# Formulary Updates

**Published December 2024**

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for October 2024. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in October 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 (PRC), which is also accessible via Availity®. Once on the PRC, go to **Policies & Programs** > **Highmark Formulary** and then scroll down to find the formulary you're looking for.

# Important Drug Safety Updates

## Continuous Glucose Monitoring (CGM) Sensor Recall: Abbott Diabetes Care Inc Issues Recall for Certain FreeStyle Libre 3 Sensors due to Risk for Inaccurate High Glucose Readings

On Sept. 9, 2024, Abbott Diabetes Care Inc began voluntarily recalling these FreeStyle Libre 3 sensors after finding that a small number of FreeStyle Libre 3 sensors may provide incorrect high glucose readings, which if undetected may pose a potential health risk for people living with diabetes.

The use of affected product may cause serious adverse health consequences, including severe low blood sugar (hypoglycemia) which can cause central nervous system problems, loss of consciousness, seizures, coma, permanent brain damage, and death.

## Bionpharma Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension Due to Bacterial Contamination

On Sept. 17, 2024, Bionpharma Inc. began voluntarily recalling one single Batch (2310083) of Atovaquone Oral Suspension, 750mg per mL to the consumer level. The product was manufactured by CoreRx, Inc. in Clearwater, FL, and distributed by Bionpharma Inc. The product was found to be contaminated with Cohnella bacteria.

In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life-threatening infections, such as inflammation of the heart and permanent damage to soft tissue. To date, Bionpharma has not received any reports of adverse events related to this recall.

## FDA is alerting patients and health care professionals about the voluntary withdrawal of Oxbryta from the market due to safety concerns

On Sept. 26, 2024, Pfizer Inc., the manufacturer of Oxbryta, announced it was voluntarily withdrawing the medication from the market, ceasing distribution, and discontinuing all active clinical trials and expanded access programs for Oxbryta because recent data indicate the benefit of Oxbryta does not outweigh the risks for the sickle cell patient population.

In post-marketing clinical trials of Oxbryta, Pfizer reported a higher rate of vaso-occlusive crisis (severe pain caused by sickled red blood cells blocking blood flow and oxygen delivery to tissues) in patients with sickle cell disease receiving Oxbryta compared to placebo. There were also more deaths in the Oxbryta treatment group as compared to the placebo group in these post-marketing studies. Pfizer also observed a higher rate of vaso-occlusive crisis in patients with sickle cell disease receiving Oxbryta in two real-world registry studies. Based on the totality of clinical data, Pfizer has determined the benefit of Oxbryta does not outweigh the risk.

## FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause

The U.S Food and Drug administration (FDA) released an FDA Drug Safety Communication warning about rare occurrences of serious liver injury with the use of Veozah for hot flashes and menopause. The FDA added a warning about the risk of liver injury to the existing warning about elevated liver blood test values and required liver blood testing in the prescribing information for Veozah. The FDA advises health care professionals to conduct hepatic laboratory testing before prescribing Veozah then every month for the first three months after patients start treatment and then at months 6 and 9 of treatment. Patients on Veozah who experience signs and symptoms of liver problems should contact their health care provider.

## Highmark Formulary Update – October 2024

### 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 October 2024, unless otherwise noted.

| Brand Name | Generic Name | Comments |
|---|---|---|
| Zurnai | nalmefene hydrochloride | Known or suspected opioid overdose induced by natural or synthetic |

| | | |
|---|---|---|
| | | opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression. |

Coverage may be contingent upon plan benefits.

