Formulary Updates

July 2023

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for June 2023. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in June 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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B. Changes to the Highmark Healthcare Reform Essential Formulary
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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.

HIGHMARK

Important Drug Safety Updates

Dronabinol Capsules 2.5mg and Ziprasidone Hydrochloride Capsules 20mg by The Harvard Drug Group, LLC

On June 13, 2023, the Harvard Drug Group, LLC d/b/a Major Pharmaceutical and Rugby Laboratories is initiating a voluntary recall of a single lot of Dronabinol Capsules, USP, 2.5 mg and Ziprasidone Hydrochloride Capsules, 20 mg to the consumer level. The Harvard Drug Group, LLC received a customer complaint from a distributor, that some unit dose cartons labeled as Ziprasidone Hydrochloride Capsules, 20 mg were found to contain blister packages labeled as and containing Dronabinol Capsules, USP, 2.5 mg for Lot T04769. The Harvard Drug Group, LLC is recalling all of Lot T04769, Dronabinol Capsules, USP, 2.5 mg, which may be in outer cartons that read Dronabinol Capsules, USP, 2.5 mg or Ziprasidone Hydrochloride Capsules, 20 mg.

Patients who mistakenly take Dronabinol Capsules, USP, 2.5 mg instead of Ziprasidone Hydrochloride, 20 mg capsules, may experience serious adverse events. Patients missing doses of Ziprasidone can experience exacerbation of underlying health issues such as bipolar disorder, schizophrenia, agitation, aggression, or delirium. Taking an unexpected dose of Dronabinol may cause mental and cognitive effects that result in impairment of mental and/or physical abilities. Elderly patients or those taking other medications that affect mental function may be particularly at risk for these reactions. The Harvard Drug Group, LLC has not received any reports of adverse events related to this recall.

Highmark Formulary Update – June 2023

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 July 2023, unless otherwise noted.

Brand Name	Generic Name	Comments
Arexvy*	Respiratory syncytial virus vaccine, adjuvanted	Respiratory syncytial virus, prevention
Kalydeco 13.4 mg granules	ivacaftor	Cystic fibrosis in patients 1 month and older
Kalydeco 5.8 mg granules*	ivacaftor	Cystic fibrosis in patients 1 month and older
Mekinist powder for oral solution	trametinib	Melanoma, NSCLC, thyroid cancer, solid tumors, low-grade glioma
Omnipod Go	insulin pump cartridge	Type 2 diabetes
Tafinlar tablets for oral suspension	dabrafenib	Melanoma, NSCLC, thyroid cancer, solid tumors, low-grade glioma
Zejula** tablets	niraparib	Epithelial ovarian, fallopian tube, or primary peritoneal cancer

Coverage may be contingent upon plan benefits.

*Effective date to be determined

**Added for Commercial Comprehensive only

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Combogesic*	acetaminophen/ibuprofen	Prescriber discretion
Daybue	trofinetide	Prescriber discretion
Joenja	leniolisib	Prescriber discretion

Brand Name	Generic Name	Preferred Alternatives
Konvomep	omeprazole/sodium bicarbonate	Omeprazole Capsule DR (Enteric coated) 40MG, Pantoprazole Sodium tab (Enteric coated) 40MG
Liqrev	sildenafil oral suspension	Sildenafil Citrate Tablet
Lumryz	sodium oxybate	modafinil, xyrem, methylphenidate hcl tablet
Motpoly XR	lacosamide ER capsules	Lacosamide Tablets,**** Provider discretion***
RizaFilm*	rizatriptan oral film	Sumatriptan Succinate tabs, Rizatriptan tabs, Zolmitriptan tabs
Sogroya	somapacitan-beco	Norditropin Flexpro, Genotropin
Trikafta oral granules	elexacaftor/tezacaftor/ivacaftor and ivacaftor	Prescriber discretion
Veozah	fezolinetant	estradiol tablet, estradiol-norethindrone acetate tablet
Vowst	fecal microbiota spores, live-brpk	Prescriber discretion
Zavzpret	zavegepant	Sumatriptan Succinate tabs, Rizatriptan tabs, Zolmitriptan tabs
Zejula tablets***	niraparib	Prescriber discretion
Zolpidem 7.5 mg capsules	Zolpidem 7.5 mg capsules	zolpidem 5 mg tablet, zolpidem 10 mg tablet

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Physicians may request coverage of these products using the Prescription Drug Medication Request Form..
***Applies for Healthcare Reform Comprehensive only
****Applies for Commercial Comprehensive only

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
Daybue	trofinetide
Joenja	leniolisib
Kalydeco 13.4 mg granules	ivacaftor
Kalydeco 5.8 mg granules	ivacaftor
Liqrev	sildenafil oral suspension
Lumryz	sodium oxybate

Mekinist powder for oral solution	trametinib
Sogroya	somapacitan-beco
Tafinlar tablets for oral suspension	dabrafenib
Trikafta	elexacaftor/tezacaftor/ivacaftor and ivacaftor
Vowst	Vowst
Zavzpret	zavegepant
Zejula tablets	niraparib

B. 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 July 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Arexvy*	Respiratory syncytial virus vaccine, adjuvanted	3	Respiratory syncytial virus, prevention
Omnipod Go	insulin pump cartridge	3	Type 2 diabetes
Mekinist powder for oral solution	trametinib	4	trametinib
Nayzilam nasal spray	midazolam	4	Intermittent, stereotypic episodes of frequent seizure activity
Tafinlar tablets for oral suspension	dabrafenib	4	Melanoma, NSCLC, thyroid cancer, solid tumors, low-grade glioma
Trikafta oral granules	elexacaftor/tezacaftor/ivacaftor and ivacaftor	4	Cystic fibrosis
Valtoco nasal spray	diazepam	4	Intermittent, stereotypic episodes of frequent seizure activity
Zejula tablets*	niraparib	4	Epithelial ovarian, fallopian tube, or primary peritoneal cancer
Items listed below were not added to the formulary			
Combogesic*	acetaminophen/ibuprofen	NF	Prescriber discretion
Daybue	trofinetide	NF	Prescriber discretion
Joenja	leniolisib	NF	Prescriber discretion
Kalydeco 13.4 mg granules	ivacaftor	NF	Prescriber discretion
Kalydeco 5.8 mg granules*	ivacaftor	NF	Prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Konvomep	omeprazole/sodium bicarbonate	NF	Omeprazole caps DR (Enteric coated) 40 MG; Pantoprazole sodium tab, (Enteric coated) 40 MG
Liqrev	sildenafil oral suspension	NF	Sildenafil Citrate tab
Lumryz	sodium oxybate	NF	modafinil, xyrem, methylphenidate hcl tablet
Motpoly XR	lacosamide ER capsules	NF	Lacosamide tab
RizaFilm	rizatriptan oral film	NF	Sumatriptan Succinate tab, Rizatriptan tabs, Zolmitriptan tabs
Sogroya	somapacitan-beco	NF	Norditropin Flexpro, Genotropin
Veozah	fezolinetant	NF	estradiol tablet, estradiol-norethindrone acetate tablet
Vowst	fecal microbiota spores, live-brpk	NF	Prescriber discretion
Zavzpret	zavegepant	NF	Sumatriptan Succinate tabs, Rizatriptan tabs, Zolmitriptan tabs

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Generic and Brand drugs; **Tier 3:** Generic and Brand drugs; **Tier 4:** Generic and Brand drugs; **Non-formulary (NF)**.
*Effective date to be determined.

