Formulary Updates

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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for **August 2021**. The formularies and pharmaceutical management procedures are updated on a bimonthly basis, and the following changes reflect the decisions made in August 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

CHANTIX by Pfizer: Recall – N-nitroso-varenicline

On July 19th, 2021, Pfizer recalled the above product. The affected product was recalled due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established Acceptable Daily Intake (ADI) level.

Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline. To date, Pfizer has not received any reports of adverse events that have been related to this recall.

Atovaquone Oral Suspension, USP 750 mg/5mL by KVK Tech. Inc.: Recall – Temperature Abuse

On August 6th, 2021, KVK Tech, Inc. recalled the above product. The affected product was recalled due to customer complaints of unusual grittiness in the product, which KVK has determined was most probably caused by prolonged exposure of these product lots to extremely cold weather during shipment.

Exposure of Atovaquone Oral Suspension to extremely low temperatures during shipment (the product is required to be protected from freezing temperatures), may result in changes to the effectiveness, appearance, taste, and thickness of the liquid. Severely immunocompromised patients who receive less effective Atovaquone Oral Suspension may experience inadequate treatment of serious and life-threatening infections. To date, KVK Tech is not aware of any adverse events associated with this problem.

CHANTIX by Pfizer: Recall – N-nitroso-varenicline

On August 16th, 2021, Pfizer expanded their recall the above product to include additional drug lots. The affected products were recalled due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established Acceptable Daily Intake (ADI) level.

Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline. To date, Pfizer has not received any reports of adverse events that have been related to this recall.

Lidocaine HCl Topical Solution 4% by Teligent Pharma, Inc.: Recall – Super Potency

On August 30th, 2021, Teligent Pharma, Inc. recalled the above product. The affected product was recalled because the firms testing has found it to be super potent based on an Out of Specification (OOS) result obtained at the 18-month stability timepoint.

Use of the super potent product would result in a higher than intended lidocaine dose above that intended. An increased lidocaine dose could lead to the development of local anesthetic systemic toxicity depending on the duration of the treatment and the specific patient. Local anesthetic systemic toxicity can result in central nervous system reactions including excitation and/or depression and more serious signs of cardiovascular toxicity such as bradycardia, hypotension, and even cardiovascular collapse can present very quickly. If local anesthetic systemic toxicity is not recognized and treated quickly, severe morbidity and even death can result. Adults and the elderly who are more likely to use this product as well as children of lower body weight are more likely to experience local anesthetic systemic toxicity if a higher than intended lidocaine concentration is administered. To date, Teligent Pharma, Inc. has not received any reports of adverse events related to this recall.

09/01/2021 FDA Drug Safety Communication: FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions. Approved uses also being limited to certain patients.

After reviewing a large, randomized safety clinical trial, the Food and Drug Administration (FDA) has concluded that there is an increased risk of serious heart-related events like heart attack, stroke, cancer, blood clots, and death with the medications Xeljanz and Xeljanz XR (tofacitinib). These products are used to treat arthritis and ulcerative colitis. A trial comparing Xeljanz with tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis showed an increased risk of blood clots and death with Xeljanz.

Based on their findings, the FDA is requiring updates to the *Boxed Warning*, the FDA's most prominent warning for Xeljanz, Xeljanz XR, Olumiant (baricitinib), and Rinvoq (upadacitinib) to include information regarding the risks of serious heart-related events, cancer, blood clots, and death. Further, updates will be made to multiple sections of the prescribing information and the patient Medication Guide. In summary, all approved uses of these agents will be limited to certain patients who have not responded or cannot tolerate one or more TNF blockers.

Like Xeljanz, Olumiant and Rinvoq are Janus kinase (JAK) inhibitors with similar mechanisms of action, so the FDA believes they may share similar risks. Two other JAK inhibitors, Jakafi (ruxolitinib) and Inrebic (fedratinib), are not indicated for the treatment of arthritis and other inflammatory conditions; as a result, these products are not included in the prescribing information updates at this time. Adverse events involving any JAK inhibitor should be reported to the FDA MedWatch program.

Highmark Formulary Update – August 2021

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Healthcare Reform Comprehensive 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
- Highmark Healthcare Reform Comprehensive 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 August 2021, unless otherwise noted.

Brand Name	Generic Name	Indication/Comments
Prevnar 20	pneumococcal 20-valent conjugate vaccine	Prevention of Pneumococcal Disease
Cosentyx 75 mg	secukinumab 75 mg	Pediatric Psoriasis
Epclusa 150 mg/37.5 mg oral pellets*	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets	Chronic Hepatitis C Infection
Epclusa 200 mg/50 mg oral pellets*	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets	Chronic Hepatitis C Infection
Mavyret oral pellets*	glecaprevir/pibrentasvir oral pellets	Chronic Hepatitis C Infection

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Brexafemme	ibrexafungerp	fluconazole tablet
Lybalvi*	olanzapine/samidorphan	quetiapine fumarate, risperidone tablet, olanzapine tablet
Noxafil PowderMix*	posaconazole PowderMix	fluconazole tablet; fluconazole suspension,

Brand Name	Generic Name	Preferred Alternatives
		reconstituted, oral (ml); itraconazole solution, oral
Pradaxa oral pellets*	dabigatran oral pellets	warfarin sodium tablet, enoxaparin sodium syringe (ml)
Verkazia ophthalmic emulsion*	cyclosporine ophthalmic emulsion	cromolyn sodium drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops
Myfembree	relugolix/estradiol/norethidrone	Oriahnn
Empaveli	pegcetacoplan	Prescriber discretion
Lumakras	sotorasib	Prescriber discretion
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets	Prescriber discretion
Truseltiq	infigratinib	Prescriber discretion
Wegovy	semaglutide	Prescriber discretion

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 Form.

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
Cosentyx 75 mg	secukinumab 75 mg
Epclusa 150 mg/37.5 mg oral pellets	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets
Epclusa 200 mg/50 mg oral pellets	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets
Mavyret oral pellets	glecaprevir/pibrentasvir oral pellets
Myfembree	relugolix/estradiol/norethidrone
Empaveli	pegcetacoplan
Lumakras	sotorasib
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets

Truseltiq	infigratinib

B. Changes to the 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 Healthcare Reform Progressive Formulary

Table 1. Formulary Updates

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

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Cosentyx 75 mg	secukinumab 75 mg	3 - Preferred Specialty	Pediatric Psoriasis
Epclusa 150 mg/37.5 mg oral pellets*	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets	3 - Preferred Specialty	Chronic Hepatitis C Infection
Epclusa 200 mg/50 mg oral pellets*	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets	3 - Preferred Specialty	Chronic Hepatitis C Infection
Mavyret oral pellets*	glecaprevir/pibrentasvir oral pellets	3 - Preferred Specialty	Chronic Hepatitis C Infection
Items listed below are non-preferred products			
Brexafemme	ibrexafungerp	3 - Nonpreferred Brand	fluconazole tablet
Lybalvi*	olanzapine/samidorphan	3 - Nonpreferred Brand	quetiapine fumerate, risperidone tablet, olanzapine tablet
Noxafil PowderMix*	posaconazole PowderMix	3 - Nonpreferred Brand	fluconazole tablet; fluconazole suspension, reconstituted, oral (ml)
Pradaxa oral pellets*	dabigatran oral pellets	3 - Nonpreferred Brand	warfarin sodium tablet, enoxaparin sodium syringe (ml)
Verkazia ophthalmic emulsion*	cyclosporine ophthalmic emulsion	3 - Nonpreferred Brand	cromolyn sodium drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops

Prevnar 20	pneumococcal 20-valent conjugate vaccine	3 - Nonpreferred Brand	Prescriber discretion
Wegovy	semaglutide	3 - Nonpreferred Brand	Prescriber discretion
Myfembree	relugolix/estradiol/norethidrone	4 - Nonpreferred Specialty	Oriahnn
Empaveli	pegcetacoplan	4 - Nonpreferred Specialty	Prescriber discretion
Lumakras	sotorasib	4 - Nonpreferred Specialty	Prescriber discretion
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets	4 - Nonpreferred Specialty	Prescriber discretion
Truseltiq	infigratinib	4 - Nonpreferred Specialty	Prescriber discretion

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

Tier 1: Preferred generic drugs; **Tier 2:** Preferred brand drugs; **Tier 3:** Non-preferred generic drugs, non-preferred brand drugs, preferred specialty drugs; **Tier 4:** Non-preferred specialty drugs.