**Table 2. Products Not Added****

| Brand Name | Generic Name | Preferred Alternatives |
|---|---|---|
| Crexont | carbidopa/levodopa | carbidopa/levodopa tablet |
| Femlyv | norethindrone acetate and ethinyl estradiol | Blisovi 24 FE, Junel FE Tablet 1mg-20(24), Hailey FE Tablet 1mg-20(24) |
| Lazcluze 240 mg, 80 mg | lazertinib | Prescriber Discretion |
| Leqselvi | deuruxolitinib | Prescriber Discretion |
| Livdelzi | seladelpar | ursodiol tablet, ursodiol 300 mg capsules |
| Neffy | epinephrine | epinephrine auto-injector (ea) 0.15mg/0.3, epinephrine auto-injector (ea) 0.3mg/0.3 |
| Nemluvio | nemolizumab-ilto | Dupixent Pen Injector (mL) 300 mg/2mL; Dupixent Syringe (mL) 300 mg/2mL |
| Prevymis oral pellets | letermovir | valganciclovir HCl tablet |
| Tezruly | terazosin | terazosin HCl, doxazosin mesylate tablet, tamsulosin HCl |
| Voranigo | vorasidenib | Prescriber Discretion |
| Yorvipath | palopegteriparatide | calcitriol capsule, calcitriol solution, oral |
| Zituvimet XR 50 mg/1,000 mg, 50 mg/500 mg, 100 mg/1,000 mg | sitagliptin and metformin hydrochloride | Januvia, Tradjenta, Janumet XR |
| Zunveyl | benzgalantamine | donepezil HCl, rivastigmine |

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. To access this form for your region, go to the **Provider Resource Center** and choose your region from the top right. Select **Resources & Education** > **Forms** > **Pharmacy Prior Authorization Forms** and then scroll down to the **Prescription Drug Medication Request Form**.

**Table 3. Additions to the Specialty Tier Copay Option**

**Note:** The specialty tier does not apply to Highmark Delaware (DE) 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. Once on the page, click on Heathcare Reform, which is under the "Line of Business" header.

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

| Brand Name | Generic Name |
|---|---|
| Lazcluze | lazertinib |
| Leqselvi | deuruxolitinib |
| Livdelzi | seladelpar |
| Nemluvio | nemolizumab-ilto |
| Prevymis oral pellets | letermovir |
| Voranigo | vorasidenib |
| Yorvipath | palopegteriparatide |

**Table 4. Products to Be Removed or Shifted to Higher Tier – Effective January 2025**

| Brand name | Generic Name | Preferred Alternatives |
|---|---|---|
| **All Commercial and Healthcare Reform Comprehensive products** | | |
| Carbaglu 200 mg tab for susp | carglumic acid | carglumic acid |
| Freestyle Libre 14-day reader | Freestyle Libre reader | Dexcom G7 receiver |
| Freestyle Libre 14-day sensor | Freestyle Libre sensor | Dexcom G7 sensor |
| Freestyle Libre 2 reader | Freestyle Libre 2 reader | Dexcom G7 receiver |
| Freestyle Libre 2 sensor | Freestyle Libre 2 sensor | Dexcom G7 sensor |
| Freestyle Libre 3 reader | Freestyle Libre 3 reader | Dexcom G7 receiver |
| Freestyle Libre 3 sensor | Freestyle Libre 3 sensor | Dexcom G7 sensor |
| Freestyle Libre 3 sensor plus | Freestyle Libre 3 sensor plus | Dexcom G7 sensor |
| Sprycel 100 mg tablet | dasatinib | dasatinib |
| Sprycel 140 mg tablet | dasatinib | dasatinib |
| Sprycel 20 mg tablet | dasatinib | dasatinib |
| Sprycel 50 mg tablet | dasatinib | dasatinib |
| Sprycel 70 mg tablet | dasatinib | dasatinib |
| Sprycel 80 mg tablet | dasatinib | dasatinib |
| Victoza 2-pak 18 mg/3 mL pen | liraglutide | Mounjaro, Ozempic |
| Victoza 3-pak 18 mg/3 mL pen | liraglutide | Mounjaro, Ozempic |
| Vyvanse 10 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine-amphet ER cap ER 24 hr |
| Vyvanse 10 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine-amphet ER cap ER 24 hr |
| Vyvanse 20 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine-amphet ER cap ER 24 hr |