C. Changes to the Highmark Core Formulary

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

Table 1. Formulary Updates
All formulary changes effective July 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Arexvy*	Respiratory syncytial virus vaccine, adjuvanted	3	Respiratory syncytial virus, prevention
Omnipod Go	insulin pump cartridge	3	Type 2 diabetes
Kalydeco 13.4 mg granules	ivacaftor	4	Cystic fibrosis in patients 1 month and older
Kalydeco 5.8 mg granules*	ivacaftor	4	Cystic fibrosis in patients 1 month and older
Mekinist powder for oral solution	trametinib	4	Melanoma, NSCLC, thyroid cancer, solid tumors, low-grade glioma
Nayzilam nasal spray	midazolam	4	Intermittent, stereotypic episodes of frequent seizure activity
Tafinlar tablets for oral suspension	dabrafenib	4	Melanoma, NSCLC, thyroid cancer, solid tumors, low-grade glioma

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Trikafta oral granules	elexacaftor/tezacaftor/iva caftor and ivacaftor	4	Cystic fibrosis
Valtoco nasal spray	diazepam	4	Intermittent, stereotypic episodes of frequent seizure activity
Zejula tablets	niraparib	4	Epithelial ovarian, fallopian tube, or primary peritoneal cancer
Items listed below were not added to the formulary			
Combogesic*	acetaminophen/ibuprofen	NF	Prescriber discretion
Daybue	trofinetide	NF	Prescriber discretion
Joenja	leniolisib	NF	Prescriber discretion
Konvomep	omeprazole/sodium bicarbonate	NF	omeprazole, DR (Enteric coated) 40 MG; pantoprazole sodium tab, (Enteric coated) 40 MG
Liqrev	sildenafil oral suspension	NF	Sildenafil citrate tab
Lumryz	sodium oxybate	NF	modafinil, methylphenidate hcl tablet
Motpoly XR*	lacosamide ER capsules	NF	Prescriber discretion
RizaFilm*	rizatriptan oral film	NF	Sumatriptan succinate tab, Rizatriptan tab, zolmitriptan tab
Sogroya	somapacitan-beco	NF	Norditropin Flexpro, Genotropin
Veozah	fezolinetant	NF	estradiol tablet, estradiol-norethindrone acetate tablet
Vowst	fecal microbiota spores, live-brpk	NF	Prescriber discretion
Zavzpret	zavegepant	NF	Sumatriptan succinate tab, Rizatriptan tab, Zolmitriptan tab
Zolpidem 7.5 mg capsules	Zolpidem 7.5 mg capsules	NF	zolpidem 5 mg tablet, zolpidem 10 mg tablet

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Generic and Brand drugs; **Tier 3:** Generic and Brand drugs; **Tier 4:** Generic and Brand drugs; **Non-formulary (NF)**.
*Effective date to be determined.

D. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (Preferred)			
Kalydeco 13.4 mg granules	ivacaftor	2	Cystic fibrosis in patients 1 month and older

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Kalydeco 5.8 mg granules*	ivacaftor	2	Cystic fibrosis in patients 1 month and older
Lumryz	sodium oxybate	2	Narcolepsy
Omnipod Go	Omnipod Go	2	Type 2 diabetes
Trikafta oral granules	elexacaftor/tezacaftor/ivacaftor and ivacaftor	2	Cystic fibrosis
Items listed below were added to the formulary (Non-Preferred)			
Mekinist powder for oral solution*	trametinib	3	prescriber discretion
Zejula tablets*	niraparib	3	prescriber discretion
Tafinlar tablets for oral suspension*	dabrafenib	3	prescriber discretion
Zolpidem 7.5 mg capsules*	Zolpidem 7.5 mg capsules	3	Zolpidem 5 mg tablet, zolpidem 10 mg tablet
Joenja	leniolisib	3	prescriber discretion
Vowst*	fecal microbiota spores, live-brpk	3	prescriber discretion
Arexvy*	Respiratory syncytial virus vaccine, adjuvanted	3	prescriber discretion
Combogesic*	acetaminophen/ibuprofen	3	prescriber discretion
Liqrev*	sildenafil oral suspension	3	Sildenafil tab
Motpoly XR*	lacosamide ER capsules	3	lacosamide tab
RizaFilm*	rizatriptan oral film	3	Sumatriptan succ tab, Rizatriptan tab, Zolmitriptan tab
Sogroya*	somapacitan-beco	3	Norditroptin Flexpro, Genotropin, Omnitrope
Veozah*	fezolinetant	3	estradiol tablet, estradiol-norethindrone acetate tablet
Zavzpret*	zavegepant	3	Sumatriptan succ tab, Rizatriptan tab, Zolmitriptan tab, Sumatriptan spray
Items listed below were not added to the formulary			
Daybue	trofinetide	NF	prescriber discretion
Konvomep	omeprazole/sodium bicarbonate	NF	Omeprazole DR cap 40mg, pantoprazole sodium tab 40mg

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Preferred Brand drugs; **Tier 3:** Non-Preferred Brand drugs; **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
Daybue	trofinetide

Joenja	leniolisib
Kalydeco 13.4 mg granules	ivacaftor
Kalydeco 5.8 mg granules	ivacaftor
Liqrev	sildenafil oral suspension
Lumryz	sodium oxybate
Mekinist powder for oral solution	trametinib
Sogroya	somapacitan-beco
Tafinlar tablets for oral suspension	dabrafenib
Trikafta oral granules	elexacaftor/tezacaftor/ivacaftor and ivacaftor
Vowst	fecal microbiota spores, live-brpk
Zavzpret	zavegepant
Zejula tablets	niraparib

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Acyclovir Topical Cream Products – Commercial	06/19/2023	Reauthorization criteria revised to add if the request is for Zovirax (acyclovir) cream, the member has tried/failed generic acyclovir 5% ointment.
Apokyn (apomorphine hydrochloride) – Commercial and Healthcare Reform	TBD	Policy revised to remove Kynmobi (apomorphine) as it will be removed from the market.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	06/19/2023	Policy revised to consolidate existing Koselugo (selumetinib) criteria from J-0265; terming J-0265. Policy revised to clarify per FDA label for Mekinist (trametinib) monotherapy that the member is BRAF-inhibitor treatment naïve. Policy revised for Mekinist (trametinib) and Tafinlar (dabrafenib): for thyroid cancer, prescriber attestation that the member has no satisfactory locoregional treatment options per FDA label; and to add criteria per FDA expanded indication for low-grade glioma. For all FDA-approved indications, policy revised for Mekinist (trametinib) to add that if the request is for Mekinist powder for oral solution and the member weighs ≥ 26 kg, the prescriber attests that the member has an inability to swallow plan-preferred Mekinist oral tablets. For all FDA-approved indications, policy revised for Tafinlar (dabrafenib) to add that if the request is for Tafinlar tablets for oral suspension and the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		member weighs ≥ 26 kg, the prescriber attests that the member has an inability to swallow plan-preferred Tafinlar oral capsules.
BTK Inhibitors – Commercial and Healthcare Reform	06/19/2023	Policy revised for Imbruvica (ibrutinib) to remove criteria for mantle cell lymphoma and marginal zone lymphoma following removal of the indication per FDA.
fCDK Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for Kisqali (ribociclib) and Kisqali Femara Co-pack (ribociclib; letrozole) to remove prescriber attestation that the member is not a candidate for therapy with both preferred agents, Ibrance and Verzenio.
CFTR Modulators – Commercial and Healthcare Reform	06/19/2023	Policy revised to update the indication for Trikafta (elexacaftor/tezacaftor/ivacaftor) of treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. Criteria updated for the member to be 2 years of age or older. Policy also revised to update the indication for Kalydeco (ivacaftor) to treatment of CF in patients 1 month of age and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. Criteria updated for the member to be 1 month of age or older.
CGRP Inhibitors – Commercial and Healthcare Reform	06/19/2023	Policy revised for Zavzpret (zavegepant) to add criteria for use in members 18 years of age or older with a diagnosis of migraine, classified as acute migraine headaches with or without aura; member has experienced therapeutic failure, contraindication, or intolerance to at least two (2) of the following: generic oral sumatriptan, generic oral rizatriptan, or generic oral zolmitriptan; requiring prescriber attestation that the member experiences significant nausea and vomiting and requires a non-oral route of administration; requiring that the member has experienced therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray; and if the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications. Policy revised for Qulipta

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(atogepant) for expanded indication to include chronic migraine defined as 15 or more headache days per month, of which 8 or more are migraine days. Reauthorization updated to allow for prescriber attestation of a reduction in migraine days per month by at least 5 days from baseline for chronic migraine.
CGRP Inhibitors and Reyvow (lasmiditan) – Commercial National Select Formulary	06/19/2023	Policy revised for Zavzpret (zavegepant) to add criteria for use in members 18 years of age or older with a diagnosis of migraine, classified as acute migraine headaches with or without aura; member has experienced therapeutic failure, contraindication, or intolerance to at least one (1) of the following: generic oral sumatriptan, generic oral rizatriptan, or generic oral zolmitriptan; requiring prescriber attestation that the member experiences significant nausea and vomiting and requires a non-oral route of administration; requiring that the member has experienced therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray; and if the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications. Policy revised for Qulipta (atogepant) for expanded indication to include chronic migraine defined as 15 or more headache days per month, of which 8 or more are migraine days. Reauthorization updated to allow for prescriber attestation of a reduction in migraine days per month by at least 5 days from baseline for chronic migraine.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	06/14/2023	Policy revised for Rinvoq (upadacitinib) expanded indication in Crohn's Disease (CD) requiring age and diagnosis based on FDA-approved indication, directed to a plan-preferred adalimumab product (a trial of infliximab product or Cimzia [certolizumab pegol] also counts). Policy revised to include a table of preferred and non-preferred adalimumab biosimilars. Non-preferred adalimumab biosimilars are directed to preferred adalimumab products and there are no clinical exception criteria. Policy revised for Sotyktu (deucravacitinib) to move from a non-preferred