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates
All formulary changes effective August 2021, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Prevnar 20	pneumococcal 20-valent conjugate vaccine	3	Prevention of Pneumococcal Disease
Cosentyx 75 mg	secukinumab 75 mg	4	Pediatric Psoriasis
Epclusa 150 mg/37.5 mg oral pellets*	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets	4	Chronic Hepatitis C Infection
Epclusa 200 mg/50 mg oral pellets*	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets	4	Chronic Hepatitis C Infection
Mavyret oral pellets*	glecaprevir/pibrentasvir oral pellets	4	Chronic Hepatitis C Infection

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets	4	Pediatric CF 6-11 years
Items listed below were not added to the formulary			
Brexafemme	ibrexafungerp	NF	fluconazole tablet
Lybalvi*	olanzapine/samidorphan	NF	quetiapine fumerate, risperidone tablet, olanzapine tablet
Myfembree	relugolix/estradiol/norethindrone	NF	Oriahnn
Noxafil PowderMix*	posaconazole PowderMix	NF	fluconazole tablet; fluconazole suspension, reconstituted, oral (ml)
Pradaxa oral pellets*	dabigatran oral pellets	NF	warfarin sodium tablet, enoxaparin sodium syringe (ml)
Verkazia ophthalmic emulsion	cyclosporine ophthalmic emulsion	NF	cromolyn sodium drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops
Empaveli	pegcetacoplan	NF	Prescriber discretion
Lumakras	sotorasib	NF	Prescriber discretion
Truseltiq	infigratinib	NF	Prescriber discretion
Wegovy	semaglutide	NF	Prescriber discretion

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 August 2021, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Prevnar 20	pneumococcal 20-valent conjugate vaccine	3	Prevention of Pneumococcal Disease
Cosentyx 75 mg	secukinumab 75 mg	4	Pediatric Psoriasis
Mavyret oral pellets*	glecaprevir/pibrentasvir oral pellets	4	Chronic Hepatitis C Infection
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets	4	Pediatric CF 6-11 years
Items listed below were not added to the formulary			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Brexafemme	ibrexafungerp	NF	fluconazole tablet
Epclusa 150 mg/37.5 mg oral pellets*	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets	NF	Mavyret pellets in packet (ea), sofosbuvir-velpatasvir tablet
Epclusa 200 mg/50 mg oral pellets*	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets	NF	Mavyret pellets in packet (ea), sofosbuvir-velpatasvir tablet
Lybalvi*	olanzapine/samidorphan	NF	quetiapine fumerate, risperidone tablet, olanzapine tablet
Myfembree	relugolix/estradiol/norethindrone	NF	Oriahnn
Noxafil PowderMix*	posaconazole PowderMix	NF	fluconazole tablet; fluconazole suspension, reconstituted, oral (ml)
Pradaxa (dabigatran) oral pellets*	dabigatran oral pellets	NF	warfarin sodium tablet, enoxaparin sodium syringe (ml)
Verkazia ophthalmic emulsion*	cyclosporine ophthalmic emulsion	NF	cromolyn sodium drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops
Empaveli	pegcetacoplan	NF	Prescriber discretion
Lumakras	sotorasib	NF	Prescriber discretion
Truseltiq	infigratinib	NF	Prescriber discretion
Wegovy	semaglutide	NF	Prescriber discretion

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)			
Myfembree	relugolix/estradiol/norethindrone	2	Uterine Fibroids
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets	2	Pediatric CF 6-11 years
Items listed below were added to the formulary (non-preferred)			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Epclusa 150mg/37.5 mg oral pellets*	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets	3	Epclusa tablets
Epclusa 200 mg/50 mg oral pellets*	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets	3	Epclusa tablets
Lybalvi*	olanzapine/samidorphan	3	quetiapine fumerate, risperidone tablet, olanzapine tablet
Mavyret oral pellets*	glecaprevir/pibrentasvir oral pellets	3	Harvoni, Epclusa tablets
Noxafil PowderMix*	posaconazole PowderMix	3	fluconazole tablet; fluconazole suspension, reconstituted, oral (ml)
Pradaxa oral pellets*	dabigatran oral pellets	3	warfarin sodium tablet, enoxaparin sodium syringe (ml)
Prevnar 20*	pneumococcal 20-valent conjugate vaccine	3	Prescriber discretion
Verkazia* ophthalmic emulsion	cyclosporine ophthalmic emulsion	3	cromolyn sodium drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops
Empaveli*	pegcetacoplan	3	Prescriber discretion
Lumakras*	sotorasib	3	Prescriber discretion
Items listed below were not added to the formulary			
Brexafemme	ibrexafungerp	NF	fluconazole tablet
Cosentyx 75 mg	secukinumab 75 mg	NF	Taltz
Truseltiq	infigratinib	NF	Pemazyre

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
Epclusa 150 mg/37.5 mg oral pellets	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets
Epclusa 200 mg/50 mg oral pellets	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets
Myfembree	relugolix/estradiol/norethidrone
Empaveli	pegcetacoplan
Lumakras	sotorasib
Truseltiq	infigratinib

Cosentyx 75 mg	secukinumab 75 mg
Mavyret oral pellets	glecaprevir/pibrentasvir oral pellets

F. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Aldara and Zyclara (imiquimod) – Commercial and Healthcare Reform	08/17/2021	Policy revised for Aldara (imiquimod) and Zyclara (imiquimod) for actinic keratosis and superficial basal cell carcinoma to require therapeutic failure or intolerance to generic imiquimod 5% cream and to one of the following: fluorouracil 5% topical cream or fluorouracil topical solution. Criteria revised for external genital warts to require therapeutic failure or intolerance to generic imiquimod 5% cream.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	09/01/2021	Policy revised for use in members 18 years of age or older for each of the following: Cabometyx (cabozantinib), Cometriq (cabozantinib), Inlyta (axitinib), Lenvima (lenvatinib), Nexavar (sorafenib), Stivarga (regorafenib).
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	09/01/2021	Policy revised for Sutent (sunitinib) to add step through generic sunitinib. Policy revised for use in members 18 years of age or older for each of the following: Cabometyx (cabozantinib), Cometriq (cabozantinib), Inlyta (axitinib), Lenvima (lenvatinib), Nexavar (sorafenib), Stivarga (regorafenib).
Apomorphine Products – Commercial and Healthcare Reform	09/01/2021	Policy revised to remove "generic" and the dosage form after each of the preferred formulary alternatives.
Brexafemme (ibrexafungerp) - Commercial and Healthcare Reform	09/01/2021	Policy created for Brexafemme (ibrexafungerp) to require documented diagnosis of vulvovaginal candidiasis (VVC) with either microscopic confirmation of budding yeasts or hyphae or a positive culture for Candida albicans, < 4 episodes of VVC in the last year, and therapeutic failure, contraindication, or intolerance to fluconazole tablet. Authorization duration of 1 month.
CFTR Modulators - Commercial and Healthcare Reform	08/20/2021	Policy revised for CFTR Modulators to change minimum patient age requirement for Trikafta

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(elexacaftor/tezacaftor/ivacaftor) from 12 years of age to 6 years of age.
CGRP Inhibitors – Commercial and Healthcare Reform	08/12/2021	Policy revised to include Nurtec ODT (rimegepant) and Ubrelvy (ubrogepant). Criteria for Nurtec ODT (rimegepant) updated to require diagnosis of acute migraine or preventive treatment of episodic migraine and therapeutic failure, contraindication, or intolerance to two of the following: generic oral sumatriptan, rizatriptan, or zolmitriptan OR two different classes of prophylactic therapies.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	09/03/2021	Policy revised for Cimzia (certolizumab) in Crohn's disease (CD) to remove therapeutic failure or intolerance to at least 2 immunosuppressants or the member is currently pregnant. Criteria revised for Humira (adalimumab) in CD for adults to remove therapeutic failure or intolerance to at least two immunosuppressants or the member is currently pregnant; for pediatric CD to remove therapeutic failure or intolerance to at least one immunosuppressant. Criteria revised for Stelara (ustekinumab) in CD to remove therapeutic failure or intolerance to at least 2 immunosuppressants, or the member is currently pregnant, or previous intolerance to a tumor necrosis factor (TNF) inhibitor. Criteria revised for Cosentyx (secukinumab) in plaque psoriasis (PsO) for the member to be 6 years of age or older. Cosentyx quantity limitations updated for pediatric PsO (≥ 50 kg) for 5 pens/prefilled syringes (150 mg/mL) within the first 4 weeks, then 1 pen/prefilled syringe (150 mg/mL) every 4 weeks; (< 50kg) for 5 prefilled syringes (75mg/mL) within the first 4 weeks of therapy, then 1 prefilled syringe (75mg/mL) every 4 weeks. Ilumya (tildrakizumab-asmn) criteria for PsO combined into policy (terminating J-0725). Quantity limitations updated for Tremfya (guselkumab) to include induction and maintenance dosing for psoriatic arthritis.
Chronic Inflammatory Diseases - Commercial National Select Formulary	09/03/2021	Policy revised for Cimzia (certolizumab) in Crohn's disease (CD) to remove therapeutic failure or intolerance to at least 2 immunosuppressants or the member is currently