| Brand name | Generic Name | Preferred Alternatives |
|---|---|---|
| Vyvanse 20 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine-amphet ER cap ER 24 hr |
| Vyvanse 30 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 30 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 40 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 40 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 50 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 50 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 60 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 60 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| Vyvanse 70 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap, ER 24hr |
| **Only Commercial Comprehensive products** | | |
| Adderall XR 5 mg capsule | dextroamphetamine-amphet er | dextroamphetamine-amphet er, methylphenidate ER tablet (generic) |
| Adderall XR 10 mg capsule | dextroamphetamine-amphet er | dextroamphetamine-amphet er, methylphenidate ER tablet (generic) |
| Adderall XR 15 mg capsule | dextroamphetamine-amphet er | dextroamphetamine-amphet er, methylphenidate ER tablet (generic) |
| Adderall XR 20 mg capsule | dextroamphetamine-amphet er | dextroamphetamine-amphet er, methylphenidate ER tablet (generic) |
| Adderall XR 25 mg capsule | dextroamphetamine-amphet er | dextroamphetamine-amphet er, methylphenidate ER tablet (generic) |
| Adderall XR 30 mg capsule | dextroamphetamine-amphet er | dextroamphetamine-amphet er, methylphenidate ER tablet (generic) |
| Lucemyra 0.18 mg tablet | lofexidine | lofexidine 0.18 mg tablet |

## 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 October 2024, unless otherwise noted.

| Brand Name | Generic Name | Tier | Comments/Preferred Alternatives |
|---|---|---|---|
| **Items listed below were added to the formulary** | | | |
| Zurnai | nalmefene hydrochloride | 2 | Known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression. |
| **Items listed below were not added to the formulary** | | | |
| Crexont | carbidopa/levodopa | NF | carbidopa/levodopa tablet |
| Femlyv | norethindrone acetate and ethinyl estradiol | NF | Blisovi 24 FE, Junel FE Tablet 1mg-20(24), Hailey FE Tablet 1mg-20(24) |
| Lazcluze 240 mg, 80 mg | lazertinib | NF | Prescriber Discretion |
| Leqselvi | deuruxolitinib | NF | Prescriber Discretion |
| Livdelzi | seladelpar | NF | ursodiol tablet, ursodiol 300 mg capsules |
| Neffy | epinephrine | NF | epinephrine auto-injector (ea) 0.15mg/0.3, epinephrine auto-injector (ea) 0.3mg/0.3 |
| Nemluvio | nemolizumab-ilto | NF | Dupixent Pen Injector (mL) 300 mg/2mL; Dupixent Syringe (mL) 300 mg/2mL |
| Prevymis oral pellets | letermovir | NF | valganciclovir HCl tablet |
| Tezruly | terazosin | NF | terazosin HCl, doxazosin mesylate tablet, tamsulosin HCl |
| Voranigo | vorasidenib | NF | Prescriber Discretion |
| Yorvipath | palopegteriparatide | NF | calcitriol capsule, calcitriol solution, oral |
| Zituvimet XR 50 mg/1,000 mg, 50 mg/500 mg, 100 mg/1,000 mg | sitagliptin and metformin hydrochloride | NF | Januvia, Tradjenta, Janumet XR |
| Zunveyl | benzgalantamine | NF | donepezil HCl, rivastigmine |

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.