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		step 3a product to a non-preferred step 3b product (directed to three step 1 agents).
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	TBD	Policy revised to add new strength of Cosentyx (secukinumab) to quantity limitations allowing for 1 x 300 mg pen or syringe every 4 weeks in adult plaque psoriasis (PsO), psoriatic arthritis, and ankylosing spondylitis. For adult PsO loading dose, 5 x 300 mg pens or syringes allowed within the first 4 weeks of therapy.
Chronic Inflammatory Diseases – Commercial National Select Formulary	06/14/2023	Policy revised for Rinvoq (upadacitinib) expanded indication in Crohn's Disease (CD) requiring age and diagnosis based on FDA-approved indication, directed to a plan-preferred adalimumab product (a trial of infliximab product or Cimzia [certolizumab pegol] also counts). Policy revised to include a table of preferred and non-preferred adalimumab biosimilars. Non-preferred adalimumab biosimilars are directed to preferred adalimumab products and there are no clinical exception criteria. Policy revised for Sotyktu (deucravacitinib) to move from a non-preferred step 3a product to a non-preferred step 3b product (directed to three step 1 agents).
Chronic Inflammatory Diseases – Commercial National Select Formulary	TBD	Policy revised to add new strength of Cosentyx (secukinumab) to quantity limitations allowing for 1 x 300 mg pen or syringe every 4 weeks in adult plaque psoriasis (PsO), psoriatic arthritis, and ankylosing spondylitis. For adult PsO loading dose, 5 x 300 mg pens or syringes allowed within the first 4 weeks of therapy.
Clotting Factor Products – Commercial and Healthcare Reform	TBD	Policy revised to remove Altuviiio (antihemophilic factor recombinant Fc-VWF-XTEN fusion protein-ehtl) as a target in the policy and to add it as a plan-preferred agent.
Compounded Medications – Commercial and NY Healthcare Reform	06/19/2023	Policy revised to add to the limitations of coverage that the use of Makena (hydroxyprogesterone caproate) or hydroxyprogesterone caproate to reduce the risk of preterm birth will not be covered by this policy.
Coverage and Care for Medically Fragile Children – Commercial and Healthcare Reform - New York	TBD	Policy created to conform with recently mandated legislation for care and coverage of medically fragile children. The following criteria must be met: the member is less than 21 years of age and the prescriber attests that the member meets the designation of "medically fragile child" as defined

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		in NY S2121C. If approved, the authorization is valid until the member reaches 21 years of age.
Daybue (trofinetide) – Commercial and Healthcare Reform	06/19/2023	New policy created for Daybue (trofinetide) to require the member is 2 years of age or older, has a diagnosis of Rett syndrome (RTT) confirmed by meeting all of the diagnostic criteria for typical RTT; and the medication is being prescribed by or in consultation with a neurologist experienced in the treatment of RTT. Reauthorization criteria requires a positive clinical response to therapy or improvement on the Rett Syndrome Behavior Questionnaire (RSBQ) or an improvement on the Clinical Global Impression-Improvement (CGI-I) score.
Demser (metyrosine) – Commercial and Healthcare Reform	TBD	New policy created for Demser (metyrosine) requiring the member to have an FDA-approved indication supported by diagnostics, the member has experienced therapeutic failure, contraindication, or intolerance to one (1) selective alpha-blocker (doxazosin, prazosin, terazosin), and if the request is for brand Demser, the member has trial and failure of generic metyrosine. Reauthorization criteria was created to require the member experienced a disease improvement or delayed disease progression.
Doptelet (avatrombopag) and Mulpleta (lusutrombopag) – Commercial and Healthcare Reform	06/19/2023	Policy revised to require the member to be 18 years of age or older for approval of Doptelet (avatrombopag) and Mulpleta (lusutrombopag) for thrombocytopenia with chronic liver disease.
Evoxac (cevimeline) – Commercial and Healthcare Reform	06/19/2023	Policy revised for Evoxac (cevimeline) to add to reauthorization criteria that if the request is for brand Evoxac (cevimeline), the member has experienced trial/failure to generic cevimeline.
Fertility – Commercial and Select Healthcare Reform Plans	06/19/2023	Policy revised for Fertility to add that cumulative authorization duration resets after each live birth.
Fertility – Pennsylvania Healthcare Reform Individual Plans	06/19/2023	Policy revised for Fertility to add that cumulative authorization duration resets after each live birth. Clarified that fertility medication is being used for a member participating in artificial insemination.
Gaucher Disease – Commercial and Healthcare Reform	06/19/2023	Policy revised in reauthorization if request is for brand Zavesca(miglustat) to require trial/failure to generic miglustat.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Hereditary Angioedema – Commercial and Healthcare Reform	TBD	Policy reauthorization revised that if the request is for brand Firazyr (icatibant), trial/failure to generic icatibant.
Human Growth Hormone – Commercial and Healthcare Reform	06/19/2023	Policy revised for Skytrofa (lonapegsomatropin-tcgd) to require age and weight based on FDA-approved indication. Policy revised to allow for use of Genotropin (somatropin), Humatrope (somatropin), Norditropin (somatropin), Nutropin (somatropin), Omnitrope (somatropin), Saizen (somatropin), or Zomacton (somatropin) in neonates. Policy revised for Sogroya (somapacitan-beco) to require diagnosis based on expanded FDA-approved indication in patients 2.5 years of age or older and supported by: clinical documentation of delayed growth (i.e., height and growth velocity); the member has had subnormal response to two standard growth hormone stimulation tests; and bone age 14 years or less if female or 16 years or less if male. If the request is for a non-preferred product, the member has tried/failed all of the plan-preferred products. Reauthorization to require 1) clinical documentation of a growth velocity of at least 2 cm/year or clinical documentation that epiphyseal fusion has occurred if growth velocity is less than 2 cm/year and 2) the member is female with chronological age greater than 14 years and bone age 14 years or less; the member is a male with chronological age greater than 16 years and bone age 16 years or less; or the member is a female with chronological age 14 years or less or a male with chronological age 16 years or less. For adult patients only, the requested dose does not exceed 8 mg once weekly for initial and reauthorization.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	06/19/2023	Policy revised for Skytrofa (lonapegsomatropin-tcgd) to require age and weight based on FDA-approved indication. Policy revised to allow for use of Genotropin (somatropin), Humatrope (somatropin), Norditropin (somatropin), Nutropin (somatropin), Omnitrope (somatropin), Saizen (somatropin), or Zomacton (somatropin) in neonates. Policy revised for Sogroya (somapacitan-beco) to require diagnosis based on expanded FDA-approved indication in patients 2.5 years of age or older and supported by: clinical

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		documentation of delayed growth (i.e., height and growth velocity); the member has had subnormal response to two standard growth hormone stimulation tests; and bone age 14 years or less if female or 16 years or less if male. If the request is for a non-preferred product, the member has tried/failed all of the plan-preferred products. For adult patients only, the requested dose does not exceed 8 mg once weekly. Reauthorization to require 1) clinical documentation of a growth velocity of at least 2 cm/year or clinical documentation that epiphyseal fusion has occurred if growth velocity is less than 2 cm/year and 2) the member is female with chronological age greater than 14 years and bone age 14 years or less; the member is a male with chronological age greater than 16 years and bone age 16 years or less; or the member is a female with chronological age 14 years or less or a male with chronological age 16 years or less. For adult patients only, the requested dose does not exceed 8 mg once weekly for initial and reauthorization.
Kuvan and Javygtor (sapropterin dihydrochloride) – Commercial and Healthcare Reform	06/19/2023	Policy revised for brand Kuvan (sapropterin dihydrochloride) or Javygtor (sapropterin dihydrochloride) in reauthorization to require trial/failure to generic sapropterin dihydrochloride. Removed "documentation" that member is on a Phe-restrictive diet.
Lacosamide products – Healthcare Reform	TBD	Policy revised to add Motpoly XR (lacosamide extended-release) capsules to require diagnosis based on FDA-approved indication and that the member has experienced therapeutic failure or intolerance to plan-preferred generic lacosamide tablets. Reauthorization requires prescriber attests that the member has experienced a reduction in seizure frequency from baseline.
Lumryz (sodium oxybate), Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) – Commercial and Healthcare Reform	06/19/2023	Policy revised to include Lumryz (sodium oxybate) requiring FDA-approved age and diagnosis confirmed by sleep studies (multiple sleep latency test [MSLT]) demonstrating mean sleep latency of less than or equal to 8 minutes with two sleep onset rapid eye movement periods (SOREMPs) or one SOREMP on MSLT and one SOREMP on polysomnography) or hypocretin levels (less than 110 pg/mL or one third the normal laboratory

