to be determined.

E. 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 here.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Kloxxado 8 mg	naloxone 8 mg	2	Opioid Overdose
Zegalogue	dasiglucagon	2	Hypoglycemia
Ponvory 20 mg tablet	ponesimod 20 mg tablet	2	Multiple Sclerosis
Ponvory starter pack	ponesimod starter pack	2	Multiple Sclerosis
Xolair prefilled syringes	omalizumab prefilled syringes	2	Asthma, chronic idiopathic urticaria, nasal polyps
Items listed below were added to the formulary (non-preferred)			
Evekeo ODT 2.5 mg*	amphetamine ODT 2.5 mg	3	dextroamphetamine-amphetamine, methylphenidate HCL tablet
Myrbetriq oral granules*	mirabegron oral granules	3	oxybutynin chloride tablet, oxybutynin chloride syrup, oxybutynin chloride ER
Roszet	rosuvastatin/ezetimibe	3	atorvastatin calcium, rosuvastatin calcium, ezetimibe
Items listed below were not added to the formulary			
Nextstellis	drospirenone/estetrol	NF	drospirenone-ethinyl estradiol, Junel Fe
Qelbree	viloxazine	NF	atomoxetine, clonidine ER, guanfacine ER

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Fotivda	tivozanib	NF	everolimus,Cabometyx, Nexavar

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
Fotivda	tivozanib
Ponvory 20 mg tablet	ponesimod 20 mg tablet
Ponvory starter pack	ponesimod starter pack
Xolair prefilled syringes	omalizumab prefilled syringes