**Table 2. Products to Be Removed or Shifted to Higher Tier – Effective January 2025**

| Brand Name | Generic Name | Preferred Alternatives |
|---|---|---|
| **All Healthcare Reform Essential Products** | | |
| Adderall XR 10 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 15 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 20 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 25 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 30 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 5 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Betadine 5% eye solution | Betadine | povidone iodine 5% eye drop |
| Carbaglu 200 mg tab for susp | carglumic acid | carglumic acid |
| Cefaclor ER 500 mg tablet | Cefaclor ER | Cefaclor 500 mg capsule, cefuroxime axetil tablet |
| Corlanor 5 mg tablet | ivabradine HCl | ivabradine HCl |
| Corlanor 7.5 mg tablet | ivabradine HCl | ivabradine HCl |
| Dihydroergotamine 4 mg/ml spry | dihydroergotamine mesylate | rizatriptan tablet,disintegrating, zolmitriptan odt |
| Diltiazem 12hr ER 120 mg cap | diltiazem ER | cartia xt, diltiazem 24hr ER (CD) |
| Diltiazem 12hr ER 60 mg cap | diltiazem ER | cartia xt, diltiazem 24hr ER (CD) |
| Diltiazem 12hr ER 90 mg cap | diltiazem ER | cartia xt, diltiazem 24hr ER (CD) |
| EC-Naproxen DR 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tablet |
| Estrogel 0.06% gel | estradiol | estradiol 0.06% 1.25g gel pump |

| | | |
|---|---|---|
| Freestyle Libre 14-day reader | Freestyle Libre Reader | Dexcom G7 Receiver |
| Freestyle Libre 14-day sensor | Freestyle Libre Sensor | Dexcom G7 Sensor |
| Freestyle Libre 2 reader | Freestyle Libre 2 Reader | Dexcom G7 Receiver |
| Freestyle Libre 2 sensor | Freestyle Libre 2 Sensor | Dexcom G7 Sensor |
| Freestyle Libre 3 reader | Freestyle Libre 3 Reader | Dexcom G7 Receiver |
| Freestyle Libre 3 sensor | Freestyle Libre 3 Sensor | Dexcom G7 Sensor |
| Freestyle Libre 3 sensor plus | Freestyle Libre 3 Sensor Plus | Dexcom G7 sensor |
| Lucemyra 0.18 mg tablet | lofexidine | lofexidine 0.18 mg tablet |
| Migranal nasal spray | dihydroergotamine mesylate | rizatriptan tablet, disintegrating, zolmitriptan ODT |
| Naproxen DR 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tab |
| Naproxen DR 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tab |
| Naproxen EC 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tab |
| Naproxen EC 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tab |
| Saxenda 18 mg/3 mL pen | liraglutide | Prescriber Discretion |
| Sprycel 100 mg tablet | dasatinib | dasatinib |
| Sprycel 140 mg tablet | dasatinib | dasatinib |
| Sprycel 20 mg tablet | dasatinib | dasatinib |
| Sprycel 50 mg tablet | dasatinib | dasatinib |
| Sprycel 70 mg tablet | dasatinib | dasatinib |
| Sprycel 80 mg tablet | dasatinib | dasatinib |
| Trudhesa nasal spray | dihydroergotamine mesylate | rizatriptan tablet, disintegrating, zolmitriptan ODT |
| Victoza 2-pak 18 mg/3 mL pen | liraglutide | Mounjaro, Ozempic |
| Victoza 3-pak 18 mg/3 mL pen | liraglutide | Mounjaro, Ozempic |
| Vyvanse 10 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |
| Vyvanse 10 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |
| Vyvanse 20 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |
| Vyvanse 20 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |

| | | |
|---|---|---|
| Vyvanse 30 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |
| Vyvanse 30 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |
| Vyvanse 70 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine – amphet-amphet ER cap ER 24hr |
| Wegovy 0.25 mg/0.5 mL pen | lisdexamfetamine dimesylate | Prescriber Discretion |
| Wegovy 0.5 mg/0.5 mL pen | lisdexamfetamine dimesylate | Prescriber Discretion |
| Wegovy 1 mg/0.5 mL pen | lisdexamfetamine dimesylate | Prescriber Discretion |
| Wegovy 1.7 mg/0.75 mL pen | lisdexamfetamine dimesylate | Prescriber Discretion |
| Wegovy 2.4 mg/0.75 mL pen | lisdexamfetamine dimesylate | Prescriber Discretion |
| Zafirlukast 10 mg tablet | montelukast sodium | montelukast sodium tablet |
| Zafirlukast 20 mg tablet | montelukast sodium | montelukast sodium tablet |