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		reference range). Prescriber provides documentation of excessive daytime sleepiness via the Epworth sleepiness scale (ESS) or maintenance of wakefulness test (MWT). Therapeutic failure, intolerance, or contraindication of a plan-preferred generic CNS stimulant is required and modafinil if the member does not have cataplexy and is over 18 years of age. Baseline number of cataplexy episodes is required for members with cataplexy. Reauthorization requires a decrease in cataplexy episodes compared to baseline and improvement in daytime sleepiness via the ESS or MWT.
Market Watch Programs – Delaware	TBD	Policy revised to add oxybutynin 2.5 mg tablet and zolpidem 7.5 mg capsules to the list of high-cost, low-value medications with oxybutynin 5 mg tablet listed as a therapeutic alternative.
Market Watch Programs – NY, PA, and WV	TBD	Policy revised to add oxybutynin 2.5 mg tablet and zolpidem 7.5 mg capsules to the list of high-cost, low-value medications with oxybutynin 5 mg tablet listed as a therapeutic alternative.
Mucosal Agents – Commercial and Healthcare Reform	06/19/2023	Policy revised to remove Aquoral (oxidized glycerol triesters) since product is no longer available on the market.
New to Market Drug Policy – Commercial and Healthcare Reform	06/15/2023	Policy revised to add that if the request is for a new to market oral liquid dosage form of a chemical entity that is commercially available as a solid oral dosage form, the member has met the criteria outlined in the non-preferred liquid dosage forms policy.
Noxafil (posaconazole) – Commercial and Healthcare Reform	06/19/2023	Policy revised to add if the request is for brand Noxafil (posaconazole) oral suspension, the member has experienced therapeutic failure or intolerance to generic posaconazole oral suspension for Aspergillus of Candida infection prophylaxis. If the request is for Noxafil PowderMix for Aspergillus or Candida infection prophylaxis, if the member is 13 years of age or older, the member has experienced therapeutic failure or intolerance to plan-preferred generic posaconazole oral suspension. For oropharyngeal candidiasis treatment added if the request is for brand Noxafil oral suspension, the member has experienced therapeutic failure or intolerance to generic posaconazole oral suspension.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
PARP Inhibitors – Commercial and Healthcare Reform	06/19/2023	Policy revised for Zejula (niraparib) to require an FDA-approved test for ovarian cancer diagnosis.
PI3K Inhibitors – Commercial and Healthcare Reform	06/19/2023	Policy revised to add Joenja (leniolisib) and require FDA approved indication, age, and weight with confirmation of a variant in the PIK3CD or PIK3R1 gene and clinical findings of Activated Phosphoinositide 3-kinase Delta (PI3Kδ) Syndrome (APDS) (e.g., lymphoproliferation, lymphadenopathy, splenomegaly, recurrent infections).
Provigil (modafinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform	06/19/2023	Policy revised to remove cataplexy requirement from narcolepsy and sleep study requirement from obstructive sleep apnea.
Pulmonary Hypertension – Commercial and Healthcare Reform	06/19/2023	Policy revised for Tracleer (bosentan) to require if the request is for brand Tracleer (bosentan) oral tablets, the member has experienced trial/failure to generic bosentan oral tablets; and if the request is for Tracleer tablets for oral suspension, the member has experienced trial/failure to generic bosentan oral tablets or has an inability to swallow tablets. For reauthorization, requiring trial/failure to generic tadalafil or Alyq (tadalafil), ambrisentan, generic sildenafil, or bosentan oral tablets if the request is for brand Adcirca (tadalafil), Letairis (ambrisentan), Revatio (sildenafil) or Tracleer (bosentan) oral tablets, respectively.
Pulmonary Hypertension – Commercial and Healthcare Reform	06/19/2023	Policy revised to add Liqrev (sildenafil) to require diagnosis based on FDA-approved indication supported by results of a right heart catheterization substantiating all of the following: mean pulmonary arterial pressure greater than 20 mmHg at rest, pulmonary wedge pressure 15 mmHg or less, and pulmonary vascular resistance 3 Wood units or greater; drug is prescribed by or in consultation with a cardiovascular or pulmonary specialist; and therapeutic failure or intolerance to generic sildenafil oral tablets or inability to swallow tablets. Reauthorization to require positive clinical response to therapy.
Sabril and Vigadrone (vigabatrin) – Commercial and Healthcare Reform	06/19/2023	Policy revised to require FDA-approved indication and age and therapeutic failure or intolerance to generic vigabatrin (for brand Sabril (vigabatrin)) for reauthorization.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Samsca (tolvaptan) – Commercial and Healthcare Reform	06/19/2023	Policy revised for Samsca (tolvaptan) to add a requirement in the reauthorization criteria for the member to experience therapeutic failure or intolerance to generic tolvaptan
Self-Administered Injectables – New York Commercial and Healthcare Reform	06/19/2023	Policy revised for Hyqvia (immune globulin infusion 10% (human) with recombinant human hyaluronidase) to update age based on expanded indication.
Sublingual Immunotherapies – Commercial and Healthcare Reform	06/19/2023	Policy revised for Odactra (House Dust Mite Allergen Extract) to update age based on FDA-approved indication. Policy revised for Grastek (Timothy Grass Pollen Allergen Extract) to add limitation of coverage that treatment should not be initiated during active allergy season.
Trientine and Penicillamine Products – Commercial and Healthcare Reform	06/19/2023	Policy revised for trientine and penicillamine products to revise step therapy in initial authorization and reauthorization: 1) removal of step therapy for generic penicillamine capsule and if request is for brand Cuprimine (penicillamine) capsule requires trial/failure of generic penicillamine capsule and tablet; 2) removal of D-penamine from policy as it is no longer on market and not an FDA-approved drug; 3) for Depen (penicillamine) tablet requires trial/failure of generic penicillamine capsule and if request is for brand Depen (penicillamine) tablet requires trial/failure of generic penicillamine tablet; 4) for Cuvrior (trientine tetrahydrochloride) require trial/failure of generic trientine hydrochloride in reauthorization only; 5) Syprine (trientine hydrochloride) requires trial/failure through generic penicillamine capsule and if request is for brand Syprine (trientine hydrochloride) trial/failure through generic trientine hydrochloride.
Veozah (fezolinetant) – Commercial and Healthcare Reform	TBD	New policy created for Veozah (fezolinetant) requiring diagnosis, the member to be 18 years of age or order, and one of the following criteria to be met: therapeutic failure, intolerance, or contraindication to a generic hormone therapy product or the prescriber to attest that hormone therapy is not clinically appropriate for the member. Reauthorization criteria added for the prescriber to attest that the member has experienced a positive clinical response to therapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Vowst (fecal microbiota spores, live-brpk) – Commercial and Healthcare Reform	06/19/2023	New policy created for Vowst (fecal microbiota spores, live-brpk) requiring age and diagnosis based on FDA-approved indication. Reauthorization requiring diagnosis based on FDA-approved indication and attestation of recurrent Clostridioides difficile infection after administration of the initial fecal microbiota product. Authorization duration of 1 month.
Xenazine (tetrabenazine) – Commercial and Healthcare Reform	06/19/2023	Policy revised for Xenazine (tetrabenazine) to require trial/failure of generic tetrabenazine for reauthorization of brand Xenazine.
Xolair (omalizumab) – Commercial and Healthcare Reform	06/19/2023	Policy revised to reflect updated indication of Xolair (omalizumab) for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in patients 18 years of age or older with inadequate response to nasal corticosteroids, as an add-on maintenance treatment. Authorization criteria updated to the member has a diagnosis of CRSwNP.
Zeposia (ozanimod) – Commercial and Healthcare Reform	06/14/2023	Policy revised for Zeposia (ozanimod) in ulcerative colitis to require trial/failure to adalimumab and Stelara (ustekinumab) subcutaneous.