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		pregnant. Criteria revised for Humira (adalimumab) in CD for adults to remove therapeutic failure or intolerance to at least two immunosuppressants or the member is currently pregnant; for pediatric CD to remove therapeutic failure or intolerance to at least one immunosuppressant. Criteria revised for Stelara (ustekinumab) in CD to remove therapeutic failure or intolerance to at least 2 immunosuppressants, or the member is currently pregnant, or previous intolerance to a tumor necrosis factor (TNF) inhibitor. Criteria revised for Cosentyx (secukinumab) in plaque psoriasis (PsO) for the member to be 6 years of age or older. Cosentyx quantity limitations updated for pediatric PsO (≥ 50 kg) for 5 pens/prefilled syringes (150 mg/mL) within the first 4 weeks and 1 pen/prefilled syringe (150 mg/mL) every 4 weeks; (< 50kg) for 5 prefilled syringes (75mg/mL) within the first 4 weeks of therapy, then one prefilled syringe (75mg/mL) every 4 weeks. Ilumya (tildrakizumab-asmn) criteria for PsO combined into policy (terminating J-1048). Quantity limitations updated for Tremfya (guselkumab) to include induction and maintenance dosing for psoriatic arthritis.
CSF1R Tyrosine Kinase Inhibitors – Commercial and Healthcare Reform	09/01/2021	Policy revised for Turalio (pexidartinib) for use in members 18 years of age or older.
Egrifta SV (tesamorelin) - Commercial and Healthcare Reform	08/18/2021	Policy revised for Egrifta SV (tesamorelin) to ask for diagnosis of human immunodeficiency virus (HIV) infection in initial authorization. Reauthorization revised to include the member continues to receive antiretroviral therapy for HIV infection.
Elidel (pimecrolimus) and Protopic (tacrolimus) - Commercial	08/18/2021	Policy revised for Protopic (tacrolimus) ointment 0.1% to require the member be 16 years of age or older, have a diagnosis of moderate to severe atopic dermatitis (AD), allow contraindication or intolerance to at least one prescription topical corticosteroid, and if request is for brand, allow intolerance to either generic topical tacrolimus or pimecrolimus. Criteria revised for Protopic (tacrolimus) ointment 0.03% to require a diagnosis

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		of moderate to severe AD, allow contraindication or intolerance to one prescription topical corticosteroid, and if request is for brand, allow intolerance to either generic topical tacrolimus or pimecrolimus.
Empaveli (pegcetacoplan) - Commercial and Healthcare Reform	08/20/2021	New policy created for Empaveli (pegcetacoplan) to require the member to be at least 18 years of age, have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), either have PNH mutant clone confirmed by flow cytometry or glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs) confirmed by flow cytometry, have baseline hemoglobin level < 10.5 g/dL, have at least one of the following symptoms: fatigue, hemoglobinuria, abdominal pain, dyspnea, dysphagia, erectile dysfunction, or history of blood cell transfusion due to PNH. Reauthorization criteria require the member to have experienced an increase in the hemoglobin levels, or a decrease in the number of transfusions, or a decrease from baseline in the lactase dehydrogenase (LDH) levels from baseline.
FGFR Kinase Inhibitors – Commercial and Healthcare Reform	09/01/2021	Policy revised to add criteria for Truseltiq (infigratinib) for members 18 years of age or older with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.
Gimoti (metoclopramide) - Commercial and Healthcare Reform	08/20/2021	Policy revised for Gimoti (metoclopramide) to specify the member has experienced therapeutic failure or intolerance to generic metoclopramide oral tablets or oral solution, or the member is unable to swallow oral dosage forms.
Hepatitis C Oral Therapy - Commercial and Healthcare Reform	11/01/2021	Policy revised for Epclusa (sofobuvir/velpatasvir) and Mavyret (glecaprevir/pibrentasvir) to allow for use in members 3 years of age or older. Removed creatinine clearance requirement from Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Added Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as a preferred treatment regimen for Zepatier (elbasvir/grazoprevir) treatment-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		experienced patients with genotypes 1-6 and with/without cirrhosis. Added Mavyret (glecaprevir/pibrentasvir) x 16 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as preferred regimens for sofosbuvir-based treatment-experienced members with genotypes 4-6. Added ribavirin to Epclusa (sofobuvir/velpatasvir) x 24 weeks (genotype 2 and 3) and updated Prior Treatment to include all treatment-experienced patients in post-liver transplant members with decompensated cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to preferred product for treatment-experienced kidney transplant patients without cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 12 weeks to preferred product for treatment-experienced kidney transplant patients with cirrhosis.
Hepatitis C Oral Therapy - Commercial Core	11/01/2021	Policy revised for Epclusa (sofobuvir/velpatasvir) and Mavyret (glecaprevir/pibrentasvir) to allow for use in members 3 years of age or older. Removed creatinine clearance requirement from Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Added Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as a preferred treatment regimen for Zepatier (elbasvir/grazoprevir) treatment-experienced patients with genotypes 1-6 and with/without cirrhosis. Added Mavyret (glecaprevir/pibrentasvir) x 16 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as preferred regimens for sofosbuvir-based treatment-experienced members with genotypes 4-6. Added ribavirin to Epclusa (sofobuvir/velpatasvir) x 24 weeks (genotype 2 and 3) and updated Prior Treatment to include all treatment-experienced patients in post-liver transplant members with decompensated cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to preferred product for treatment-experienced kidney transplant patients without cirrhosis.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 12 weeks to preferred product for treatment-experienced kidney transplant patients with cirrhosis.
Hepatitis C Oral Therapy - Commercial National Select Formulary	11/01/2021	Policy revised for Epclusa (sofobuvir/velpatasvir) and Mavyret (glecaprevir/pibrentasvir) to allow for use in members 3 years of age or older. Removed creatinine clearance requirement from Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Added Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as a preferred treatment regimen for Zepatier (elbasvir/grazoprevir) treatment-experienced patients with genotypes 1-6 and with/without cirrhosis. Added Mavyret (glecaprevir/pibrentasvir) x 16 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as preferred regimens for sofosbuvir-based treatment-experienced members with genotypes 4-6. Added ribavirin to Epclusa (sofobuvir/velpatasvir) x 24 weeks (genotype 2 and 3) and updated Prior Treatment to include all treatment-experienced patients in post-liver transplant members with decompensated cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to preferred product for treatment-experienced kidney transplant patients without cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 12 weeks to preferred product for treatment-experienced kidney transplant patients with cirrhosis.
Ilumya (tildrakizumab-asmn) - Commercial and Healthcare Reform	09/02/2021	Policy terminated; criteria combined into J-0558.
Ilumya (tildrakizumab-asmn) - Commercial National Select	09/02/2021	Policy terminated; criteria combined into J-1049.
Increlex (mecasermin) – Commercial and Healthcare Reform	08/18/2021	Policy revised for Increlex (mecasermin) to add gene deletion indication including age 17 years or younger, subnormal response in growth hormone stimulation tests, growth velocity at least 2

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		standard deviations (SD) below the age-appropriate mean or height at least 2.25 SD below age-appropriate mean, the member has developed neutralizing antibodies to growth hormone product(s), and bone age.
KRAS G12C Inhibitors - Commercial and Healthcare Reform	09/01/2021	New policy created for Lumakras (sotorasib) to ask that member is 18 years of age or older, diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA-approved test who has received at least one (1) prior systemic therapy. Reauthorization criteria attesting member has experienced disease improvement or delayed disease progression.
Lotronex (alosetron) - Commercial and Healthcare Reform	08/13/2021	Policy revised for Lotronex (alosetron) to require the member to experience therapeutic failure or intolerance to two (2) agents from two (2) different medication classes: anti-diarrheal, bile acid sequestrant, anti-spasmodic, tricyclic antidepressant, or selective serotonin reuptake inhibitor; or contraindication to all. If the request is for brand Lotronex, the member has experienced therapeutic failure or intolerance to generic alosteron. Reauthorization criteria updated for additional attestation that the member's irritable bowel syndrome with diarrhea (IBS-D) symptoms continue to persist. Limitations of coverage section revised to remove black box warning for serious gastrointestinal adverse reactions and discontinuation in patients who develop constipation or symptoms of ischemic colitis (moved to prescribing considerations). Authorization duration revised for an initial authorization duration of 12 weeks, and reauthorization duration of 12 months. Policy combined with Healthcare Reform (J-0953).
Lotronex (alosetron) - Healthcare Reform	08/12/2021	Policy for Lotronex (alosetron) - Healthcare Reform terminated. Criteria combined into Commercial policy J-0227.
Lybalvi (olanzapine/samidorphan) - Commercial and Healthcare Reform	TBD	New policy created for Lybalvi (olanzapine/samidorphan) to require the member to be at least 18 years of age, have a diagnosis of schizophrenia or bipolar I disorder, either have