## C. 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 October 2024 unless otherwise noted.

| Brand Name | Generic Name | Tier | Comments/Preferred Alternatives |
|---|---|---|---|
| **Items listed below were added to the formulary** | | | |
| Zurnai | nalmefene hydrochloride | 3 | Known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression. |
| **Items listed below were not added to the formulary** | | | |
| Crexont | carbidopa/levodopa | NF | carbidopa/levodopa tablet |
| Femlyv | norethindrone acetate and ethinyl estradiol | NF | Blisovi 24 FE, Junel FE Tablet 1mg-20(24), Hailey FE Tablet 1mg-20(24) |
| Lazcluze 240 mg, 80 mg | lazertinib | NF | Prescriber Discretion |
| Leqselvi | deuruxolitinib | NF | Prescriber Discretion |
| Livdelzi | seladelpar | NF | ursodiol tablet, ursodiol 300 mg capsules |
| Neffy | epinephrine | NF | epinephrine auto-injector (ea) 0.15mg/0.3, epinephrine auto-injector (ea) 0.3mg/0.3 |

| Brand Name | Generic Name | Tier | Comments/Preferred Alternatives |
|---|---|---|---|
| Nemluvio | nemolizumab-ilto | NF | Dupixent Pen Injector (mL) 300 mg/2mL; Dupixent Syringe (mL) 300 mg/2mL |
| Prevymis oral pellets | letermovir | NF | valganciclovir HCl tablet |
| Tezruly | terazosin | NF | terazosin HCl, doxazosin mesylate tablet, tamsulosin HCl |
| Voranigo | vorasidenib | NF | Prescriber Discretion |
| Yorvipath | palopegteriparatide | NF | calcitriol capsule, calcitriol solution, oral |
| Zituvimet XR 50 mg/1,000 mg, 50 mg/500 mg, 100 mg/1,000 mg | sitagliptin and metformin hydrochloride | NF | Januvia, Tradjenta, Janumet XR |
| Zunveyl | benzgalantamine | NF | donepezil HCl, rivastigmine |

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.

**Table 2. Products to Be Removed or Shifted to Higher Tier – Effective January 2025**

| Brand Name | Generic Name | Preferred Alternatives |
|---|---|---|
| **All Core Products** | | |
| Adderall XR 5 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 10 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 15 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 20 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 25 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Adderall XR 30 mg capsule | dextroamphetamine-amphet ER | dextroamphetamine-amphet ER capsule, ext release 24 hr, methylphenidate ER cap ER 30-70 |
| Carbaglu 200 mg tab for susp | carglumic acid | carglumic acid |
| Dihydroergotamine 1 mg/ml amp | dihydroergotamine mesylate | sumatriptan succinate vial, rizatriptan tab, disintegrating |

| | | |
|---|---|---|
| EC-Naproxen DR 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tablet |
| Freestyle Libre 14-day reader | Freestyle Libre reader | Dexcom G7 receiver |
| Freestyle Libre 14-day sensor | Freestyle Libre sensor | Dexcom G7 sensor |
| Freestyle Libre 2 reader | Freestyle Libre 2 reader | Dexcom G7 receiver |
| Freestyle Libre 2 sensor | Freestyle Libre 2 sensor | Dexcom G7 sensor |
| Freestyle Libre 3 reader | Freestyle Libre 3 reader | Dexcom G7 receiver |
| Freestyle Libre 3 sensor | Freestyle Libre 3 sensor | Dexcom G7 sensor |
| Freestyle Libre 3 sensor plus | Freestyle Libre 3 sensor plus | Dexcom G7 sensor |
| Lucemyra 0.18 mg tablet | lofexidine | lofexidine 0.18 mg tablet |
| Naproxen DR 500 mg tablet | naproxen | naproxen 500 mg tablet, naproxen DR 375mg tab |
| Sprycel 100 mg tablet | dasatinib | dasatinib |
| Sprycel 140 mg tablet | dasatinib | dasatinib |
| Sprycel 20 mg tablet | dasatinib | dasatinib |
| Sprycel 50 mg tablet | dasatinib | dasatinib |
| Sprycel 70 mg tablet | dasatinib | dasatinib |
| Sprycel 80 mg tablet | dasatinib | dasatinib |
| Victoza 2-pak 18 mg/3F mL pen | liraglutide | Mounjaro, Ozempic |
| Victoza 3-pak 18 mg/3 mL pen | liraglutide | Mounjaro, Ozempic |
| Vyvanse 10 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap ER 24 hr |
| Vyvanse 10 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap ER 24 hr |
| Vyvanse 20 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap ER 24 hr |
| Vyvanse 20 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap ER 24 hr |
| Vyvanse 30 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap ER 24 hr |
| Vyvanse 30 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine- amphet ER cap ER 24 hr |
| Vyvanse 40 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |

| | | |
|---|---|---|
| Vyvanse 40 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |
| Vyvanse 50 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |
| Vyvanse 50 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |
| Vyvanse 60 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |
| Vyvanse 60 mg chewable tablet | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |
| Vyvanse 70 mg capsule | lisdexamfetamine dimesylate | lisdexamfetamine dimesylate, dextroamphetamine –amphet ER cap ER 24hr |

## 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)** | | | |
| | None at this time | | |
| **Items listed below were added to the formulary (Non-Preferred)** | | | |
| Crexont | carbidopa/levodopa | 3 | carbidopa/levodopa tablet |
| Femlyv | norethindrone acetate and ethinyl estradiol | 3 | Blisovi 24 Fe, Junel Fe Tablet 1mg-20(24), Hailey Fe Tablet 1mg-20(24) |
| Lazcluze 240 mg | lazertinib | 3 | Prescriber Discretion |
| Lazcluze 80 mg | lazertinib | 3 | Prescriber Discretion |
| Leqselvi* | deuruxolitinib | 3 | Prescriber Discretion |
| Livdelzi | seladelpar | 3 | ursodiol tablet, ursodiol 300 mg capsules |
| Neffy | epinephrine | 3 | epinephrine auto-injector (ea) 0.15mg/0.3, epinephrine auto-injector (ea) 0.3mg/0.3 |
| Nemluvio* | nemolizumab-ilto | 3 | Dupixent pen pen injector (ml) 300 mg/2mL; Dupixent syringe (ml) 300 mg/2mL |

| Brand Name | Generic Name | Tier | Comments/Preferred Alternatives |
|---|---|---|---|
| Prevymis oral pellets* | letermovir | 3 | valganciclovir HCl tablet |
| Tezruly* | terazosin | 3 | terazosin HCl, doxazosin mesylate tablet, tamsulosin HCl |
| Voranigo | vorasidenib | 3 | Prescriber Discretion |
| Yorvipath | palopegteriparatide | 3 | calcitriol capsule, calcitriol solution, oral |
| Zituvimet XR 50 mg/1,000 mg | sitagliptin and metformin hydrochloride | 3 | Januvia, Tradjenta, Janumet XR |
| Zituvimet XR 50 mg/500 mg; 100 mg/1,000 mg | sitagliptin and metformin hydrochloride | 3 | Januvia, Tradjenta, Janumet XR |
| Zunveyl* | benzgalantamine | 3 | donepezil HCl, rivastigmine |
| Zurnai* | nalmefene hydrochloride | 3 | Prescriber Discretion |
| **Items listed below were not added to the formulary** | | | |
| | None at this time | | |

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 |
|---|---|
| Lazcluze | lazertinib |
| Leqselvi | deuruxolitinib |
| Livdelzi | seladelpar |
| Nemluvio | nemolizumab-ilto |
| Prevymis oral pellets | letermovir |
| Voranigo | vorasidenib |
| Yorvipath | palopegteriparatide |