*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	TBD	Policy revised for RizaFilm (rizatriptan) oral film to require diagnosis based on FDA-approved indication and trial/failure/contraindication to generic oral sumatriptan, generic oral rizatriptan, generic oral zolmitriptan, and to generic rizatriptan ODT.
Atypical Antipsychotics – Commercial	06/19/2023	Policy revised to add criteria for a new indication for Rexulti (brexpiprazole): Treatment of agitation associated with dementia due to Alzheimer's disease. Member must meet the following criteria for approval of coverage: the member has a diagnosis of Alzheimer's disease, and the member is experiencing agitation due to dementia of the Alzheimer's disease. Also, added

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		olanzapine/fluoxetine therapy as a qualifier for the use of Vraylar (caiprazine) in the treatment of depressive episodes associated with bipolar I disorder or bipolar II disorder (bipolar depression).
Atypical Antipsychotics – Healthcare Reform	06/19/2023	Policy revised to add criteria for a new indication for Rexulti (brexpiprazole): Treatment of agitation associated with dementia due to Alzheimer's disease. Member must meet the following criteria for approval of coverage: the member has a diagnosis of Alzheimer's disease, and the member is experiencing agitation due to dementia of the Alzheimer's disease. Also, added olanzapine/fluoxetine therapy as a qualifier for the use of Vraylar (cariprazine) in the treatment of depressive episodes associated with bipolar I disorder or bipolar II disorder (bipolar depression).
Authorized Generics of Inhaler Products – Commercial and Healthcare Reform	10/01/2023	Policy revised to add fluticasone propionate/salmeterol HFA – authorized generic to policy and require a diagnosis of asthma and therapeutic failure or intolerance to brand Advair HFA (fluticasone propionate/salmeterol).
Azilect (rasagiline) – Commercial and Healthcare Reform	06/19/2023	Policy revised to add step through generic rasagiline for request for brand Azilect (rasagiline) in reauthorization criteria.
Brand lacosamide products – Commercial	TBD	Policy revised to add Motpoly XR (lacosamide extended-release) capsules to require diagnosis based on FDA-approved indication and that the member has experienced therapeutic failure or intolerance to plan preferred generic lacosamide tablets. Reauthorization requires prescriber attests that the member has experienced a reduction in seizure frequency from baseline.
Bystolic (nebivolol) – Healthcare Reform Essential Formulary	06/19/2023	Policy revised for Bystolic (nebivolol) to require trial, failure, or contraindication to generic nebivolol for approval of brand Bystolic.
Continuous Glucose Monitoring Systems – Commercial and Healthcare Reform	10/01/2023	New policy for Dexcom G6, Dexcom G7, Eversense, Eversense E3, Freestyle Libre, Freestyle Libre 2, Freestyle Libre 3, and Guardian Connect to require one of the following: 1) the member is pregnant, has a diagnosis of diabetes mellitus, and has a history of poorly controlled diabetes or 2) the member has a diagnosis of diabetes mellitus or gestational diabetes and is utilizing an insulin regimen or has experienced problematic hypoglycemia. Automatic approval

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		criteria to allow for automatic adjudication if there is at least two (2) claims for insulin in the member's prescription drug claims history within the previous 180 days.
Glycate (glycopyrrolate) – Commercial and Healthcare Reform	06/19/2023	Policy revised for Glycate (glycopyrrolate) to require therapeutic failure or intolerance to both plan-preferred generic glycopyrrolate 1 mg and 2 mg tablets. Reauthorization criteria revised to require attestation of recurrence or unresolved peptic ulcer disease (PUD), use of Glycate (glycopyrrolate) as adjunctive therapy for PUD, and attestation of positive clinical response to previous course(s) of therapy. Authorization duration revised to 3 months. Automatic authorization removed.
Gralise (gabapentin) – Commercial and Healthcare Reform	06/19/2023	Policy for Gralise (gabapentin) revised to add Quantity Limit Section to policy. A one-time quantity limit override may be approved for 5 tablets per day for the 300 mg strength only, at the start of therapy to allow for FDA-approved titration schedule.
Insomnia Medications – Commercial and Healthcare Reform	06/19/2023	Policy revised to include Zolpidem tartrate capsules. Members must have an FDA-approved diagnosis and have experienced therapeutic failure, contraindication, or intolerance to two (2) plan-preferred agents. In addition, the member must be below 65 years of age.
Intranasal Benzodiazepines – Commercial and Healthcare Reform	06/19/2023	Policy revised to remove step through rectal diazepam.
Luzu (luliconazole 1% cream) – Commercial and Healthcare Reform	06/19/2023	Policy revised for Luzu (luliconazole) to add reauthorization requiring attestation of positive clinical response to therapy and additional topical antifungal therapy is needed.
Non-Preferred Topical Antifungals – Commercial and Healthcare Reform	06/19/2023	Policy revised to add criteria for generic naftifine 2% gel requiring diagnosis and therapeutic failure, contraindication, or intolerance to econazole 1% cream and ketoconazole 2% cream. If the request is for brand Naftin (naftifine) 2% gel, the member must experience therapeutic failure or intolerance to generic naftifine 2% gel. If the request is for brand Naftin (naftifine) 1% gel, the member must experience therapeutic failure or intolerance to generic naftifine 1% gel.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Proton Pump Inhibitors (PPIs) – Commercial and Healthcare Reform	06/19/2023	Policy revised to add Konvomep (omeprazole and sodium bicarbonate) oral suspension requiring FDA- approved indication and trial/failure of at least a 30-day supply and 80 mg dosing of omeprazole and pantoprazole. For reauthorization, clinical improvement or response to therapy.
Proton Pump Inhibitors (PPIs) – Commercial National Select Formulary	06/19/2023	Policy revised to add Konvomep (omeprazole and sodium bicarbonate) oral suspension requiring FDA- approved indication and trial/failure of at least a 30-day supply and 80 mg dosing of omeprazole and pantoprazole. For reauthorization, clinical improvement, or response to therapy.
Vimpat (lacosamide) – Commercial National Select Formulary	06/20/2023	Terminating policy – Vimpat is now non-formulary on NSF.

*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
Arexvy (respiratory syncytial virus vaccine, adjuvanted)	1 dose per 185 days	1 dose per 185 days
Cosentyx 300 mg UnoReady pen and syringe	1 pen/syringe (300 mg/2mL) per 28 days	3 pens/syringes (300 mg/2 mL) per 84 days
Daybue (trofinetide)	8 bottles (450 mL each) per 30 days	24 bottles (450 ml each) per 90 days
Lumryz (sodium oxybate)	30 packets per 25 days	90 packets per 75 days
Lupron Depot-PED (leuprolide acetate for depot suspension) 45 mg	1 kit per 180 days	1 kit per 180 days
Luzu (luliconazole)	1 tube (60 grams) per 28 days	1 tube (60 grams) per 28 days
Mekinist (trametinib) powder for oral solution	14 bottles per 30 days	40 bottles per 90 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Omnipod Go	10 pods per 30 days	30 pods per 90 days
Rinvoq (upadacitinib) 45 mg oral tablet	84 tablets per 365 days	84 tablets per 365 days
RizaFilm (rizatriptan oral film)	120 mg per 30 days	360 mg per 90 days
Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) oral granules	56 tablets (1 carton) per 28 days	168 tabets (3 cartons) per 84 days
Vowst (fecal microbiota spores, live-brpk)	12 capsules per 56 days	12 capsules per 56 days
Zavzpret (zavegepant)	8 units per 30 days	24 units per 90 days

*Effective date to be determined.

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

No changes at this time.