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		experienced therapeutic failure on, intolerance to, or contraindication to generic risperidone and generic quetiapine or currently be stable on and responding to olanzapine, but experiencing weight gain from the medication, have been counseled on appropriate lifestyle modifications (e.g., diet, exercise), and have experienced therapeutic failure on, intolerance to, or contraindication to metformin. Reauthorization criteria require the member to have experienced a positive clinical response to therapy.
New York Plan-Preferred Step Therapy Exception - Commercial and Healthcare Reform	08/11/2021	New policy created to allow for exception to plan-preferred step therapy (not including clinical step therapy) for New York members according to New York Legislature Bill A2834D, who meet one of the following: the plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member, the plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member's prescription drug regimen, the member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, or the member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where "stable" is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of "stable"), provided that this shall not prevent a utilization review agent from requiring an insured to try an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Northera (droxidopa) - Commercial and Healthcare Reform	08/17/2021	Policy revised for Northera (droxidopa) to combine Healthcare Reform policy J-0562 and to update maintenance criteria to reauthorization criteria and only include response to therapy criteria. Policy also revised to require therapeutic failure or intolerance to one alternative or contraindication to both other alternatives (previously allowed contraindication to one additional generic alternative).
Northera (droxidopa) - Healthcare Reform	08/16/2021	Policy retired and combined with J-0489 Northera (droxidopa) – Commercial.
Noxafil (posaconazole) - Commercial and Healthcare Reform	11/01/2021	Policy revised for Noxafil (posaconazole) to include Noxafil (posaconazole) PowderMix for delayed-release oral suspension. Clotrimazole removed as a generic alternative step when requesting Noxafil (posaconazole) for *Aspergillus* or *Candida* infection prophylaxis. If the request is for Noxafil (posaconazole) oral suspension, the member must be unable to swallow tablets. If the request is for Noxafil (posaconazole) PowderMix for delayed-release oral suspension, the member must be unable to swallow tablets and weigh less than or equal to 40 kg.
Nutritional Supplements - Commercial and Healthcare Reform (HMNY)	08/11/2021	New policy created for select New York plans for enteral formulas (e.g., carbohydrates, dietary supplements, emollients, infant formulas, protein replacement, water) requiring the member has a valid prescription from a licensed prescriber, the benefits of the requested enteral formula cannot be obtained through dietary means alone, and the formula is medically necessary and has been proven effective as a disease-specific treatment regimen for an appropriate diagnosis as supported by clinical progress notes and/or appropriate diagnostic testing. Reauthorization criteria added for the member to meet all initial authorization criteria, and for chronic conditions, the prescriber attests the member has experienced disease improvement, stabilization, or delayed disease progression. Authorization duration added for 1 year.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Palynziq (pegvaliase-pqpz) - Commercial and Healthcare Reform	08/20/2021	Policy revised for Palynziq (pegvaliase-pqpz) to remove reauthorization criterion that the member experienced at least a 20% reduction in phenylalanine level from pretreatment baseline and update the maximum dose in the reauthorization criteria to 60 mg/day.
PDGFR Tyrosine Kinase Inhibitors – Commercial and Healthcare Reform	09/01/2021	Policy revised for Ayvakit (avapritinib) to add criteria for use in members 18 years of age or older with platelet count >/= 50 x 10^9/L with a diagnosis of one of the following: aggressive systemic mastocytosis; systemic mastocytosis with an associated hematological neoplasm (SM-AHN); or mast cell leukemia (MCL).
Provigil (modafinil) and Nuvigil (armodafinil) - Commercial and Healthcare Reform	09/03/2021	Policy revised for Provigil (modafinil) to add approval criteria for quantities up to 400 mg daily for diagnoses of obstructive sleep apnea and multiple sclerosis fatigue when the member is inadequately controlled on 200 mg daily.
Provigil (modafinil) and Nuvigil (armodafinil) - Commercial and Healthcare Reform (Delaware Only)	09/01/2021	Policy revised for Provigil (modafinil) to add approval criteria for quantities up to 400 mg daily for diagnoses of obstructive sleep apnea, shift work sleep disorder, and multiple sclerosis fatigue when the member is inadequately controlled on 200 mg daily.
Pulmonary Hypertension – Commercial and Healthcare Reform	08/17/2021	Policy revised for Adcirca/Alyq (tadalafil) that if request is for brand Adcirca, the member experienced therapeutic failure or intolerance to generic tadalafil or Alyq.
Samsca (tolvaptan) - Commercial and Healthcare Reform	08/18/2021	Policy revised for Samsca (tolvaptan) that if the request is for brand Samsca (all strengths), the member has experienced therapeutic failure or intolerance to generic tolvaptan.
Spleen Tyrosine Kinase Inhibitors - Healthcare Reform	11/01/2021	Policy terminated and combined with J-0735 Spleen Tyrosine Kinase Inhibitors - Commercial and Healthcare Reform.
Synarel (nafarelin) - Commercial and Healthcare Reform	08/16/2021	Policy revised for Synarel (nafarelin acetate) for CPP to expand age to 11 years if female and 12 years if male or there is medical necessity for use above those ages, has advancement of bone age ≥ 12 months beyond chronological age, and revised lab values that member has elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/L or elevated leuprolide-stimulated LH level >

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		3.3 - 5 IU/L. For endometriosis, added that member is female, changed documentation to attestation that member is not pregnant, removed normal bone density as demonstrated by T-score > -1.0, and added step that member has tried and failed Orilissa. Combined J-0665 Synarel (nafarelin) - Healthcare Reform into this policy which allows for an expansion of step therapy with a gonadotropin releasing hormone agonist option for endometriosis.
Synarel (nafarelin) - Healthcare Reform	08/15/2021	Policy terminated and combined with J-0223 Synarel (nafarelin) - Commercial and Healthcare Reform.
Thrombopoiesis Stimulating Agents - Commercial and Healthcare Reform	08/24/2021	Policy revised for Nplate (romiplostim) to allow use to increase survival in adults and pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]) in members who have been exposed to radiation levels > 2 gray (Gy).
Uterine Leiomyomas - Commercial and Healthcare Reform	09/01/2021	Policy revised to add criteria for Myfembree (relugolix, estradiol, norethindrone acetate) requiring the member to be a premonpausal woman with a diagnosis of uterine leiomyomas experiencing heavy menstrual bleeding. A baseline assesment of BMD specifying that the member does not have osteoporosis is required for Myfembree (relugolix, estradiol, norethindrone acetate) and Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules). The total combined treatment duration cannot exceed 24 months.
Verkazia (cyclosporine ophthalmic emulsion) – Commercial and Healthcare Reform	TBD	New policy created for Verkazia (cyclosporine ophthalmic emulsion) requiring member to be 4 years of age or older, diagnosis of moderate to severe vernal keratoconjunctivitis (VKC), and therapeutic failure or intolerance to one (1) agent from two (2) of the following different medication classes, or all are contraindicated: Generic ophthalmic antihistamines (e.g., olopatadine), Generic ophthalmic mast cell stabilizers (e.g., cromolyn sodium), or Generic ophthalmic corticosteroids (e.g., dexamethasone,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		prednisolone, fluorometholone). Reauthorization criteria requires prescriber attestation that the member has experienced positive clinical response to therapy.
Viberzi (eluxadoline) - Commercial and Healthcare Reform	08/20/2021	Policy revised for Viberzi (eluxadoline) to require the member experience therapeutic failure or intolerance to two (2) agents from two (2) different medication classes: anti-diarrheal, bile acid sequestrant, anti-spasmodic, tricyclic antidepressant, or selective serotonin reuptake inhibitor; or contraindication to all. Limitations of coverage section revised to remove known or suspected biliary duct obstruction, sphincter of oddi disease, history of pancreatitis, severe constipation, and dosing exceeding 75 mg twice daily (moved to prescribing considerations).
Viberzi (eluxadoline) - Commercial National Select Formulary	08/20/2021	Policy revised for Viberzi (eluxadoline) to require the member experience therapeutic failure or intolerance to one (1) agent from any of the following medication classes: anti-diarrheal, bile acid sequestrant, anti-spasmodic, tricyclic antidepressant, or selective serotonin reuptake inhibitor; or contraindication to all. Limitations of coverage section revised to remove known or suspected biliary duct obstruction, sphincter of oddi disease, history of pancreatitis, severe constipation, and dosing exceeding 75 mg twice daily (moved to prescribing considerations).
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) - Commercial and Healthcare Reform	08/24/2021	Policy revised for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) to move criteria that member does not have primary (light chain) amyloidosis into limitations of coverage.
Zytiga and Yonsa (abiraterone acetate) - Commercial and Healthcare Reform	09/01/2021	Policy revised for Zytiga (abiraterone) for use in members 18 years of age or older; and for Yonsa (abiraterone) for use in members 18 years of age or older.