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	6/24/2021	Policy revised for Sutent (sunitinib) to specify use in advanced renal cell carcinoma; and to add criteria for new drug Fotivda (tivozanib) to require that the member is 18 years of age or older with a diagnosis of relapsed or refractory advanced renal cell carcinoma after receipt of at least two prior systemic therapies.
Anti-Obesity - Commercial and Healthcare Reform	6/14/2021	Policy revised for Saxenda (liraglutide) to create new section for Saxenda (liraglutide) use in adolescents or previously used as an adolescent, in which case continuation criteria removed and maintenance changed to 3 or more months of previous therapy. If member falls under maintenance, member has experienced 1% or more weight loss from baseline and maintained weight loss from baseline.
BRAF Mutation-Targeting & MEK 1/2 Kinase Inhibitors - Commercial and Healthcare Reform	6/24/2021	Policy revised to require an FDA-approved test for BRAF V600E or V600K mutation for all the following: Braftovi (encorafenib) when used as monotherapy or in combination with Mektovi (binimetinib); Mekinist (trametinib) when used as monotherapy or in combination with Tafinlar (dabrafenib). Policy revised to require an FDA-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		approved test for a BRAF V600E mutation for all the following: Tafinlar (dabrafenib) when used as monotherapy; or Zelboraf (vemurafenib).
CGRP Inhibitors - Commercial and Healthcare Reform	6/21/2021	Policy revised for Ajovy (fremanezumab), Emgality (galcanezumab), and Aimovig (erenumab) to require attestation that the benefits of therapy outweigh the risks if the treatment plan is to use a calcitonin gene-related peptide inhibitor for acute treatment of migraine with Ajovy (fremanezumab), Emgality (galcanezumab), or Aimovig (erenumab).
Chelating Agents - Commercial and Healthcare Reform	6/14/2021	Policy revised to include new indications for Ferriprox (deferiprone); for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age (oral tablets) and older or 3 years of age (oral solution) and older with thalassemia syndromes and sickle cell disease or other anemias. Policy revised for chronic iron overload due to blood transfusions to add liver iron concentration (LIC) of at least 7 mg/g on initial authorization and LIC of at least 3 mg/g on reauthorization as an alternative to serum ferritin. Policy revised for brand Exjade (deferasirox), brand Jadenu (deferasirox), and Ferriprox (deferiprone) to require trial and failure of the generic deferasirox tablets.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	6/15/2021	Policy revised to update quantity limitations for Skyrizi (risankizumab) to include induction therapy of two prefilled pens/syringes (150 mg/mL) within the first 4 weeks of therapy and maintenance therapy of one prefilled syringe/pen (150 mg/mL) every 12 weeks.
Chronic Inflammatory Diseases - Commercial National Select Formulary	6/15/2021	Policy revised to update quantity limitations for Skyrizi (risankizumab) to include induction therapy of two prefilled pens/syringes (150 mg/mL) within the first 4 weeks of therapy and maintenance therapy of one prefilled syringe/pen (150 mg/mL) every 12 weeks.
Cuvposa (glycopyrrolate) oral solution - Commercial and Healthcare Reform	6/18/2021	Policy revised to combine Commercial and HCR.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Cuvposa (glycopyrrolate) oral solution - Healthcare Reform	6/18/2021	Policy retired and combined with J-0216 Cuvposa (glycopyrrolate) oral solution - Commercial
Dibenzyline (phenoxybenzamine) - Commercial and Healthcare Reform	TBD	Policy was revised to require the member to be experiencing excessive sweating and hypertension. Policy for the Healthcare reform line of business J-0659 was combined with J-0224.
Dibenzyline (phenoxybenzamine) - Healthcare Reform	TBD	Terminating policy. Policy combined with the Commercial policy J-0224.
Doptelet (avatrombopag) and Mulpleta (lusutrombopag) - Healthcare Reform	6/18/2021	Terminated Healthcare Reform J-0780 policy and combined it with Commercial policy J-0779 Doptelet (avatrombopag) and Mulpleta (lusutrombopag) - Commercial and Healthcare Reform.
Evekeo (amphetamine sulfate) - Healthcare Reform	6/18/2021	Termination; combined with Commercial Policy J-0218.
Evoxac (cevimeline) - Healthcare Reform	6/18/2021	Policy terminated as combined with J-0220 Evoxac (cevimeline) - Commercial and Healthcare Reform.
FGFR Kinase Inhibitors - Commercial and Healthcare Reform	6/24/2021	Policy revised for Balversa (erdafitinib) to add age limitation for use in members 18 years of age or older.
Gattex (teduglutide) - Commercial and Healthcare Reform	6/14/2021	Policy revised for Gattex (teduglutide) to remove medical records documenting dietary needs and goals. Reauthorization criteria revised include that member continues to be dependent on parenteral nutrition support.
Gilenya (fingolimod) - Commercial and Healthcare Reform	6/17/2021	Policy revised to move limitations of coverage regarding contraindications and baseline assessments to the background.
Interleukin-1b blockers - Commercial and Healthcare Reform	6/16/2021	Policy revised for Arcalyst (rilonacept) to add new indication for recurrent pericarditis (RP) to require the member to be 12 years of age or older; have a diagnosis of RP; experienced at least 1 episode of acute pericarditis in the past 365 days; experienced therapeutic failure, intolerance, or contraindication to colchicine tablets; and experienced therapeutic failure or intolerance to either an oral nonsteroidal anti-inflammatory drug (NSAID) or systemic corticosteroid or contraindication to both.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
JAK Inhibitors – Commercial and Healthcare Reform	6/24/2021	Policy revised for Jakafi (ruxolitinib) for prescriber attestation that the member has intermediate or high-risk myelofibrosis; and for Jakafi (ruxolitinib) to remove criteria for respective starting dose based on platelet count; policy revised for Jakafi (ruxolitinib) to require baseline platelet count ≥ 50 x 10^9/L for new starts to therapy. Policy revised for Inrebic (fedratinib) for prescriber attestation that the member has intermediate-2 or high-risk myelofibrosis; and for Inrebic (fedratinib) to remove initial authorization criteria for continuing therapy requiring documentation of reduction in spleen size or symptom improvement.
Lonsurf (trifluridine/tipiracil) - Commercial and Healthcare Reform	6/24/2021	Policy revised for Lonsurf (trifluridine/tipiracil) for use in members 18 years of age or older.
Loprox (ciclopirox 1% shampoo) - Healthcare Reform	6/18/2021	Policy for Loprox (ciclopirox) Shampoo terminated so that Healthcare Reform and Commercial lines of business can be combined into a single policy (Policy J-0225).
Luzu (luliconazole) - Healthcare Reform	6/18/2021	Policy for Luzu (luliconazole 1% cream) terminated so that Healthcare Reform and Commercial lines of business can be combined into a single policy (Policy J-0801).
Market Watch Programs - Delaware	07/09/2021	Policy revised to add Roszet (ezetimibe/rosuvastatin) to the High Cost Low Value table with the alternatives of atorvastatin + ezetimibe and rosuvastatin + ezetimibe. Additionally, Elepsia XR (levetiracetam ER) was added to the High Cost Low Value table with the alternatives of levetiracetam ER and Roweepra XR.
Market Watch Programs - PA and WV	07/09/2021	Policy revised to add Roszet (ezetimibe/rosuvastatin) to the High Cost Low Value table with the alternatives of atorvastatin + ezetimibe and rosuvastatin + ezetimibe. Additionally, Elepsia XR (levetiracetam ER) was added to the High Cost Low Value table with the alternatives of levetiracetam ER and Roweepra XR.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Mayzent (siponimod) - Commercial and Healthcare Reform	6/17/2021	Policy revised to move limitations of coverage regarding contraindications and baseline assessments to the background.
Mucosal Agents - Healthcare Reform	6/30/2021	Policy terminated as combined with J-0869 (Mucosal Agents - Commercial).
Neurogenic Detrusor Overactivity Products – Commercial and Healthcare Reform	TBD	Policy revised for Neurogenic Detrusor Overactivity Products to include Myrbetriq (mirabegron extended-release) granules requiring member is 3 to 17 years of age, diagnosis of neurogenic detrusor overactivity (NDO), and if member is 6 years of age or older tried and failed generic oxybutynin. Reauthorization attesting positive clinical response. Policy revised for Vesicare LS (solifenacin succinate) to remove that NDO is caused by neurologic cause.
Nityr and Orfadin (nitisinone) - Commercial and Healthcare Reform	6/14/2021	Policy for Nityr (nitisinone) and Orfadin (nitisinone) revised to include a step through both generic nitisinone capsules and brand Nityr (nitisinone) tablets if the request is for either brand Orfadin (nitisinone) capsules or brand Orfadin (nitisinone) suspension.
Noxafil (posaconazole) - Commercial and Healthcare Reform	6/18/2021	Policy revised for Noxafil (posaconazole) to require member to experience therapeutic failure or intolerance to two generic alternatives or have contraindication to all generic alternatives. If the request is for brand Noxafil (posaconazole) delayed-release tablets, the member must have experienced therapeutic failure or intolerance to generic posaconazole delayed-release tablets.
Noxafil (posaconazole) - Healthcare Reform	6/18/2021	Policy for Noxafil (posaconazole) terminated so that Healthcare Reform and Commercial lines of business can be combined into a single policy (Policy J-0217).
Ocaliva (obeticholic acid) - Commercial and Healthcare Reform	6/14/2021	Policy revised for Ocaliva (obeticholic acid) to require therapeutic failure to ursodiol therapy defined as alkaline phosphatase (ALP) levels ≥ 1.67 x upper limit of normal (ULN) or bilirubin levels > 1-2 x ULN or experienced contraindication or intolerance to ursodiol monotherapy. Reauthorization criteria revised to require member to experience positive clinical response defined by ALP level < 1.67 x ULN or total bilirubin level < ULN.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Ongentys (opicapone) - Commercial and Healthcare Reform	6/18/2021	Policy revised to remove generic rotigotine tablets and add selegiline as an alternative and to remove the specific generic dosage forms for each of the other alternatives except entacapone.
Panretin (alitretinoin) - Commercial and Healthcare Reform	TBD	New policy created for Panretin requiring members to be 18 years of age or older, have the Panretin prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist, using for the treatment of cutaneous lesions in patients with AIDS-related Kaposi sarcoma, and the member is not receiving systemic therapy for Kaposi sarcoma.
PCSK9 Inhibitors – Commercial and Healthcare Reform	6/09/2021	Policy revised for homozygous familial hypercholesterolemia (HoFH) to include Praluent (alirocumab) if the member is 18 years of age or older, prescriber specialty, untreated low-density lipoprotein cholesterol (LDL-C) > 400 mg/dL or untreated total cholesterol (TC) > 500 mg/dL, if the member is 17 years of age or younger, LDL-C > 135 mg/dL, tried and failed statins unless statin intolerant and Repatha (evolocumab), and will continue to receive concurrent lipid-lowering therapies for the treatment of HoFH. Quantity limit override allowed for Repatha (evolocumab) Pushtronex 420 mg/3.5 mL if used for HoFH with a dosing of 420 mg every 2 weeks to allow for 2 units per 23 days.
Ponvory (ponesimod) - Commercial and Healthcare Reform	6/17/2021	New policy for Ponvory (ponesimod) requiring age of 18 years or older, diagnosis of a relapsing form of multiple sclerosis, therapeutic failure, intolerance or contraindication to dimethyl fumarate, and limitation of coverage not authorizing use of combination disease modifying multiple sclerosis agents.
Pulmonary Hypertension - Commercial and Healthcare Reform	6/10/2021	Policy revised for Tyvaso (treprostinil) for expanded indication of pulmonary hypertension associated with interstitial lung disease (PH-ILD) that it is prescribed or in consultation with a cardiovascular or pulmonary specialist, diagnosis of World Health Organization (WHO) Group 3 pulmonary hypertension, submitted the results of a right heart catheterization substantiating all of the following mean pulmonary arterial pressure >