*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
Combogesic (acetaminophen/ibuprofen)	12 tablets per day
Gilenya 0.25 mg capsules (fingolimod)	1 capsule per day
Glycate (glycopyrrolate) 1.5 mg tablet	5 tablets per day
Gralise (gabapentin) 300 mg*	1 tablet per day
Gralise (gabapentin) 450 mg	1 tablet per day
Gralise (gabapentin) 600 mg*	2 tablets per day
Gralise (gabapentin) 750 mg	2 tablets per day
Gralise (gabapentin) 900 mg	2 tablets per day
Joenja (leniolisib)	2 tablets per day
Kalydeco (ivacaftor) 5.8 mg granules	2 packets per day
Kalydeco (ivacaftor) 13.4 mg granules	2 packets per day
Konvomep (omeprazole/sodium bicarbonate)	20 mL (40 mg) per day
Liqrev (sildenafil oral suspension)	6 mL per day
Motpoly XR (lacosamide ER capsules)	100 mg capsule ER: 1 capsule per day. 150 mg capsule ER: 2 capsules per day. 200 mg capsule ER: 2 capsules per day.
Oxybutynin chloride 2.5 mg tablet	3 tablets per day

Drug Name	Daily Limit
Tafinlar (dabrafenib) tablets for oral suspension	30 tablets per day
Veozah (fezolinetant)	1 tablet per day
Zejula (niraparib) tablets	1 tablet per day
Zolpidem 7.5 mg capsules	1 capsule 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 Open Formularies

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

Incentive Formulary
Compass 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
Arexvy	Respiratory syncytial virus vaccine, adjuvanted	Respiratory syncytial virus, prevention

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

Brand Name	Generic Name	Preferred Alternatives
Combogesic	Acetaminophen /ibuprofen	acetaminophen/ibuprofen
Konvomep	omeprazole/sodium bicarbonate	omeprazole capsule, delayed release (DR/EC); pantoprazole tablet, delayed release (DR/EC); omeprazole-sodium bicarbonate capsule
Omnipod Go	Omnipod Go	Prescriber discretion
RizaFilm	rizatriptan oral film	sumatriptan succ tab, rizatriptan tab, zolmitriptan tab
Veozah	fezolinetant	estradiol tablet, estradiol-norethindrone acetate tablet
Zolpidem 7.5 mg capsules	Zolpidem 7.5 mg capsules	zolpidem 5 mg tablet, zolpidem 10 mg tablet

B. Changes to the Highmark Medicare Part D 5-Tier Closed Formularies

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

- **Performance Formulary**
- **Venture Formulary**
- **Fundamental Formulary**

Table 1. Preferred Products

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

Brand Name	Generic Name	Comments
Arexvy	Respiratory syncytial virus vaccine, adjuvanted	Respiratory syncytial virus, prevention

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

No changes at this time.

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

Brand Name	Generic Name	Preferred Alternatives
Abilify Asimtufii	aripiprazole	Abilify Maintena
Combogesic	Acetaminophen /ibuprofen	Prescriber discretion
Konvomep	omeprazole/sodium bicarbonate	omeprazole capsule, delayed release(DR/EC); pantoprazole tablet, delayed release (DR/EC)
Liqrev	sildenafil oral suspension	sildenafil (pulm.hypertension) suspension for reconstitution
Lumryz	sodium oxybate	modafinil, armodafinil, methylphenidate hcl tablet
Motpoly XR	lacosamide ER capsules	lacosamide tablet
Omnipod Go	Omnipod Go	Prescriber discretion
RizaFilm	rizatriptan oral film	Sumatriptan succ tab, rizatriptan tab, zolmitriptan tab
Sogroya	somapacitan-beco	Norditropin FlexPro
Sogroya	somapacitan-beco 15 mg/1.5 mL	Norditropin FlexPro
Uzedy	risperidone ER injection susp	Risperdal Consta
Veozah	fezolinetant	estradiol tablet, estradiol-norethindrone acetate tablet
Zolpidem 7.5 mg capsules	Zolpidem 7.5 mg capsules	zolpidem 5 mg tablet, zolpidem 10 mg tablet

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form.

C. Additions to the Specialty Tier
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name

Daybue	trofinetide
Elfabrio	pegunigalsidase alfa-iwxj
Joenja	leniolisib
Kalydeco 13.4 mg granules	ivacaftor
Kalydeco 5.8 mg granules	ivacaftor
Qalsody	tofersen
Rezzayo	rezafungin
Trikafta oral granules	elexacaftor/tezacaftor/ivacaftor and ivacaftor
Vowst	fecal microbiota spores, live-brpk
Zavzpret	zavegepant
Zejula tablets	niraparib
Zynyz	retifanlimab-dlwr

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	1/1/2024	Policy revised for Sutent (sunitinib) to require for all FDA-approved indications therapeutic failure or intolerance to generic sunitinib if the request is for brand Sutent (sunitinib).
Apokyn (apomorphine hydrochloride) – Medicare	TBD	Policy revised to remove Kynmobi (apomorphine) as it will be removed from the market.
Atypical Antipsychotics – Medicare	06/19/2023	Policy revised to add criteria for a new indication for Rexulti (brexpiprazole): Treatment of agitation associated with dementia due to Alzheimer's disease. Member must meet the following criteria for approval of coverage: the member has a diagnosis of Alzheimer's disease, and the member is experiencing agitation due to dementia of the Alzheimer's disease.
BCR-ABL Kinase Inhibitors – Medicare	06/19/2023	Policy revised for Bosulif (bosutinib), Iclusig (ponatinib), and Scemblix (asciminib) to remove requirement for age.
BCR-ABL Kinase Inhibitors – Medicare	TBD	Policy revised for Gleevec (imatinib) for all FDA-approved indications to require therapeutic failure or intolerance to generic imatinib if the request is for brand Gleevec.
Blood Glucose Testing Product Quantity Limits – Medicare	TBD	Policy revised to reference updated Medicare Local Coverage Determination L33822 and attestation from treating practitioner that the additional quantity is necessary

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Blood Glucose Testing Products – Medicare	TBD	Policy revised to reference updated Medicare Local Coverage Determination L33822
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	06/19/2023	Policy revised to consolidate existing Koselugo (selumetinib) criteria from J-0262 (terming J-0262); and for Koselugo (selumetinib) to remove requirement for age. Policy revised to clarify per FDA label for Mekinist (trametinib) monotherapy that the member is BRAF-inhibitor treatment naïve. Policy revised for Mekinist (trametinib) and Tafinlar (dabrafenib) to add criteria per FDA expanded indication for low-grade glioma. For all FDA-approved indications, policy revised for Mekinist (trametinib) to add that if the request is for Mekinist powder for oral solution and the member weighs ≥ 26 kg, the prescriber attests that the member has an inability to swallow Mekinist oral tablets. For all FDA-approved indications, policy revised for Tafinlar (dabrafenib) to add that if the request is for Tafinlar tablets for oral suspension and the member weighs ≥ 26 kg, the prescriber attests that the member has an inability to swallow Tafinlar oral capsules.
BTK Inhibitors – Medicare	06/19/2023	Policy revised for Imbruvica (ibrutinib) to remove criteria for mantle cell lymphoma and marginal zone lymphoma following removal of the indication per FDA.
CDK Inhibitors – Medicare	5/5/2023	Policy revised for Kisqali (ribociclib) and Kisqali Femara Co-pack (ribociclib; letrozole) to remove prescriber attestation that the member is not a candidate for therapy with both preferred agents, Ibrance and Verzenio. Policy revised for Ibrance (palbociclib), Kisqali (ribociclib), Kisqali Femara Co-pack (ribociclib; letrozole), and Verzenio (abemaciclib) to remove requirement that the member is 18 years of age or older.
CGRP Inhibitors – Medicare	06/19/2023	Policy revised for Zavzpret (zavegepant) to require that the member has a diagnosis of acute migraine headaches with or without aura; and that the member has

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		experienced therapeutic failure, contraindication, or intolerance to one (1) generic triptan (e.g., sumatriptan); and that the member has an inability to swallow capsules/tablets. Policy revised for Qulipta (atogepant) for expanded indication to include chronic migraine defined as 15 or more headache days per month, of which 8 or more are migraine days.
Chelating Agents – Medicare	06/19/2023	Policy revised to update reauthorization criteria to require a step through generic deferasirox if the request is for brand Exjade (deferasirox), brand Jadenu (deferasirox), or Ferriprox (deferiprone) if not previously trialed.
Chronic Inflammatory Diseases – Medicare	06/19/2023	Policy revised for Rinvoq (upadacitinib) expanded indication in Crohn's Disease (CD) requiring diagnosis based on FDA-approved indication
Chronic Inflammatory Diseases – Medicare	TBD	Policy revised to add new strength of Cosentyx (secukinumab) to quantity limitations allowing for 1 x 300 mg pen or syringe every 4 weeks in adult plaque psoriasis (PsO), psoriatic arthritis, and ankylosing spondylitis. For adult PsO loading dose, 5 x 300 mg pens or syringes allowed within the first 4 weeks of therapy.
Colony-Stimulating Factors – Medicare	TBD	New policy created for the following filgrastim products: Neupogen (filgrastim), Releuko (filgrastim-ayow), Granix (tbo-filgrastim); and the following pegfilgrastim products: Fylentra (pegfilgrastim-pbbk); Udenyca (pegfilgrastim-cbvq); Nyvepria (pegfilgrastim-apgf) requiring diagnosis. For filgrastim products, the policy requires therapeutic failure or intolerance to Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz). For pegfilgrastim products, the policy requires therapeutic failure or intolerance to 2 of the following: Neulasta (filgrastim), Fulphila (pegfilgrastim-jmdb), and Ziextenzo (pegfilgrastim-bmez). For both filgrastim and pegfilgrastim products, therapeutic failure or intolerance is limited to qualifiers