*For Commercial and Healthcare Reform policies, an exception to some or all of 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	08/12/2021	Policy revised to remove Nurtec (rimegepant) and Ubrelvy (ubrogepant) and move them to J-0730. Policy revised to clarify that generic zolmitriptan nasal spray is included in the prior authorization criteria. Policy revised to remove Migranal (dihydroergotamine) and Reyvow (lasmiditan) from the quantity limit chart. Policy revised to include OnabotulinumtoxinA as a potential prophylactic treatment option for the triptan quantity limit.
Acute Migraine Therapies – Commercial and Healthcare Reform	09/01/2021	Policy revised to include reference to new quantity limits of D.H.E (dihydroergotamine) and Ergomar (ergotamine).
Atypical Antipsychotics - Commercial	09/01/2021	Policy revised to remove Abilify Discmelt (brand name product discontinued) and replace with the generic, aripiprazole orally disintegrating tablets (ODT).
Atypical Antipsychotics - Healthcare Reform	09/02/2021	Policy revised to remove Abilify Discmelt (brand name product discontinued) and replace with the generic, aripiprazole orally disintegrating tablets (ODT).
Avandia (rosiglitazone) – Healthcare Reform Essential	08/18/2021	Policy for Avandia (rosiglitazone) terminated as product is off market.
Buprenorphine Non-Opioid Dependence Use - Commercial and Healthcare Reform	08/11/2021	Specified Butrans patch (brand) as targeted, along with Belbuca (buprenorphine). Policy revised to require the use of a buprenorphine patch (generic) before Butrans (brand) or Belbuca (buprenorphine) may be approved. Removed criteria options of therapeutic failure, intolerance, or contraindication to tramadol or opioids (e.g. oxycodone, hydrocodone). In addition to meeting the criteria of 18 years of age or older, a diagnosis of moderate to severe pain requiring a continuous, around-the-clock opioid analgesic for an extended period of time, and therapeutic failure or intolerance to buprenorphine transdermal patch (generic), the member must have experienced therapeutic failure or intolerance to a generic, preferred NSAID (non-steroidal anti-inflammatory drug) (e.g. ibuprofen, meloxicam, naproxen).
Carafate (sucralfate) – Commercial and Healthcare Reform	TBD	New policy for Carafate (sucralfate) oral suspension requiring age 18 years of age or older, diagnosis of

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		active duodenal ulcer, and therapeutic failure or intolerance to generic sucralfate oral tablets.
Duobrii (halobetasol propionate/tazarotene) - Commercial and Healthcare Reform	08/17/2021	Policy revised for Duobrii (halobetasol propionate/tazarotene) for the member to experience therapeutic failure or intolerance to one (1) generic formulary high-potency topical corticosteroid; and the member experience therapeutic failure or intolerance to both generic tazarotene cream and generic halobetasol propionate 0.05% cream or ointment, available separately and used together in combination. Reauthorization criteria updated to additionally require the prescriber attests the member requires additional therapy with Duobrii. Limitations of coverage section revised to remove Duobrii is contraindicated in pregnancy (moved to prescribing considerations).
Elepsia XR (levetiracetam) - Commercial and Healthcare Reform	09/01/2021	Policy revised for Elepsia XR (levetiracetam) to update reauthorization criteria to require prescriber attestation that the member has experienced a reduction in seizure frequency from baseline.
Extavia (interferon beta-1b) - Select Healthcare Reform	09/01/2021	Policy revised to update reauthorization criteria to prescriber attestation of disease stability, disease improvement, or delayed disease progression.
Furadantin (nitrofurantoin) Suspension - Commercial and Healthcare Reform	TBD	Policy created for Furadantin (nitrofurantoin) suspension to require diagnosis of treatment or prevention of urinary tract infection (UTI), trial and failure of nitrofurantoin macrocrystals or nitrofurantoin monohydrate/macrocrystals capsules or has an inability to swallow capsules. If request is for brand Furadantin, member has tried and failed generic nitrofurantoin suspension. For reauthorization, member has new episode of UTI or using as prevention of UTI. If using for prevention, prescriber attests positive clinical response and continued treatment outweighs the risk. If approved on initial authorization due to an inability to swallow, the member continues to have an inability to swallow capsules or tried and failed nitrofurantoin macrocrystals or monohydrate/macrocrystals capsules. Authorization duration 1 week for treatment and 6 months for prophylaxis.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Opioid Management - Commercial	09/01/2021	Arymo ER and MorphaBond no longer commercially available and removed from policy. Extended-Release Opioid approval criteria revised so that member does not have to be opioid naive to obtain the buprenorphine containing products (Butrans, Belbuca).
Opioid Management - Healthcare Reform	09/01/2021	Arymo ER and MorphaBond no longer commercially available and removed from policy. Extended-Release Opioid approval criteria revised so that member does not have to be opioid naive to obtain the buprenorphine containing products (Butrans, Belbuca).
Opioid Management NY - Commercial and Healthcare Reform	TBD	New Opioid Management Policy created for NY. Short-acting opioids-differentiates between acute and chronic pain, for both adults and pediatric patients (definitions for acute and chronic pain taken from New York State Public Health Law Section 3331, 5). In long-acting opioid section, buprenorphine is the exception for the requirement that the member NOT be opioid naive. The rest of the policy is the same as Opioid Management - Commercial and Opioid Management - HCR for PA, WV, and DE.
Picato (ingenol mebutate) - Healthcare Reform	08/12/2021	Policy J-0955 Picato (ingenol mebutate) - Healthcare Reform is terminated and combined with J-0221 Picato (ingenol mebutate) - Commercial and Picato (ingenol mebutate) - Healthcare Reform Essential to create J-0221 Picato (ingenol mebutate) - Commercial and Healthcare Reform.
Picato (ingenol mebutate) - Healthcare Reform Essential	08/12/2021	Policy J-0375 Picato (ingenol mebutate) - Healthcare Reform Essential is terminated and combined with J-0221 Picato (ingenol mebutate) - Commercial and J-0955 Picato (ingenol mebutate) - Healthcare Reform to create J-0221 Picato (ingenol mebutate) - Commercial and Healthcare Reform.
Qternmet XR (dapagliflozin and saxagliptin and metformin ER) - Commercial and Healthcare Reform	08/18/2021	Policy terminated as Qternmet XR (dapagliflozin and saxagliptin and metformin ER) is off market.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Selenium Sulfide Products - Commercial and Healthcare Reform	TBD	New policy created to ensure safety, appropriate utilization, and use of the most cost-effective therapeutic selenium sulfide product. The targeted products are selenium sulfide 2.3% shampoo, Selrx 2.3% shampoo, and Tersi 2.25% Foam. Criteria require that all the following criteria are met: the member is 12 years of age or older, the member has a diagnosis of seborrheic dermatitis or dandruff or tinea versicolor, and the member has experienced therapeutic failure or intolerance to selenium sulfide shampoo 2.25%.

*For Commercial and Healthcare Reform policies, an exception to some or all of 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

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
Self-Administered Injectables - New York Commercial and Healthcare Reform	08/11/2021	New policy to apply to New York only for certain medications to obtain through the pharmacy benefit if the medication is self-administered. Medications include Cutaquig (immune globulin subcutaneous (human) – hipp), Cuvitru (immune globulin subcutaneous (human)) 20% solution, Flolan (epoprostenol sodium), Gammagard Liquid (immune globulin infusion (human), 10% solution), Gammaked (immune globulin injection (human), 10% caprylate/chromatography purified), Gamunex-C (immune globulin injection (human), 10% caprylate/chromatography purified), Glassia (alpha1-proteinase inhibitor (human)), Hizentra (immune globulin subcutaneous (human)) 20% liquid, Hyqvia (immune globulin infusion 10% (human) with recombinant human hyaluronidase), Synribo (omacetaxine mepesuccinate), Veletri (epoprostenol), Xembify (immune globulin subcutaneous, human – klhw) 20% solution. Authorization criteria include FDA indication, FDA

Policy Name	Policy Effective Date	Updates and/or Approval Criteria
		age, and criteria to match Highmark's medical policies.