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		20 mmHg at rest, pulmonary wedge pressure ≤ 15 mmHg, and pulmonary vascular resistance ≥ 3 Wood units, diagnosis of interstitial lung disease, and is a non-smoker or is currently engaged in smoking cessation.
Rayos (prednisone) - Commercial and Healthcare Reform	6/14/2021	Policy revised for Rayos (prednisone) to include criteria that it is prescribed for FDA approved indication.
Relistor (methylnaltrexone bromide) - Commercial and Healthcare Reform	6/14/2021	For both Relistor tablets and syringes, under a diagnosis of opioid-induced constipation (OIC) with chronic non-cancer pain, added requirement that member does not require frequent (e.g., weekly) opioid dosage increases. For Relistor syringes, clarified that patient has OIC with advanced illness or pain caused by active cancer and requires opioid dosage escalation for palliative care. Combined the HCR policy into this Commercial policy.
Relistor (methylnaltrexone bromide) -Healthcare Reform	6/14/2021	Termination; combined with Commercial Policy J-0502.
Sublingual Immunotherapy – Commercial and Healthcare Reform	6/16/2021	Policy revised to extend the indication for Ragwitek (Short Ragweed Pollen Allergen Extract) for use in members 5 to 65 years of age.
Sucraid (sacrosidase) - Commercial and Healthcare Reform	6/18/2021	Policy revised for Sucraid (sacrosidase) to combine Commercial and Healthcare Reform lines of business into a single policy (J-0219). Policy revised so the member must meet all the following: 1) stool pH < 6; 2) breath hydrogen increase > 10 ppm during fasting sucrose challenge; 3) negative lactose breath test. Finally, initial criteria step of one week trial with improved clinical response was removed.
Sucraid (sacrosidase) - Healthcare Reform	6/18/2021	Policy for Sucraid (sacrosidase) terminated so that Healthcare Reform and Commercial lines of business can be combined into a single policy (Policy J-0219).
Tegsedi (inotersen) - Commercial and Healthcare Reform	6/14/2021	Policy revised for Tegsedi (inotersen) that functional ambulation performance (FAP) was removed as abbreviation for FAP stands for familial amyloidotic polyneuropathy and stage 1 or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		2 equates to member has baseline performance status of ambulatory or ambulatory with assistance.
Tolsura (itraconazole) - Commercial and Healthcare Reform	6/16/2021	Policy revised to remove reauthorization criteria and requirement for attestation for need of Super-BioAvailable (SUBA) technology.
Topical Non-Steroid Therapy for Atopic Dermatitis - Healthcare Reform	6/14/2021	Policy revised for Protopic (tacrolimus) ointment 0.1% to require the member be 16 years of age or older, a diagnosis of moderate to severe atopic dermatitis (AD), allow contraindication or intolerance to two topical corticosteroids, and allow intolerance to either generic topical tacrolimus or pimecrolimus. Criteria revised for Protopic (tacrolimus) ointment 0.03% to require a diagnosis of moderate to severe AD, allow contraindication or intolerance to two topical corticosteroids, and allow intolerance to either generic topical tacrolimus or pimecrolimus. Criteria revised for Eucrisa (crisaborole) to allow contraindication or intolerance to two topical corticosteroids and allow contraindication or intolerance to either generic topical tacrolimus or pimecrolimus.
Xadago (safinamide) - Commercial and Healthcare Reform	6/17/2021	Policy revised to move selegiline to the list of alternative options including pramipexole, ropinirole, and entacapone.
Xerese (acyclovir 5%/hydrocortisone 1%) Topical Cream - Commercial	6/16/2021	Policy revised for Xerese (acyclovir 5%/hydrocortisone 1%) to require minimum member age of 6 years old. Further, member must experience therapeutic failure or intolerance to one (1) of the following generic oral antivirals or both are contraindicated: famciclovir or valacyclovir.
Xolair (omalizumab) - Commercial and Healthcare Reform	06/03/2021	New policy created for Xolair (omalizumab) prefilled syringe requiring members to have a diagnosis of asthma, chronic idiopathic urticaria (CIU), or nasal polyps. For asthma, member needs to be at least 6 years of age, has a positive skin test or reactivity to a perennial aeroallergen, baseline IgE greater than or equal to 30 IU/mL, has uncontrolled asthma despite trial of a medium-dose inhaled corticosteroid (ICS) or systemic steroid and a long-acting beta-agonist