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		with the same indications as the target product.
Cresemba (isavuconazonium sulfate) capsules – Medicare	1/1/2024	New policy for Cresemba (isavuconazonium sulfate) capsules to require a diagnosis of invasive aspergillosis and the member has experienced therapeutic failure, contraindication, or intolerance to voriconazole or the member has a diagnosis of invasive mucormycosis infection.
Cuvrior (trientine tetrahydrochloride) – Medicare	06/19/2023	Policy created for Cuvrior (trientine tetrahydrochloride) to require diagnosis based on FDA-approved indication and trial/failure of a penicillamine product and generic trientine hydrochloride.
Daybue (trofinetide) – Medicare	06/19/2023	New policy created for Daybue (trofinetide) to require the member has a diagnosis of Rett syndrome (RTT) confirmed by meeting all of the diagnostic criteria for typical RTT.
Enzyme Replacement Therapy for Fabry Disease – Medicare	1/1/2024	Policy revised for Elfabrio (pegunigalsidase alfa-iwxj) and Fabrazyme (agalsidase beta) to require diagnosis based on FDA-approved indication confirmed by deficiency in alpha-galactosidase A enzyme activity or gene sequencing demonstrating galactosidase alpha gene enzyme mutation.
Erythropoiesis-Stimulating Agents – Medicare	TBD	New policy created for Epogen (epoetin alfa) and Aranesp (darbepoetin alfa) requiring diagnosis and therapeutic failure or intolerance to Procrit (epoetin alfa) and Retacrit (epoetin alfa-epbx).
Enzyme Replacement Therapy for Fabry Disease – Medicare	06/19/2023	Policy revised to add Elfabrio (pegunigalsidase alfa-iwxj) to require diagnosis based on FDA-approved indication and that the member is not receiving concomitant therapy with Galafold (migalastat).
Fecal Microbiota Products – Medicare	1/1/2024	Policy revised for Rebyota (fecal microbiota, live-jslm) and Vowst (fecal microbiota spores, live-brpk) reauthorization to require attestation the member has completed or will complete

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		antibiotic treatment for the most recent recurrent Clostridioides difficile infection.
Fecal Microbiota Products – Medicare	TBD	Policy revised to add Vowst (fecal microbiota spores, live-brpk) requiring diagnosis based on FDA-approved indication. Reauthorization requiring prophylaxis use and attestation of recurrent Clostridioides difficile infection after administration of the initial fecal microbiota product. Authorization duration of 1 month.
Fecal Microbiota Products – Medicare	06/19/2023	Policy revised for Rebyota (fecal microbiota, live-jslm) allowing attestation the member has completed or will complete antibiotic treatment for recurrent Clostridioides difficile infection.
Fingolimod – Medicare	1/1/2024	Policy revised to require for Tascenso ODT (fingolimod), in addition to a diagnosis based on the FDA-approved indication, the member must have an inability to swallow capsules.
Glatiramer Acetate – Medicare	1/1/2024	Policy revised to require FDA-labeled diagnosis for Copaxone (glatiramer acetate) and Glatopa (glatiramer acetate).
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	1/1/2024	Policy revised to remove that step therapy for Bydureon Bcise (exenatide extended-release) and Byetta (exenatide) applies to Medicare Incentive formulary.
Glycate (glycopyrrolate) – Medicare	1/1/2024	Policy revised for Glycate (glycopyrrolate) 1.5 mg tablets to require diagnosis and therapeutic failure or intolerance to both generic glycopyrrolate 1 mg and 2 mg tablets. Reauthorization criteria removed. Authorization duration revised to 3 months.
Homozygous Familial Hypercholesterolemia – Medicare	06/19/2023	Policy revised for Evkeeza (evinacumab-dgnb) and Juxtapid (lomitapide) to remove age limitations. Age requirement for step through Repatha (evolocumab) for Evkeeza (evinacumab-dgnb) removed.
Human Growth Hormone – Medicare	06/19/2023	Policy revised for Sogroya (somapacitan-beco) to require diagnosis based on expanded FDA-approved indication and supported by: clinical documentation of delayed growth (i.e., height and growth velocity); the member has had subnormal response to two standard growth hormone

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		stimulation tests; and bone age 14 years or less if female or 16 years or less if male. If the member is a neonate and, their growth hormone level less than 10 ng/mL. Reauthorization to require 1) clinical documentation of a growth velocity of at least 2 cm/year or clinical documentation that epiphyseal fusion has occurred if growth velocity is less than 2 cm/year and 2) the member is female with chronological age greater than 14 years and bone age 14 years or less; the member is a male with chronological age greater than 16 years and bone age 16 years or less; or the member is a female with chronological age 14 years or less or a male with chronological age 16 years or less.
Interferon Beta – Medicare	1/1/2024	New policy to require FDA labeled diagnosis for Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), and Rebif (interferon beta-1a).
Long-Acting Muscarinic Agents – Medicare	1/1/2024	New policy created for Incruse Ellipta (umeclidinium) and Tudorza Pressair (aclidinium bromide) to require a diagnosis of chronic obstructive pulmonary disease and for the member to experience a therapeutic failure, contraindication or intolerance to either Spiriva Handihaler (tiotropium) or Spiriva Respimat (tiotropium).
Lumryz (sodium oxybate), Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) – Medicare	TBD	Policy revised to include Lumryz (sodium oxybate) requiring FDA-approved diagnosis confirmed by sleep studies (multiple sleep latency test [MSLT]) demonstrating mean sleep latency of less than or equal to 8 minutes with two sleep onset rapid eye movement periods (SOREMPs) or one SOREMP on MSLT and one SOREMP on polysomnography) or hypocretin levels (less than 110 pg/mL or one third the normal laboratory reference range). Prescriber provides documentation of excessive daytime sleepiness via the Epworth sleepiness scale (ESS) or maintenance of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		wakefulness test (MWT). Therapeutic failure, intolerance, or contraindication of a plan-preferred generic CNS stimulant and modafinil is required for members without cataplexy. Baseline number of cataplexy episodes is required for members with cataplexy. Reauthorization requires improvement in symptoms of narcolepsy and cataplexy if applicable.
Motpoly XR – Medicare	TBD	New policy for Motpoly XR (lacosamide extended-release) capsules to require diagnosis based on FDA-approved indication and that the member has experienced therapeutic failure or intolerance to generic lacosamide tablets.
Nityr and Orfadin (nitisinone) – Medicare	1/1/2024	Policy revised for Orfadin (nitisinone) oral suspension to add alternative to inability to swallow to allow therapeutic failure/intolerance to generic nitisinone capsules.
Non-preferred Inhaler Products – Medicare	1/1/2024	Policy revised to add Flovent HFA (fluticasone propionate) to the policy and require a diagnosis of asthma and therapeutic failure or intolerance to two of the following: Asmanex (mometasone), fluticasone propionate HFA, or QVAR (beclomethasone). Symbicort (budesonide/formoterol fumarate) also added to the policy to require a diagnosis of either asthma or COPD and if the request is for brand Symbicort (budesonide/formoterol fumarate), the member has experienced therapeutic failure or intolerance to budesonide/formoterol fumarate. Criteria for fluticasone/salmeterol HFA removed.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	06/16/2023	Policy revised to add Flovent HFA (fluticasone propionate) to the policy and require a diagnosis of asthma and therapeutic failure or intolerance to two of the following: Asmanex (mometasone), fluticasone propionate HFA, or QVAR (beclomethasone). Symbicort (budesonide/formoterol fumarate) also added to the policy to require a diagnosis of either asthma or COPD and if the