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
Cosentyx (secukinumab) 75 mg	1 syringe (75 mg or 0.5 mL) per 28 days	3 syringes (225 mg or 1.5 mL) per 84 days
D.H.E (dihydroergotamine mesylate)	24 mL per 25 days	72 mL per 75 days
Empaveli (pegcetacoplan)	8 vials (8,640 mg or 160 mL) per 28 days	24 vials (25,920 mg or 480 mL) per 84 days
Ergomar (ergotamine tartrate)	20 tablets per 25 days	60 tablets per 75 days
Noxafil (posaconazole) PowderMix*	32 packets per 30 days	96 packets per 90 days
Nurtec ODT (rimegepant)	18 tablets per 25 days	54 tablets per 75 days
Prevnar 20 (pneumococcal 20-valent conjugate vaccine)*	0.5 mL per 365 days	0.5 mL per 365 days
Saxenda (liraglutide)	5 pens (15 mL) per 30 days	15 pens (45 mL) per 90 days
Trikafta (elexacaftor/tezacaftor/ivacaftor + ivacaftor) 50-25-37.5 mg tablets	84 tablets per 28 days	252 tablets per 84 days
Truseltiq (infigratinib)	1 pack per 28 days	3 packs per 84 days
Verkazia (cyclosporine) ophthalmic emulsion	120 single-dose vials (36 mL) per 30 days	360 single-dose vials (108 mL) per 90 days
Wegovy (semaglutide)	1 carton (4 pens) per 28 days	3 cartons (12 pens) per 84 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
Brexafemme (ibrexafungerp)	1 pack (4 tablets) per dispensing event	1 pack (4 tablets) per dispensing event

Xofluza (baloxavir marboxil) 40 mg*	1 tablet per dispensing event	1 tablet per dispensing event
Xofluza (baloxavir marboxil) 80 mg	1 tablet per dispensing event	1 tablet 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
Contrave (naltrexone hydrochloride and bupropion hydrochloride)	4 tablets per day
Epclusa (sofosbuvir/velpatasvir) 150 mg/37.5 mg oral pellets*	1 packet per day
Epclusa (sofosbuvir/velpatasvir) 200 mg/50 mg oral pellets*	2 packets per day
Lumakras (sotorasib)	8 tablets per day
Lybalvi (olanzapine/samidorphan)	1 tablet per day
Mavyret (glecaprevir/pibrentasvir) oral pellets*	5 packets per day
Myfembree (relugolix/estradiol/norethidrone)	1 tablet per day
Pradaxa (dabigatran) capsules	4 capsules per day
Pradaxa (dabigatran) oral pellets*	4 packets 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 here.

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
Brexafemme	ibrexafungerp	fluconazole tablet
Lybalvi	olanzapine/samidorphan	Risperidone Tablet, Quetiapine Tablet, Olanzapine
Verkazia ophthalmic emulsion	cyclosporine ophthalmic emulsion	cromolyn drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops
Pradaxa oral pellets	dabigatran oral pellets	Prescriber 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:

- Performance Formulary
- Venture Formulary

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
Lybalvi	olanzapine/samidorphan	Risperidone Tablet, Quetiapine Tablet, Olanzapine

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

Brand Name	Generic Name	Preferred Alternatives
Aduhelm	aducanumab-avwa	memantine, donepezil, galantamine
Brexafemme	ibrexafungerp	fluconazole tablet
Noxafil PowderMix**	posaconazole PowderMix	fluconazole tablet; fluconazole suspension for reconstitution

Verkazia ophthalmic emulsion	cyclosporine ophthalmic emulsion	cromolyn drops; dexamethasone sodium phosphate drops; prednisolone sodium phosphate drops
Empaveli	pegcetacoplan	Prescriber discretion
Pradaxa oral pellets	dabigatran oral pellets	Prescriber discretion

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

**Product was added to Specialty Tier for Incentive Formulary and Venture Formulary but not added to Performance Formulary.

C. Additions to the Specialty Tier

Effective immediately pending CMS approval and upon completion of internal review and implementation. Unless otherwise noted, product was added to Specialty Tier for Incentive Formulary, Venture Formulary, and Performance Formulary.

Brand Name	Generic Name
Camcevi	leuprolide mesylate
Cosentyx 75 mg	secukinumab) 75 mg
Empaveli*	pegcetacoplan
Epclusa 150 mg/37.5 mg oral pellets	sofosbuvir/velpatasvir 150 mg/37.5 mg oral pellets
Epclusa 200 mg/50 mg oral pellets	sofosbuvir/velpatasvir 200 mg/50 mg oral pellets
Lumakras	sotorasib
Mavyret oral pellets	glecaprevir/pibrentasvir oral pellets
Myfembree	relugolix/estradiol/norethidrone
Noxafil PowderMix**	28osaconazole PowderMix
Rybrevant	amivantamab-vmjw
Rylaze	asparaginase erwinia chrysanthemi [recombinant]-rywn
Ryplazim	plasminogen, human-tvmh
Trikafta 50-25-37.5 mg tablets	elexacaftor/tezacaftor/ivacaftor + ivacaftor 50-25-37.5 mg tablets
Truseltiq	infigratinib

*Product was added to Specialty Tier for Incentive Formulary but not added to Venture Formulary or Performance Formulary.

**Product was added to Specialty Tier for Incentive Formulary and Venture Formulary but not added to Performance Formulary.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Administrative Prior Authorizations for Medicare Part D Plans - Medicare	08/20/2021	Policy revised to add Blincyto, Cyramza, epoprostenol, Gallium, and Vectibix as target drugs for BvD infusion pump criteria. Aduhelm, Arzerra, Cyramza, Empaveli, Empliciti, Nulibry, Portrazza, Vectibix, Vidaza and Vyxeos added as targets for BvD incident to provider services criteria. Nulojix and Simulect moved to be targets for BvD immunosuppressant criteria.
Banzel (rufinamide) – Medicare	08/25/2021	Policy revised to remove limitation of coverage regarding 3,200 mg dose limit.
Brand ADHD Step Therapy– Medicare	07/17/2021	Policy revised to add dexmethylphenidate as an additional alternative to the generic step requirement.
Brineura (cerliponase alfa) - Medicare	NEVER POSTED	Policy terminated for Brineura (cerliponase alfa) because it is not a Medicare Part D drug and only a healthcare provider experienced in intraventricular administration would administer the drug to a patient.
Carac Cream (fluorouracil) - Medicare	08/17/2021	Policy revised for brand Carac (fluorouracil 0.5% cream) to require the member is 18 years of age or older; have a diagnosis of multiple actinic or solar keratosis of the face and anterior scalp; and experienced therapeutic failure or intolerance to one (1) generic topical fluorouracil product for multiple actinic or solar keratosis.
Chronic Inflammatory Diseases - Medicare	09/03/2021	Policy revised for Cimzia (certolizumab) in Crohn's disease (CD) to remove therapeutic failure or intolerance to at least 2 immunosuppressants. Criteria revised for Humira (adalimumab) in CD for adults to remove therapeutic failure or intolerance to at least two immunosuppressants; for pediatric CD to remove therapeutic failure or intolerance to at least one immunosuppressant. Criteria revised for Stelara (ustekinumab) in CD to remove therapeutic failure or intolerance to at least 2 immunosuppressants or previous intolerance to a tumor necrosis factor (TNF) inhibitor. Added Avsola (infliximab-

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		axxq), Inflectra (infliximab-dyyb), and Renflexis (infliximab-abda) to policy. Criteria revised for infliximab products in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis (AS), and plaque psoriasis for the member to be 18 years of age or older. Criteria revised for infliximab products in CD and ulcerative colitis (UC) to remove therapeutic failure or intolerance to at least 2 immunosuppressants. Criteria revised for Cosentyx (secukinumab) in plaque psoriasis (PsO) for the member to be 6 years of age or older. Cosentyx quantity limitations updated for pediatric PsO (≥ 50 kg) for 5 pens/prefilled syringes (150 mg/mL) within the first 4 weeks, then 1 pen/prefilled syringe (150 mg/mL) every 4 weeks; (< 50kg) for 5 prefilled syringes (75mg/mL) within the first 4 weeks of therapy, then 1 prefilled syringe (75mg/mL) every 4 weeks. Criteria revised for Simponi Aria (golimumab) in AS for the member to experience therapeutic failure or intolerance to one non-steroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.
Cyramza (ramucirumab) - Medicare	08/12/2021	New policy created for Cyramza (ramucirumab) for use in members 18 years of age or older as a single agent or in combination with paclitaxel, for treatment of advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy; in combination with erlotinib, for first-line treatment of metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations; in combination with docetaxel, for treatment of metastatic non-small cell lung cancer with disease progression on or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		after platinum-based chemotherapy (members with EGFR or anaplastic lymphoma kinase [ALK] genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza); in combination with irinotecan, folinic acid, and fluorouracil [FOLFIRI], for the treatment of metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; or as a single agent, for the treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of ≥400 ng/mL and have been treated with sorafenib.
Dibenzyline (phenoxybenzamine) – Medicare	TBD	Policy revised for Dibenzyline (phenoxybenzamine) to add that member is experiencing excessive sweating and hypertension.
Duobrii (halobetasol propionate/tazarotene) - Medicare	08/18/2021	Policy revised for Duobrii (halobetasol propionate/tazarotene) for the member to experience therapeutic failure or intolerance to one (1) high-potency topical corticosteroid.
Empaveli (pegcetacoplan) - Medicare	08/11/2021	New policy created for Empaveli (pegcetacoplan) to require the product to be eligible for coverage under Part D. Policy requires the member to have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), either have PNH mutant clone confirmed by flow cytometry or glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs) confirmed by flow cytometry, and have at least one of the following symptoms: fatigue, hemoglobinuria, abdominal pain, dyspnea, dysphagia, erectile dysfunction, or history of blood cell transfusion due to PNH. Reauthorization criteria require the member to have experienced an increase in the hemoglobin levels, or a decrease in the