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(LABA) or leukotriene antagonist. The member also needs to be using a LABA, leukotriene modifier, or theophylline. Documentation of current weight and pretreatment serum IgE is required. For reauthorization for asthma, the prescriber resubmits weight and pretreatment serum IgE and attests to decreased rescue medication or oral corticosteroid use, decrease in severe asthma exacerbations, increase in pulmonary function from baseline, or a reduction in asthma symptoms. For CIU, policy requires the member to be at least 12 years of age, has tried and failed a second-generation non-sedating H1 antihistamine at the maximum recommended doses. Reauthorization requires the member to have improved CIU symptoms. For nasal polyps, the policy requires the member to be at least 18 years of age and tried and failed intranasal corticosteroid. For reauthorization, the member needs to have a decrease in the nasal polyp score or the nasal congestion/obstruction severity score. For all indications, the member does not have a history of anaphylaxis and has received at least 3 doses of Xolair under the guidance of a healthcare provider with no hypersensitivity reactions.
Zeposia (ozanimod) - Commercial and Healthcare Reform	6/18/2021	Policy revised to move limitations of coverage regarding contraindications and baseline assessments to the background.
Zytiga and Yonsa (abiraterone acetate) - Commercial and Healthcare Reform	6/24/2021	Policy revised to allow additional quantities of Zytiga 250 mg, up to 8 tablets per day when the member is taking a strong CYP3A4 inducer.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

**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
Acute Migraine Therapies - Commercial and Healthcare Reform	6/18/2021	Combined Healthcare Reform policy J-0790 with this policy to create J-0714 - Acute Migraine Therapies - Commercial and Healthcare Reform. Policy revised to remove brand Alsuma (sumatriptan injection), Sumavel (sumatriptan injection), and Zecuity (sumatriptan transdermal system) from the list of targeted products as these are no longer on the market. Policy revised for Ubrelvy (ubrogepant) and Nurtec ODT (rimegepant) to require attestation that the benefits of therapy outweigh the risks if the treatment plan is to use a calcitonin gene-related peptide inhibitor for prevention of migraine with either Ubrelvy (ubrogepant) or Nurtec ODT (rimegepant).
Additional Quantities of Albuterol and Levalbuterol Inhalers - Commercial and Healthcare Reform	6/09/2021	New policy for additional quantities of albuterol or levalbuterol inhalers (up to 6 per 90 days) requiring prescriber attestation that the member is adherent to maximally tolerated controller medications, counseled on proper inhaler technique, and requires chronic maintenance of a short-acting beta agonist therapy.
Antimalarial Agents - Healthcare Reform	6/16/2021	Policy revised for Antimalarial Agents to require treatment of uncomplicated malaria to be due to one (1) of the following species: unknown, P. falciparum, P. vivax, P. ovale, P. malariae, or P. knowlesi. Also, treatment of severe malaria must occur in one (1) of the following situations: IV artesunate is not readily available or member has received 24 hours of IV artesunate and parasite density is less than or equal to 1%. Removed "nausea" as a symptom for babesiosis infection.
Antiviral Therapy - Healthcare Reform	6/16/2021	Policy revised for Antiviral Therapy to require minimum member age of 18 years old for Sitavig (acyclovir), 12 years old for Denavir (penciclovir), and 6 years old for Xerese (acyclovir 5%/hydrocortisone 1%). Further, member must experience therapeutic failure or intolerance to one (1) of the following generic oral antivirals or both are contraindicated: famciclovir or valacyclovir.
Antiviral Therapy (Sitavig and Denavir) - Commercial	6/16/2021	Policy revised for Antiviral Therapy (Sitavig (acyclovir) and Denavir (penciclovir)) to require minimum member age of 18 years old for Sitavig

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		(acyclovir) and 12 years old for Denavir (penciclovir). Further, member must experience therapeutic failure or intolerance to one (1) of the following generic oral antivirals or both are contraindicated: famciclovir or valacyclovir.
Azilect (rasagiline) - Commercial and Healthcare Reform	7/14/2021	Policy revised to combine Commercial and Healthcare Reform. Policy revised to add/move selegiline from required to the list of alternatives requiring a step through two agents.
Azilect (rasagiline) - Healthcare Reform	7/14/2021	Policy terminated and combined with J-0208 Azilect - Commercial and Healthcare Reform.
Beta Blocker Management - Commercial National Select	6/09/2021	Policy revised to remove Bystolic (nebivolol) and Byvalson (nebivolol; valsartan) as non-preferred beta blockers targeted in this policy.
Beta Blocker Management - Healthcare Reform	6/18/2021	Policy terminated as combined with J-0614 Beta Blocker Management - Commercial and Healthcare Reform.
Doxepin 5% Cream - Healthcare Reform	6/11/2021	Policy revised for doxepin hydrochloride 5% cream to add an alternate step therapy if the member has experienced therapeutic failure, intolerance, or contraindication to generic topical tacrolimus or pimecrolimus if the member has atopic dermatitis with facial or anogenital involvement. Quantity limitation criteria revised for the member has received a prior authorization for the use of doxepin hydrochloride 5% cream within the past 90 days (previously 30 days).
Eucrisa (crisaborole) - Commercial	TBD	Policy revised for Eucrisa (crisaborole) to require members experience therapeutic failure, contraindication, or intolerance to at least two corticosteroids (or have facial or anogenital involvement); and if the member is 2 years of age or older have experienced therapeutic failure, contraindication, or intolerance to generic topical tacrolimus or pimecrolimus. Policy combined both Commercial and Commercial Core policies with J-0918.
Eucrisa (crisaborole) - Commercial Core	TBD	Policy terminated. Criteria combined with Commercial policy J-0657.
Evekeo (amphetamine sulfate) - Commercial and Healthcare Reform	6/24/2021	Policy revised to change attention deficit hyperactivity disorder (ADHD) criteria for Evekeo ODT (amphetamine sulfate) to include patients 3-17