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		request is for brand Symbicort (budesonide/formoterol fumarate), the member has experienced therapeutic failure or intolerance to budesonide/formoterol fumarate. Criteria for fluticasone/salmeterol HFA removed.
Nonpreferred Topical Antifungals – Medicare	06/16/2023	Policy revised to add criteria for generic naftifine 2% gel requiring diagnosis and therapeutic failure, contraindication, or intolerance to econazole 1% cream and ketoconazole 2% cream.
Northera (droxidopa) – Medicare	1/1/2024	Policy revised to update reauthorization criteria to require a step through generic droxidopa if the request is for brand Northera (droxidopa) if not previously trialed.
Noxafil (posaconazole) – Medicare	1/1/2024	Policy revised for Noxafil (posaconazole) suspension, if the request is for the brand the member has tried/failed generic posaconazole suspension. For Noxafil (posaconazole) oral suspension and the indication of Aspergillus or Candida Infection Prophylaxis, the member has experienced therapeutic failure or intolerance to generic posaconazole delayed-release tablets or has an inability to swallow tablets.
Ocaliva (obeticholic acid) – Medicare	06/19/2023	Policy revised for Ocaliva (obeticholic acid) to remove requirement for age.
Ofev (nintedanib) and Esbriet (pirfenidone) – Medicare	1/1/2024	Policy revised for Esbriet (pirfenidone) to require trial/failure of generic pirfenidone tablets if the request is for brand Esbriet (pirfenidone).
PI3K Inhibitors – Medicare	06/19/2023	Policy revised to add Joenja (leniolisib) and require FDA-approved indication and confirmed variant in the PIK3CD or PIK3R1 gene.
Polivy (polatuzumab vedotin-piiq) – Medicare	06/19/2023	Policy revised for Polivy (polatuzumab vedotin-piiq) to require diagnosis based on FDA-approved expanded indication and to remove requirement for age.
Programmed Death Receptor Therapies – Medicare	06/19/2023	Policy revised to add for Zynyz (retifanlimab-dlwr) criteria based on FDA-approved indication. Policy revised for Keytruda (pembrolizumab) for use in

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		combination with Padcev (enfortumab vedotin-ejfv) based on FDA-approved expanded indication; and for use in members with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy, or who have disease progression during or following platinum-containing chemotherapy or within twelve months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
Pulmonary Hypertension – Medicare	06/19/2023	Policy revised to add Liqrev (sildenafil) to require diagnosis based on FDA-approved indication supported by results of a right heart catheterization substantiating all of the following: mean pulmonary arterial pressure greater than 20 mmHg at rest, pulmonary wedge pressure 15 mmHg or less, and pulmonary vascular resistance 3 Wood units or greater; and therapeutic failure or intolerance to generic sildenafil for oral suspension.
Qalsody (tofersen) – Medicare	TBD	Policy created for Qalsody (tofersen) to require diagnosis based on FDA-approved indication and member has a mutation in the superoxide dismutase 1 (SOD1) gene. Quantity limitation override included to allow for induction dosing of three (3) vials (45 mL) within the first 28 days of therapy.
Sabril and Vigadrone (vigabatrin) – Medicare	1/1/2024	Policy revised to require therapeutic failure or intolerance to generic vigabatrin for requests for brand Sabril (vigabatrin).
Samsca (tolvaptan) – Medicare	1/1/2024	Policy revised for Samsca (tolvaptan) to add a requirement in the reauthorization criteria for the member to experience therapeutic failure or intolerance to generic tolvaptan if not previously trialed.
Saphris (asenapine) – Medicare	1/1/2024	New policy for Saphris (asenapine) requiring diagnosis and therapeutic failure or intolerance to generic asenapine sublingual tablets; and therapeutic failure, intolerance, or contraindication through one of the following generic products: olanzapine, quetiapine, or risperidone.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Sublingual Immunotherapies – Medicare	06/19/2023	Policy revised for Odactra (House Dust Mite Allergen Extract) to update age based on FDA-approved indication.
Sublingual Immunotherapies – Medicare	1/1/2024	Policy revised for Grastek (Timothy Grass Pollen Allergen Extract) to add limitation of coverage that treatment should not be initiated during active allergy season.
Sucraid (sacrosidase) – Medicare	1/1/2024	New policy for Sucraid (sacrosidase) to require diagnosis based on FDA-approved indication supported by one of the following: small bowel biopsy or meet all of the following: 1) stool pH < 6; 2) negative lactose breath test or 3) sucrase deficiency.
Syfovre (pegcetacoplan) – Medicare	06/19/2023	Policy updated to update the reauthorization criteria to the member has experienced a decrease in growth of lesion(s) from baseline.
Trikafta (elexacaftor/ivacaftor/tezacaftor) – Medicare	06/16/2023	Policy revised to update indication for treatment of cystic fibrosis in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. Criteria for age removed.
Veozah (fezolinetant) – Medicare	06/16/2023	New policy created for Veozah (fezolinetant) requiring diagnosis and one of the following criteria to be met: therapeutic failure, intolerance, or contraindication to a generic hormone therapy product or the prescriber to attest that hormone therapy is not clinically appropriate for the member.
Xolair (omalizumab) – Medicare	06/16/2023	Policy revised to reflect updated FDA-approved indication of Xolair (omalizumab) for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP).
Zolpidem Tartrate (zolpidem tartrate) 7.5 mg Capsules – Medicare	06/16/2023	Policy created to require member to meet the following criteria to obtain Zolpidem Tartrate 7.5 mg capsules: member is less than 65 years of age, member has a diagnosis of insomnia, characterized by difficulties with sleep onset and the member has experienced therapeutic

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		failure or intolerance to two (2) of the following, or contraindication to all: eszopiclone, zaleplon, zolpidem or zolpidem ER.

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

2. Updates to Step Therapy

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)
Abilify Asimtufii (aripiprazole)	1 injection per 60 days	1 injection per 60 days
Combogesic (acetaminophen/ibuprofen)	12 tablets per day	12 tablets per day
Cosentyx 300 mg UnoReady pen and syringe	1 pen/syringe (300 mg/2mL) per 28 days	3 pens/syringes (300 mg/2 mL) per 84 days
Daybue (trofinetide)	8 bottles (450 mL each) per 30 days	24 bottles (450 ml each) per 90 days
Gilenya 0.25 mg capsules (fingolimod)	1 capsule per day	1 capsule per day
Glycate (glycopyrrolate) 1.5 mg tablet	5 tablets per day	5 tablets per day
Gralise (gabapentin) 450 mg	1 tablet per day	1 tablet per day
Gralise (gabapentin) 600 mg	2 tablets per day	2 tablets per day
Gralise (gabapentin) 750 mg	2 tablets per day	2 tablets per day
Gralise (gabapentin) 900 mg	2 tablets per day	2 tablets per day
Joenja (leniolisib)	2 tablets per day	2 tablets per day
Kalydeco (ivacaftor) 13.4 mg granules	2 packets per day	2 packets per day
Kalydeco (ivacaftor) 5.8 mg granules	2 packets per day	2 packets per day
Liqrev (sildenafil oral suspension)	24 mL per day	24 mL per day
Lumryz (sodium oxybate)	1 packet per day	1 packet per day
Lupron Depot-PED (leuprolide acetate for depot suspension) 45 mg	45 mg every 6 months	45 mg every 6 months
Mekinist (trametinib) powder for oral solution	14 bottles per 30 days	40 bottles per 90 days
Motpoly XR (lacosamide ER capsules)	100 mg capsule ER: 1 capsule per day. 150 mg capsule ER: 2 capsules per day. 200 mg capsule ER: 2 capsules per day.	100 mg capsule ER: 1 capsule per day. 150 mg capsule ER: 2 capsules per day. 200 mg capsule ER: 2 capsules per day.
Omnipod Go	10 pods per 30 days	30 pods per 90 days
Oxybutynin chloride 2.5 mg tablet	3 tablets per day	3 tablets per day

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Qalsody (tofersen)	1 vial (15 mL) per 28 days	3 vials (45 mL) per 84 days
Rebyota (fecal microbiota, live-jslm)	1 unit per 2 weeks	1 unit per 2 weeks
Rinvoq (upadacitinib) 45 mg oral tablet	168 tablets per 365 days	168 tablets per 365 days
RizaFilm (rizatriptan oral film)	12 EA per 28 days	36 EA per 84 days
Tafinlar (dabrafenib) tablets for oral suspension	30 tablets per day	30 tablets per day
Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) oral granules	1 carton per 28 days	3 cartons per 84 days
Uzedy (risperidone ER injection susp)	1 injection per 30 days	1 injection per 30 days
Veozah (fezolinetant)	1 tablet per day	1 tablet per day
Vowst (fecal microbiota spores, live-brpk)	12 capsules per 14 days	12 capsules per 14 days
Zavzpret (zavegepant)	80 mg per 30 days	240 mg per 90 days
Zejula (niraparib) tablets	1 tablet per day	1 tablet per day
Zolpidem 7.5 mg capsules	1 capsule per day	1 capsule per day

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