**Table 3. Products to Be Removed or Shifted to Higher Tier – Effective January 2025**

| Brand Name | Generic Name | Preferred Alternatives |
|---|---|---|
| **All National Select Products** | | |
| Aralast NP 1,000 mg vial | alpha-1-proteinase inhibitor | Prolastin C |
| Aralast NP 500 mg vial | alpha-1-proteinase inhibitor | Prolastin C |
| Basaglar 100 unit/ml kwikpen | insulin glargine,hum.rec.anlog | Semglee (yfgn) pen, Toujeo Solostar |
| Basaglar tempo pen 100 unit/ml | insulin glargine,hum.rec.anlog | Semglee (yfgn) pen, Toujeo Solostar |

| | | |
|---|---|---|
| Cinvanti 130 mg/18 ml vial | aprepitant | fosaprepitant dimeglumine |
| Dymista nasal spray | azelastine/fluticasone | azelastine-fluticasone |
| Emend 150 mg vial | fosaprepitant dimeglumine | fosaprepitant dimeglumine |
| Euflexxa 1% 20 mg/2 ml syringe | hyaluronate sodium | Monovisc, Orthovisc |
| Forteo 600 mcg/2.4 ml pen inj | teriparatide | teriparatide (generic) |
| Glassia 1 gm/50 ml vial | alpha-1-proteinase inhibitor | Prolastin c |
| Karbinal ER 4 mg/5 ml susp | carbinoxamine maleate | carbinoxamine (generic) |
| Lumigan 0.01% eye drops | bimatoprost | latanoprost (generic), travoprost |
| Relistor 150 mg tablet | methylnaltrexone bromide | lubiprostone, Movantik |
| Saxenda 18 mg/3 ml pen | liraglutide | Wegovy, Zepbound |
| Segluromet 2.5-1,000 mg tablet | ertugliflozin/metformin | Xigduo XR, Synjardy |
| Segluromet 2.5-500 mg tablet | ertugliflozin/metformin | Xigduo XR, Synjardy |
| Segluromet 7.5-1,000 mg tablet | ertugliflozin/metformin | Xigduo XR, Synjardy |
| Segluromet 7.5-500 mg tablet | ertugliflozin/metformin | Xigduo XR, Synjardy |
| Steglatro 15 mg tablet | ertugliflozin pidolate | Farxiga, Jardiance |
| Steglatro 5 mg tablet | ertugliflozin pidolate | Farxiga, Jardiance |
| Trudhesa nasal spray | dihydroergotamine mesylate | dihydroergotamine mesylate nasal spray |
| Vyzulta 0.024% ophth solution | latanoprostene bunod | latanoprost (generic), travoprost |
| Zemaira 1,000 mg vial | alpha-1-proteinase inhibitor | Prolastin C |
| Zemaira 4,000 mg vial | alpha-1-proteinase inhibitor | Prolastin C |
| Zemaira 5,000 mg vial | alpha-1-proteinase inhibitor | Prolastin C |