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		years of age, as per revised FDA guidance. Also, combined HCR policy (J-0787) in this policy. Added ICD-10 codes for various diagnoses. In Narcolepsy criteria, added requirement for documentation of baseline data for either Excessive Daytime Sleepiness (EDS) or Maintenance of Wakefulness Test (MWT). Separated out reauthorization criteria for ADHD-documentation that member has experienced positive clinical response to therapy. Reauthorization criteria for narcolepsy requires a decrease in EDS or MWT compared to baseline.
Fibrates - Healthcare Reform	6/18/2021	Policy terminated as combined with J-0868 Fibrates - Commercial.
Hemangeol (propranolol) oral solution - Healthcare Reform	6/18/2021	Terminated Healthcare Reform J-0788 policy and combined it with Commercial policy J-0686 Hemangeol (propranolol) oral solution.
Herpetic Keratitis - Commercial and Healthcare Reform	TBD	Policy revised to remove Avaclyr (acyclovir) ophthalmic ointment from the list of targeted medications because the product has not been launched. Policy revised to remove Viroptic (trifluridine) ophthalmic solution from the list of targeted medications because the product is no longer available on the market.
Herpetic Keratitis - Commercial and Healthcare Reform	TBD	Policy revised to add Avaclyr (acyclovir) ophthalmic ointment to the list of targeted medications when the product is launched. Policy revised to remove Viroptic (trifluridine) ophthalmic solution from the list of targeted medications because the product is no longer available on the market.
HIV-1 Therapies - Commercial and Healthcare Reform	7/1/2021	New policy for brand Truvada requires a diagnosis of HIV-1 infection or pre-exposure prophylaxis (PrEP) indication and that the member has tried and failed generic emtricitabine - tenofovir disoproxil fumarate. For PrEP, policy requires attestation that the member is not infected with HIV-1. For reauthorization, policy requires positive clinical response for treatment of HIV-1 and that the member is not infected with HIV-1 for PrEP.
HIV-1 Therapies - Commercial National Select Formulary	7/1/2021	New policy for brand Truvada (emtricitabine - tenofovir disoproxil fumarate) requires a diagnosis of HIV-1 infection or pre-exposure prophylaxis (PrEP) indication and that the member has tried and failed either generic emtricitabine-tenofovir

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		disoproxil fumarate or Descovy (emtricitabine - tenofovir alafenamide). For PrEP, policy requires attestation that the member is not infected with HIV-1. For reauthorization, policy requires positive clinical response for treatment of HIV-1 and that the member is not infected with HIV-1 for PrEP.
Luzu (luliconazole) - Commercial and Healthcare Reform	6/18/2021	Policy revised for Luzu (luliconazole 1% cream) to combine Commercial and Healthcare Reform lines of business into a single policy (J-0801) and require therapeutic failure or intolerance to generic luliconazole 1% cream if brand Luzu is being requested.
Lyrica (pregabalin) and Lyrica CR (pregabalin ER) - Commercial and Healthcare Reform	6/16/2021	Policy revised to include a step though generic pregabalin extended-release tablets if the request is for brand Lyrica CR (pregabalin extended release).
Non-preferred Atypical Antipsychotic Medications - Healthcare Reform Essential Formulary	6/24/2021	Criteria for the use of Saphris in Manic or Mixed Episodes Associated with Bipolar I Disorder changed from a member age of 13 years or older to a member age of 10 years of age or older.
Non-Preferred Benign Prostatic Hyperplasia Therapy - Commercial and Healthcare Reform	7/14/2021	Policy revised to add terazosin as an option for trial and failure.
Non-Preferred Benign Prostatic Hyperplasia Therapy - Healthcare Reform	7/14/2021	Terminating policy. Policy combined with the Commercial policy J-0756.
Non-Preferred Bupropion Therapy - Healthcare Reform	6/18/2021	Termination: policy combined with Commercial policy J-0839.
Non-Preferred Nasal Steroids - Commercial and Healthcare Reform	6/18/2021	Policy revised to remove Flonase (fluticasone propionate), Rhinocort (budesonide), Veramyst (fluticasone), and brand Nasacort (triamcinolone acetonide) from the list of targeted drugs since these products are no longer available as prescription products. Policy revised to include Nasacort (triamcinolone acetonide) brand over-the-counter products in the targeted list of medications.
Non-preferred NSAIDs - Commercial and Healthcare Reform	TBD	Policy revised to add Mefenamic acid, Meclofenamate, Lodine (etodolac), and Etodolac extended-release as targets requiring use for an

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		FDA-approved indication and trial and failure of three more cost-effective generic alternatives.
Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Commercial and Healthcare Reform	6/14/2021	Policy revised for Farxiga (dapagliflozin) that if member has chronic kidney disease not classified as diabetic nephropathy, then is using in combination with an angiotensin-converting enzyme inhibitor or angiotensin ii receptor blocker. If member has type 2 diabetes mellitus and diabetic nephropathy then member has tried and failed metformin or metformin-containing product and canagliflozin containing product. J-0662 Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Healthcare Reform combined to this policy.
Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Healthcare Reform	6/16/2021	Policy terminated and combined with J-0737 Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Commercial and Healthcare Reform.
Non-Preferred Statins – Healthcare Reform Essential Formulary	7/14/2021	Policy revised to add Roszet (rosuvastatin/ezetimibe). Criteria added for Roszet (rosuvastatin/ezetimibe) requiring diagnosis of an FDA-approved indication and failure on two preferred statin medications in combination with ezetimibe, available separately and taken together.
Non-Stimulant Treatment of ADHD - Commercial and Healthcare Reform	7/14/2021	Policy revised to include Qelbree (viloxazine). Members must be between the ages of 6-17, have a diagnosis of ADHD, have had one of the following: have had trial, failure, contraindication, or intolerance to a stimulant or personal history of substance abuse, or concern about illegal drug diversion. In addition, member must have had trial, failure, intolerance, or contraindication to generic guanfacine extended-release and member must also have had therapeutic failure, intolerance, or contraindication to atomoxetine or inability to swallow capsules. For automatic criteria, member must have a claim for a generic stimulant, generic guanfacine ER and generic atomoxetine all within the past 180 days.
Pulmicort (budesonide) nebulizer suspension - Commercial and Healthcare Reform	6/18/2021	Combined Commercial and Healthcare Reform (HCR) into one policy: archiving previous HCR policy. Policy revised for Pulmicort (budesonide) suspension to require one of the following for