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		number of transfusions, or a decrease from baseline in the lactase dehydrogenase (LDH) levels from baseline.
FGFR Kinase Inhibitors – Medicare	08/25/2021	Policy revised to add criteria for Truseltiq (infigratinib) for members 18 years of age or older with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.
Fumarate Products - Medicare	TBD	Policy revised to add limitation of coverage stating combination use of disease modifying MS agents will not be authorized.
Gattex (teduglutide) - Medicare	08/03/2021	Policy revised for Gattex (teduglitude) to remove age criteria of 18 years of age or older as not filed.
Gattex (teduglutide) - Medicare	TBD	Policy revised for Gattex (teduglitude) that short bowel syndrome diagnosis is defined as less than 200 cm of functional small bowel. Added that adult members are 18 years of age or older. Added that pediatric members weigh at least 10 kg. Reauthorization added that member has experienced one of the following: 1) increase in weight from baseline or 2) decrease in intravenous parenteral nutrition requirement from baseline and continues to be dependent on parenteral nutrition/intravenous nutrition support.
Gimoti (metoclopramide) - Medicare	08/20/2021	Policy revised for Gimoti (metoclopramide) to specify the member has experienced therapeutic failure or intolerance to generic metoclopramide oral tablets or oral solution, or the member is unable to swallow oral dosage forms.
Gonadotropin-releasing Hormone Agonists - Medicare	08/16/2021	Policy revised to include criteria for Camcevi (leuprolide mesylate), a new salt form of leuprolide, to require a diagnosis of advanced prostate cancer and trial and failure of Eligard (leuprolide acetate). Policy applies to new starts only for Camcevi (leuprolide mesylate).

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Hepatitis C Oral Therapy - Medicare	08/25/2021	Policy revised for Epclusa (sofobuvir/velpatasvir) and Mavyret (glecaprevir/pibrentasvir) to allow for use in members 3 years of age or older. Removed creatinine clearance requirement from Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Added Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as a preferred treatment regimen for Zepatier (elbasvir/grazoprevir) treatment-experienced patients with genotypes 1-6 and with/without cirrhosis. Added Mavyret (glecaprevir/pibrentasvir) x 16 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks as preferred regimens for sofosbuvir-based treatment-experienced members with genotypes 4-6. Added ribavirin to Epclusa (sofobuvir/velpatasvir) x 24 weeks (genotype 2 and 3) and updated Prior Treatment to include all treatment-experienced patients in post-liver transplant members with decompensated cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to preferred product for treatment-experienced kidney transplant patients without cirrhosis. Updated Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 12 weeks to preferred product for treatment-experienced kidney transplant patients with cirrhosis.
Human Growth Hormone - Medicare	TBD	Policy revised for growth hormone deficiency to remove diagnosis in reauthorization criteria. For children with chronic kidney disease removed creatine clearance in place of estimated glomerular filtration rate (GFR) < 89 ml/min per 1.73 m2. For Turner's syndrome removed mention of age or bone age of males as disease only in females. For Acquired Immune Deficiency Syndrome (AIDS)-wasting clarified it can also be Human Immunodeficiency Virus (HIV)-wasting,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		removed that weight loss caused by other conditions have been ruled out, and added reauthorization that member has maintained or increased weight from the start of therapy. Removed approval criteria for burn patients as it is not an FDA indication. For short bowel syndrome added that it is defined as < 200 cm of functional small bowel and added reauthorization that member continues to be dependent on parenteral/intravenous nutrition support. For children with idiopathic short stature (ISS) added criteria for diagnosis, height less than 2.25 standard deviation (SD) below the age, growth velocity less than 10th percentile over 12 months, and bone age. Reauthorization criteria of growth velocity of at least 2 cm/year and bone age has not closed. For small for gestational age (SGA) added that member has failed to catch up by 2 years of age, diagnosis, and birth weight and length at least 2 SD below age-appropriate mean. Reauthorization criteria of growth velocity of at least 2 cm/year and bone age has not closed.
Human Growth Hormone - Medicare	TBD	Policy revised to add Sogroya (somapacitan-beco) to require member is an adult and meets one (1) of the following: 1) has multiple pituitary growth hormone deficiencies, 2) has central nervous system irradiation, or 3) has reconfirmation of growth hormone deficiency in adulthood defined as all of the following: growth velocity of < 2 cm/year, epiphyseal fusion has occurred (e.g., bone age > 14 years for females and > 16 years for males), has not used growth hormone for at least 1 month, and has the following response to all of the following standard growth hormone stimulation tests A) arginine or macimorelin and B) insulin or glucagon.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Increlex (mecasermin) – Medicare	TBD	Policy revised for Increlex (mecasermin) to add gene deletion indication including age 17 years or younger, growth velocity at least 2 standard deviations (SD) below the age-appropriate mean or height at least 2.25 SD below age appropriate mean, subnormal response in growth hormone stimulation tests, the member has developed neutralizing antibodies to growth hormone product(s), and bone age. For IGF-1 deficiency removed growth velocity less than or equal to 4.6 cm/year and added bone age. For reauthorization in both indications, the member is 17 years of age or younger, growth velocity of at least 2 cm/year, and bone age or chronological age.
Infliximab Biosimilars - Medicare	08/13/2021	Policy terminated; criteria combined into J-0561.
Injectable Octreotide Products – Medicare	TBD	Policy revised for acromegaly that the member has experienced therapeutic failure or cannot be treated with all the following (a. and b.): a) surgical resection or pituitary irradiation and b) for Bynfezia (octreotide acetate), octreotide, or Sandostatin (octreotide acetate) - bromocriptine mesylate at maximally tolerated doses. For acromegaly reauthorization removed asking for diagnosis.
Keveyis (dichlorphenamide) - Medicare	08/20/2021	Policy revised for Keveyis (dichlorphenamide) to remove the quantity limit of 200 mg per day from the limitations of coverage section as this limit is already listed on policy J-0032 Quantity Level Limits - Medicare.
KRAS G12C Inhibitors - Medicare	08/25/2021	New policy created for Lumakras (sotorasib) to ask that member is 18 years of age or older, diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA-approved test who has received at least one (1) prior systemic therapy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Lybalvi (olanzapine/samidorphan) - Medicare	TBD	New policy created for Lybalvi (olanzapine/samidorphan) to require the member to be at least 18 years of age, have a diagnosis of schizophrenia or bipolar I disorder, either have experienced therapeutic failure on, intolerance to, or contraindication to generic risperidone and generic quetiapine or currently be stable on and responding to olanzapine, but experiencing weight gain from the medication.
Mavenclad (cladribine) – Medicare	08/25/2021	Policy revised to move limitations of coverage regarding contraindications and baseline assessments to background.
Mycapssa (octreotide) - Medicare	08/18/2021	Policy revised for Mycapssa (octreotide) to remove age criteria.
Natpara (parathyroid hormone) - Medicare	TBD	Policy revised for Natpara (parathyroid hormone) that prescriber attests that the member's 25-hydroxyvitamin D stores are sufficient and the member's serum calcium level is > 7.5 mg/dL. Reauthorization added that the member's serum calcium level is > 7.5 mg/dL and ≤ 10.6 mg/dL.
Omega 3 Fatty Acid Products - Medicare	TBD	Policy revised for Vascepa (icosapent ethyl) that member is currently receiving maximally tolerated statin therapy unless statin intolerant. Statin intolerance defined as follows: statin related rhabdomyolysis or skeletal muscle symptoms while receiving at least 2 separate trials of different statins which resolved upon discontinuation of statin or member experienced creatinine kinase increase to 10 times upper limit of normal (ULN), or liver function tests increase to 3 times ULN, or hospitalization due to severe statin-related adverse event (e.g., rhabdomyolysis).
Palynziq (pegvaliase-pqpz) - Medicare	08/20/2021	Policy revised for Palynziq (pegvaliase-pqpz) to update the maximum dose in the reauthorization criteria to 60 mg/day.
PDGFR Tyrosine Kinase Inhibitors – Medicare	08/30/2021	Policy revised for Ayvakit (avapritinib) to add criteria for use in members with platelet count >/= 50 x 10^9/L with a