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		reauthorization: decreased rescue medication or oral corticosteroid, or a decrease in frequency of severe asthma exacerbations, or an increase in pulmonary function from baseline, or reduction in reported asthma-related symptoms.
Pulmicort (budesonide) nebulizer suspension - Healthcare Reform	6/18/2021	Terminate Healthcare Reform J-712 policy and combine it with Commercial policy J-0226 Pulmicort (budesonide) nebulizer suspension - Commercial.
Rhopressa (netarsudil) - Commercial Core	6/18/2021	Policy revised to require therapeutic failure or intolerance to one additional generic alternative or contraindication to all other generic alternatives (previously allowed contraindication to one additional generic alternative).
Tivorbex (indomethacin) - Healthcare Reform	6/18/2021	Policy terminated as combined with J-0870 Tivorbex (indomethacin) - Commercial.
Trulance (plecanatide) - Healthcare Reform	6/14/2021	Termination: policy combined with Commercial policy, J-687.
Viibryd (vilazodone) and Trintellix (vortioxetine) - Commercial	6/24/2021	Policy revised to include criteria for reauthorization: the prescriber attests that the member has experienced positive clinical response to therapy.
Yupelri (revefenacin) - Commercial and Healthcare Reform	6/18/2021	Policy for Yupelri (revefenacin) revised to require members to meet one of the following criteria for reauthorization: a reduction in symptoms of chronic obstructive pulmonary disease, an improvement in exercise tolerance, delayed disease progression, or a reduction in the number of exacerbations.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

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

No changes at this time.

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
Fotivda (tivozanib)	21 capsules per 28 days	63 capsules per 84 days
Myrbetriq (mirabegron) oral granules	3 bottles (24.9 g granules or 300 mL) per 30 days	9 bottles (74.7 g granules or 900 mL) per 30 days
Ponvory (ponesimod) starter pack	1 starter pack per 720 days	1 starter pack per 720 days
Skyrizi (risankizumab-rzaa)	1 syringe/pen (1 mL) per 63 days	1 syringe/pen (1 mL) per 63 days
Xolair (omalizumab) prefilled syringes	1 mL per 21 days	3 mL per 63 days
Xpovio 100 mg once weekly dose (NDC 72237010305)*	8 tablets per 28 days	8 tablets per 28 days
Xpovio 40 mg once weekly dose (NDC 72237010207)*	4 tablets per 28 days	4 tablets per 28 days
Xpovio 40 mg twice weekly dose (NDC 72237010206)*	8 tablets per 28 days	8 tablets per 28 days
Xpovio 60 mg once weekly dose (NDC 72237010401)*	4 tablets per 28 days	4 tablets per 28 days
Xpovio 60 mg twice weekly dose (NDC 7223710103)*	24 tablets per 28 days	24 tablets per 28 days
Xpovio 80 mg once weekly dose (NDC 72237010202)*	8 tablets per 28 days	8 tablets per 28 days
Xpovio 80 mg twice weekly dose (NDC 7223710104)*	32 tablets per 28 days	32 tablets per 28 days

*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
Ulesfia (benzyl alcohol)	6 bottles (3 packages) per dispensing event	6 bottles (3 packages) per dispensing event
Zegalogue (dasiglucagon)	2 prefilled syringes/autoinjectors per dispensing event	2 prefilled syringes/autoinjectors per dispensing event

*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
Bunavail (buprenorphine/naloxone) 2.1-0.3 mg*	2 films per day

Drug Name	Daily Limit
Bunavail (buprenorphine/naloxone) 4.2-0.7 mg*	2 films per day
Buprenorphine/naloxone 2-0.5 mg tablets*	4 tablets per day
Evekeo (amphetamine) ODT 2.5 mg	1 tablet per day
Ingrezza (valbenazine) 60 mg	1 tablet per day
Ponvory (ponesimod) 20 mg tablet	1 tablet per day
Qelbree (viloxazine)	2 capsules per day
Roszet (rosuvastatin/ezetimibe)	1 tablet per day
Suboxone (buprenorphine/naloxone) 2-0.5 mg*	4 films per day
Suboxone (buprenorphine/naloxone) 4-1 mg*	2 films per day
Zubsolv (buprenorphine/naloxone) 0.7-0.18 mg*	2 tablets per day
Zubsolv (buprenorphine/naloxone) 1.4-0.36 mg	4 tablets per day
Zubsolv (buprenorphine/naloxone) 11.4-2.9 mg*	1 tablet per day
Zubsolv (buprenorphine/naloxone) 2.9-0.71 mg*	2 tablets per day

*Effective date to be determined.

**Quantity per Duration (QD) rule also applies to this medication (refer to Table 1).
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:

- **Performance Formulary**
- **Venture Formulary**
- **Incentive Formulary**

Table 1. 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	Comments
Kloxxado 8 mg	naloxone 8 mg	Opioid Overdose
Myrbetriq oral granules	mirabegron oral granules	Pediatric neurogenic detrusor overactivity (NDO)

Fotivda	tivozanib	Renal cell carcinoma
Jemperli	dostarlimab-gxly	Endometrial Cancer
Kimyrsa	oritavancin	ABSSSI
Ponvory 20 mg tablet	ponesimod 20 mg tablet	Multiple Sclerosis
Ponvory starter pack	ponesimod starter pack	Multiple Sclerosis
Zynlonta	loncastuximab tesirine-lpyl	Large B-cell lymphoma

Table 2. Non-Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Evekeo ODT 2.5 mg	amphetamine ODT 2.5 mg	amphetamine sulfate, methylphenidate HCl
Nextstellis	drospirenone/estetrol	drospirenone-ethinyl estradiol 3-0.02 mg, drospirenone-ethinyl estradiol 3-0.03 mg, drospirenone-e.estradiol-lm.FA 3-0.02-0.451 mg (24) (4)
Qelbree	viloxazine	guanfacine ER, clonidine ER
Roszet	rosuvastatin/ezetimibe	atorvastatin calcium
Zegalogue	dasiglucagon	Baqsimi, Glucagon Emergency Kit, Glucagen Hypokit

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:

- Performance Formulary
- Venture Formulary
- Incentive Formulary

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

Brand Name	Generic Name	Comments
Kloxxado 8 mg	naloxone 8 mg	Opioid Overdose
Myrbetriq oral granules	mirabegron oral granules	Pediatric neurogenic detrusor overactivity (NDO)
Fotivda	tivozanib	Renal cell carcinoma
Jemperli	dostarlimab-gxly	Endometrial Cancer
Kimyrsa	oritavancin	ABSSSI

Ponvory 20 mg tablet	ponesimod 20 mg tablet	Multiple Sclerosis
Ponvory starter pack	ponesimod starter pack	Multiple Sclerosis
Zynlonta	loncastuximab tesirine-lpyl	Large B-cell lymphoma

Table 2. Non-Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Zegalogue	dasiglucagon	Baqsimi, Glucagon Emergency Kit, Glucagen Hypokit

Table 3. Products Not Added*
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Evekeo ODT 2.5 mg	amphetamine ODT 2.5 mg	amphetamine sulfate, methylphenidate HCl
Nextstellis	drospirenone/estetrol	drospirenone-ethinyl estradiol 3-0.02 mg, drospirenone-ethinyl estradiol 3-0.03 mg, drospirenone-e.estradiol-lm.FA 3-0.02-0.451 mg (24) (4)
Qelbree	viloxazine	guanfacine ER, methylphenidate IR
Roszet	rosuvastatin/ezetimibe	atorvastatin calcium

*Physicians may request coverage of these products using the 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
Fotivda	tivozanib
Jemperli	dostarlimab-gxly
Kimyrsa	oritavancin
Ponvory 20 mg tablet	ponesimod 20 mg tablet
Ponvory starter pack	ponesimod starter pack

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Anti-Angiogenesis and VEGF Kinase Inhibitors - Medicare	7/1/2021	Policy revised to add criteria for new drug Fotivda (tivozanib) to require that the member is 18 years of age or older with a diagnosis of relapsed or refractory advanced renal cell carcinoma after receipt of at least two prior systemic therapies.
Chelating Agents - Medicare	6/14/2021	Policy revised to include new indications for Ferriprox (deferiprone); for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age (oral tablets) and older or 3 years of age (oral solution) and older with thalassemia syndromes and sickle cell disease or other anemias. Policy revised for chronic iron overload due to blood transfusions to add liver iron concentration (LIC) of at least 7 mg/g on initial authorization and LIC of at least 3 mg/g on reauthorization as an alternative to serum ferritin.
Chronic Inflammatory Diseases - Medicare	6/15/2021	Policy revised to update quantity limitations for Skyrizi (risankizumab) to include induction therapy of two prefilled pens/syringes (150 mg/mL) within the first 4 weeks of therapy and maintenance therapy of one prefilled syringe/pen (150 mg/mL) every 12 weeks.
Combination Prescription Drug Safety - Medicare	6/14/2021	Policy revised for 7 day opioid safety edit to allow approval for long term care residents.
Doxepin Cream 5% – Medicare	TBD	Policy revised for doxepin hydrochloride 5% cream to add an alternate step therapy if the member has experienced therapeutic failure, intolerance, or contraindication to generic topical tacrolimus or pimecrolimus if the member has atopic dermatitis with facial or anogenital involvement.
Eucrisa (crisaborole) - Medicare	6/11/2021	Policy revised for Eucrisa (crisaborole) to allow therapeutic failure, contraindication, or intolerance to at least one (1) topical corticosteroid and therapeutic failure, contraindication or intolerance to generic topical tacrolimus or pimecrolimus.
Gilenya (fingolimod) - Medicare	6/16/2021	Policy revised to move limitations of coverage regarding contraindications and baseline assessments to the background.
Herpetic Keratitis - Medicare	6/18/2021	Policy revised to remove Viroptic (trifluridine) (brand only) as a drug product that is targeted by