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		diagnosis of one of the following: aggressive systemic mastocytosis; systemic mastocytosis with an associated hematological neoplasm (SM-AHN); or mast cell leukemia (MCL).
PDGFR Tyrosine Kinase Inhibitors – Medicare	TBD	Policy revised for Ayvakit (avapritinib) to add criteria for use in members 18 years of age or older with platelet count >/= 50 x 10^9/L with a diagnosis of one of the following: aggressive systemic mastocytosis; systemic mastocytosis with an associated hematological neoplasm (SM-AHN); or mast cell leukemia (MCL).
Programmed Death Receptor Therapies - Medicare	08/25/2021	Policy revised for Keytruda (pembrolizumab) to add criteria for members with locally advanced cutaneous squamous cell carcinoma that is not curable by surgery or radiation. Policy revised for Keytruda (pembrolizumab) to remove criteria for treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 [combined positive score (CPS ≥1)] as determined by a U.S. Food and Drug Administration (FDA)-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy following removal of the indication per FDA.
Qternmet XR (dapagliflozin and saxagliptin and metformin ER) - Medicare	08/25/2021	Policy terminated as Qternmet XR (dapagliflozin and saxagliptin and metformin ER) is off market.
Rybrevant (amivantamab-vmjw) - Medicare	08/25/2021	New policy created for Rybrevant (amivantamab-vmjw) to require the member is 18 years of age or older, have a diagnosis of non-small cell lung cancer, disease classified as locally advanced or metastatic, disease progression on or after

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		platinum-based chemotherapy (e.g., carboplatin, oxaliplatin), and EGFRex20 insertion mutation as detected by an FDA approved test. Quantity limitations added for induction therapy of 16 vials within the first 28 days of therapy, and maintenance therapy of 8 vials per 28 days. Authorization duration added for 12 months.
Ryplazim (plasminogen, human-tvmh) - Medicare	TBD	New policy created for Ryplazim (plasminogen, human-tvmh) to require a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) and documented history of external and/or internal lesions. Reauthorization criteria added for the prescriber to attest the member has experienced a reduction of external and/or internal lesions. Authorization duration of 12 months.
Ryvent (carbinoxamine) - Medicare	08/24/2021	Policy revised for Ryvent (carbinoxamine) to require therapeutic failure, contraindication, or intolerance to two different antihistamines.
Samsca (tolvaptan) – Medicare	TBD	Policy revised for Samsca (tolvaptan) that prescriber attests that the member has been initiated or re-initiated on Samsca (tolvaptan) therapy in a hospital setting and if the request is for brand Samsca, the member has experienced therapeutic failure or intolerance to generic tolvaptan.
Soliris (eculizumab) - Medicare	TBD	Policy revised for Soliris (eculizumab) to remove the age limit of 18 years or older for paroxysmal nocturnal hemoglobinuria (PNH) indication. For PNH, policy revised to require that the member has PNH mutant clone or glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs) confirmed by flow cytometry. One of the following symptoms is required for PNH: fatigue, hemoglobinuria, abdominal pain, dyspnea, dysphagia, erectile dysfunction, or history

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		of blood cell transfusion due to PNH. Reauthorization criteria require an increase from baseline in the hemoglobin levels, or a decrease from baseline in the number of transfusions, or a decrease from baseline in the lactate dehydrogenase levels.
Tecentriq (atezolizumab) – Medicare	08/25/2021	Policy revised for Tecentriq (atezolizumab) to remove criteria for prior-platinum treated metastatic urothelial carcinoma following removal of the indication per FDA.
Thrombopoiesis Stimulating Agents - Medicare	08/24/2021	Policy revised for Nplate (romiplostim) to allow use to increase survival in adults and pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]) in members who have been exposed to radiation levels > 2 gray (Gy).
Trelstar (triptorelin pamoate) – Medicare	08/15/2021	Policy J-1021 Trelstar (triptorelin pamoate) - Medicare is terminated. Combined J-1021 Trelstar (triptorelin pamoate) - Medicare policy with J-1024 Lupron Depot and Lupron Depot Ped (leuprolide acetate for depot suspension) - Medicare to create J-1024 GnRH Agonists - Medicare policy.
Trikafta (elexacaftor/tezacaftor/ivacaftor) - Medicare	08/20/2021	Policy revised for Trikafta (elexacaftor/tezacaftor/ivacaftor) to change minimum patient age requirement from 12 years of age to 6 years of age.
Tysabri (natalizumab) - Medicare	TBD	Policy revised to change step requirements for Crohn's disease to one immunosuppressant and one tumor necrosis factor-alpha (TNF-alpha) inhibitor.
Uterine Leiomyomas - Medicare	08/25/2021	Policy revised to add criteria for Myfembree (relugolix, estradiol, norethindrone acetate) requiring the member to be a premenopausal woman with a diagnosis of uterine leiomyomas experiencing heavy menstrual bleeding. The total combined treatment duration cannot exceed 24 months.
Vectibix (panitumumab) - Medicare	08/12/2021	New policy created for Vectibix (panitumumab) for use in members 18

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		years of age or older with wild-type RAS (rat sarcoma) (both wild-type KRAS [Kirsten RAt Sarcoma] and wild-type NRAS [Neuroblastoma RAt Sarcoma], per an FDA-approved test) metastatic colorectal cancer first-line therapy in conjunction with FOLFOX (fluorouracil, leucovorin, and oxaliplatin); or as monotherapy after disease progression following prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.
Verkazia (cyclosporine ophthalmic emulsion) – Medicare	08/12/2021	New policy created for Verkazia (cyclosporine ophthalmic emulsion) requiring diagnosis of vernal keratoconjunctivitis (VKC) and therapeutic failure or intolerance to one (1) agent from two (2) of the following different medication classes, or all are contraindicated: Generic ophthalmic antihistamines (e.g., olopatadine), Generic ophthalmic mast cell stabilizers (e.g., cromolyn sodium), or Generic ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone).
Vyxeos (daunorubicin/cytarabine) – Medicare	J-0642	Policy revised for Vyxeos (daunorubicin and cytarabine) to add criteria that the product has been determined to be eligible for coverage under Part D per policy J-30.

*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/or Approval Criteria
Buprenorphine/Naloxone Step Therapy - Medicare	TBD	Bunavail (buprenorphine/naloxone) has been discontinued by the manufacturer, however, it is still in the ESI system. Bunavail (buprenorphine/naloxone) removed from policy, however, this policy is not to be posted until Bunavail (buprenorphine/naloxone) is dropped from ESI.

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)
Brexafemme (ibrexafungerp)	4 tablets per 31 days	12 tablets per 90 days
Cosentyx (secukinumab) 75 mg	1 syringe (75 mg or 0.5 mL) per 28 days	3 syringes (225 mg or 1.5 mL) per 84 days
Empaveli (pegcetacoplan)	10 vials (10,800 mg or 200 mL) per 30 days	30 vials (32,400 mg or 600 mL) per 90 days
Epclusa (sofosbuvir/velpatasvir) 150 mg/37.5 mg oral pellets	1 packet per day	1 packet per day
Epclusa (sofosbuvir/velpatasvir) 200 mg/50 mg oral pellets	2 packets per day	2 packets per day
Lumakras (sotorasib)	8 tablets per day	8 tablets per day
Lybalvi (olanzapine/samidorphan)	1 tablet per day	1 tablet per day
Mavyret (glecaprevir/pibrentasvir) oral pellets	5 packets per day	5 packets per day
Myfembree (relugolix/estradiol/norethidrone)	1 tablet per day	1 tablet per day
Noxafil (posaconazole) PowderMix	32 packets per 31 days	96 packets per 90 days
Nurtec ODT (rimegepant)	18 tablets per 25 days	54 tablets per 75 days
Pradaxa (dabigatran) capsules	4 capsules per day	4 capsules per day
Pradaxa (dabigatran) oral pellets	4 packets per day	4 packets per day
Rybrevant (amivantamab-vmjw)	8 vials (2,800 mg or 56 mL) per 28 days	24 vials (8,400 mg or 168 mL) per 84 days
Trikafta (elexacaftor/tezacaftor/ivacaftor + ivacaftor) 50-25-37.5 mg tablets	3 tablets per day	3 tablets per day
Truseltiq (infigratinib) 100 MG DAILY DOSE PK	0.75 capsules per day	0.75 capsules per day
Truseltiq (infigratinib) 125 MG DAILY DOSE PK	1.5 capsules per day	1.5 capsules per day
Truseltiq (infigratinib) 50 MG DAILY DOSE PK	1.5 capsules per day	1.5 capsules per day
Truseltiq (infigratinib) 75 MG DAILY DOSE PK	2.25 capsules per day	2.25 capsules per day
Verkazia (cyclosporine) ophthalmic emulsion	124 single-dose vials (37.2 mL) per 31 days	360 single-dose vials (108 mL) per 90 days
Xofluza (baloxavir marboxil) 40 mg	9 tablets per 365 days	9 tablets per 365 days
Xofluza (baloxavir marboxil) 80 mg	9 tablets per 365 days	9 tablets per 365 days

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