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		the policy because it is no longer available on the market.
High Risk Medications in the Elderly - Medicare	TBD	Addition of drugs based on High-Risk medication guidelines
Interleukin-1b blockers - Medicare	6/14/2021	Policy revised for Arcalyst (rilonacept) to add new indication for recurrent pericarditis requiring an age of 12 years or older; a diagnosis of recurrent pericarditis; and therapeutic failure or intolerance to an oral nonsteroidal anti-inflammatory drug (NSAID), systemic corticosteroid, or colchicine or contraindication to all. Policy revised for Cryopyrin-Associated Periodic Syndromes (CAPS) criteria to add age requirement for Arcalyst (rilonacept) for the member to be 12 years of age or older and Ilaris (canakinumab) for the member to be 4 years of age or older.
JAK Inhibitors – Medicare	6/24/2021	Policy revised for Jakafi (ruxolitinib) for prescriber attestation that the member has intermediate or high-risk myelofibrosis; and for Jakafi (ruxolitinib) to remove criteria for respective starting dose based on platelet count; and for Jakafi (ruxolitinib) to require baseline platelet count ≥ 50 x 10^9/L for new starts to therapy. Policy revised for Inrebic (fedratinib) for prescriber attestation that the member has intermediate-2 or high-risk myelofibrosis.
Mayzent (siponimod) - Medicare	6/16/2021	Policy revised to move limitations of coverage regarding contraindications and baseline assessments to the background.
Non-preferred Nasal Steroids – Medicare	TBD	Policy terminated due to the drugs being managed through formulary tiers.
Non-Stimulant Treatment of ADHD - Medicare	7/1/2021	Policy revised to include Qelbree (viloxazine), a new selective norepinephrine reuptake inhibitor (SNRI) for ADHD. Criteria include ages between 6-17, use of a stimulant or reason that stimulants cannot be used, and trial, failure, contraindication, or intolerance to generic atomoxetine. Authorization is for a period of 12 months.
Ongentys (opicapone) - Medicare	6/17/2021	Policy revised to remove the specific generic dosage forms for each of the alternatives except entacapone.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Panretin (alitretinoin) - Medicare	TBD	New policy created for Panretin requiring members to be 18 years of age or older, using for the treatment of cutaneous lesions in patients with AIDS-related Kaposi sarcoma, and the member is not receiving systemic therapy for Kaposi sarcoma.
PCSK9 Inhibitors - Medicare	6/10/2021	Policy revised for homozygous familial hypercholesterolemia (HoFH) to include Praluent (alirocumab) if the member is 18 years of age or older. For both Praluent (alirocumab) and Repatha (evolocumab) untreated low-density lipoprotein cholesterol (LDL-C) > 400 mg/dL or untreated total cholesterol (TC) > 500 mg/dL, if the member is 17 years of age or younger, LDL-C > 135 mg/dL, and moved that member will continue to receive concurrent lipid-lowering therapies for the treatment of HoFH from limitations of coverage to approval criteria.
Ponvory (ponesimod) - Medicare	6/17/2021	New policy for Ponvory (ponesimod) requiring diagnosis of a relapsing form of multiple sclerosis and limitation of coverage not authorizing use of combination disease modifying multiple sclerosis agents.
Programmed Death Receptor Therapies - Medicare	6/18/2021	Policy revised to add criteria for new drug Jemperli (dostarlimab-gxly) to require that the member has a diagnosis of recurrent or advanced endometrial carcinoma and has experienced disease progression on or following prior treatment with a platinum-containing regimen. Policy revised to add criteria for Keytruda (pembrolizumab) in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma. Policy revised to add criteria for Opdivo (nivolumab) for members with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy (CRT); and for members with advanced or metastatic gastric cancer,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Pulmonary Hypertension - Medicare	6/10/2021	Policy revised for Tyvaso (treprostinil) for expanded indication of pulmonary hypertension associated with interstitial lung disease (PH-ILD) that member has been determined to be eligible for Part D coverage, diagnosis of World Health Organization (WHO) Group 3 pulmonary hypertension, right heart catheterization substantiating all of the following mean pulmonary arterial pressure > 20 mmHg at rest, pulmonary wedge pressure ≤ 15 mmHg, and pulmonary vascular resistance ≥ 3 Wood units, diagnosis of interstitial lung disease, and is a non-smoker or is currently engaged in smoking cessation.
Reblozyl (luspatercept-aamt) - Medicare	TBD	Policy terminated due to the drug being healthcare administered with low chance of self-administration.
Roszet (rosuvastatin/ezetimibe) - Medicare	6/10/2021	New policy for Roszet (rosuvastatin/ezetimibe) to require failure on or intolerance to generic rosuvastatin in combination with generic ezetimibe, available separately and taken together.
Sublingual Immunotherapies - Medicare	6/16/2021	Policy revised to extend the indication for Ragwitek (Short Ragweed Pollen Allergen Extract) for use in members 5 to 65 years of age.
Tolsura (itraconazole) - Medicare	6/18/2021	Policy revised to remove requirement for attestation for need of Super-BioAvailable (SUBA) technology.
Tramadol 100 mg - Medicare	TBD	Terminating policy.
Trodelvy (sacituzumab govitecan-hziy) – Medicare	6/28/2021	Policy revised for Trodelvy (sacituzumab govitecan-hziy) for use in members 18 years of age or older with locally advanced or metastatic urothelial cancer after previous receipt of a platinum-containing chemotherapy and either a programmed death receptor-1 or a programmed death-ligand 1 receptor; and for use in members with triple negative breast cancer with disease classified as unresectable locally advanced after

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		receipt of at least two prior systemic therapies, with at least one prior systemic therapy for metastatic disease.
Zeposia (ozanimod) - Medicare	6/18/2021	Policy revised to remove age limit and move baseline assessments and contraindications to background. Addition of limitation of coverage stating combination use of disease modifying multiple sclerosis agents will not be authorized.
Zynlonta (loncastuximab tesirine-lpyl) - Medicare	6/18/2021	New policy created for Zynlonta (loncastuximab tesirine-lpyl) to require the member is 18 years of age or older, have a diagnosis of relapsed or refractory large B-cell lymphoma, and experienced therapeutic failure, intolerance, or contraindication to at least two lines of systemic therapy.

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

2. Managed Prescription Drug Coverage (MRxC) Program *

No changes at this time.

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)
Evekeo (amphetamine) ODT 2.5 mg	1 tablet per day	1 tablet per day
Fotivda (tivozanib)	21 capsules per 28 days	21 capsules per 28 days
Myrbetriq (mirabegron) oral granules	3 bottles (24.9 g granules or 300 mL)	9 bottles (74.7 g granules or 900 mL)
Ponvory (ponesimod) 20 mg tablet	1 tablet per day	1 tablet per day
Ponvory (ponesimod) starter pack	2 starter packs per year	2 starter packs per year
Qelbree (viloxazine)	2 capsules per day	2 capsules per day
Repatha 140mg/ml pen and syringe	3mL (3 injections) per 28 days	9mL (9 injections) per 84 days
Repatha pushtronex 420mg/3.5ml	7ml (2 pushtronex) per 28 days	21ml (6 pushtronex) per 84 days
Roszet (rosuvastatin/ezetimibe)	1 tablet per day	1 tablet per day
Skyrizi (risankizumab-rzaa)	1 syringe/pen per 84 days	1 syringe/pen per 84 days
Xpovio 100 mg once weekly dose (NDC 72237010305)	8 tablets per 28 days	24 tablets per 84 days

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Xpovio 40 mg once weekly dose (NDC 72237010207)	4 tablets per 28 days	12 tablets per 84 days
Xpovio 40 mg twice weekly dose (NDC 72237010206)	8 tablets per 28 days	24 tablets per 84 days
Xpovio 60 mg once weekly dose (NDC 72237010401)	4 tablets per 28 days	12 tablets per 84 days
Xpovio 60 mg twice weekly dose (NDC 7223710103)	24 tablets per 28 days	72 tablets per 84 days
Xpovio 80 mg once weekly dose (NDC 72237010202)	8 tablets per 28 days	24 tablets per 84 days
Xpovio 80 mg twice weekly dose (NDC 7223710104)	32 tablets per 28 days	96 tablets per 84 days
Zegalogue (dasiglucagon)	2 prefilled syringes/autoinjectors per dispensing event	2 prefilled syringes/autoinjectors per dispensing event

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