## E. Updates to the Pharmacy Utilization Management Programs

### 1. Prior Authorization Program

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| Adbry (tralokinumab-ldrm) – Commercial and Healthcare Reform | 10/28/2024 | Policy initial authorization duration updated to 12 months for DE. |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| Alkindi Sprinkle (hydrocortisone) – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |
| Anti-Obesity – Administrative Services Only (ASO) – Commercial | 9/9/2024 | Policy revised for Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide) maintenance criteria to allow approval for attestation of titration to maintenance dose. |
| Anti-Obesity – Administrative Services Only (ASO) Commercial | 9/1/2024 | Policy revised for Zepbound (tirzepatide) to allow maintenance approval of 7.5 mg and 12.5 mg doses. For Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide), policy revised to require documentation of baseline height, weight, and BMI. |
| Anti-Obesity – Commercial and Healthcare Reform | 9/9/2024 | Policy revised for Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide) maintenance criteria to allow approval for attestation of titration to maintenance dose. |
| Anti-Obesity – Fully Insured Commercial and Healthcare Reform | 9/9/2024 | Policy revised for Wegovy (semaglutide) to include previously reviewed criteria allowing approval for cardiovascular disease risk reduction in overweight members in Delaware. For Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide) maintenance criteria, criteria revised to allow approval for attestation of titration to maintenance dose. |
| Anti-Obesity – Fully Insured Commercial and Healthcare Reform | 9/1/2024 | Policy revised to remove criteria requiring documentation of an-person appointment for all agents. For Contrave (bupropion and naltrexone), Qsymia (phentermine and topiramate extended-release), and Xenical (orlistat), policy revised to require documentation of baseline height, weight, and BMI. |
| Bylvay (odevixibat) – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| CDK Inhibitors – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Kisqali (ribociclib) to remove requirement that the member is a postmenopausal woman or man when used in combination with fulvestrant with disease progression following endocrine-based therapy, based on expanded indication. |
| CFTR Modulators – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE-specific disclaimer allowing 12+ months. |
| CGRP Inhibitors – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE-specific disclaimer allowing 12 months. |
| Chronic Inflammatory Diseases – Commercial and Healthcare Reform | TBD | Policy revised to add Leqselvi (deuruxolitinib) for alopecia areata to require age, severe alopecia areata defined as greater than or equal to 50% calp hair loss, prescribed by or in consultation with a dermatologist, current episode lasting 6 months or more without spontaneous re-growth, trial/failure to systemic therapy or high potency topical corticosteroids or contraindication to all and reauthorization requires attestations of disease stability or beneficial response to therapy. |
| Chronic Inflammatory Diseases – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to update quantity limitations for Taltz (ixekizumab) to include induction therapy and maintenance therapy for pediatric plaque psoriasis per FDA label. Policy revised for Tremfya (guselkumab) SC for ulcerative colitis to require diagnosis and age based on FDA approved indication, prescribed in consultation or by a gastroenterologist, currently undergoing or has received 3 induction doses of Tremfya IV within 3 to 4 months before initiating Tremfya SC. |
| Chronic Inflammatory Diseases – Commercial National Select Formulary | TBD | Policy revised to add Leqselvi (deuruxolitinib) for alopecia areata to require age, severe alopecia areata defined as greater than or equal to 50% calp hair loss, prescribed by or in consultation with a dermatologist, |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| | | current episode lasting 6 months or more without spontaneous re-growth, trial/failure to systemic therapy or high potency topical corticosteroids or contraindication to all and reauthorization requires attestations of disease stability or beneficial response to therapy. |
| Chronic Inflammatory Diseases – Commercial National Select Formulary | 10/28/2024 | Policy revised to update quantity limitations for Taltz (ixekizumab) to include induction therapy and maintenance therapy for pediatric plaque psoriasis per FDA label. Policy revised for Tremfya (guselkumab) SC for ulcerative colitis to require diagnosis and age based on FDA approved indication, prescribed in consultation or by a gastroenterologist, currently undergoing or has received 3 induction doses of Tremfya IV within 3 to 4 months before initiating Tremfya SC. |
| Corlanor (ivabradine) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Corlanor (ivabradine) to remove generic step for pediatric patients. |
| Coverage Outside Contract Parameters – Commercial and Healthcare Reform | 9/12/2024 | Policy revised for Wegovy (semaglutide) allowing approval for cardiovascular disease risk reduction in overweight members in Delaware without the anti-obesity benefit. |
| Cystadrops and Cystaran (cysteamine ophthalmic solution) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to add additional criteria of the need of the medication to be prescribed by or consulted with an ophthalmologist. |
| Dupixent (dupilumab) – Commercial and Healthcare Reform | 10/28/2024 | Policy initial authorization duration updated to 12 months for DE. |
| EGFR-Targeting Kinase Inhibitors – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to include Lazcluze (lazertinib). Approval of coverage of Lazcluze requires the member to meet the following criteria: first-line treatment in patients 18 years of age and older with locally advanced or metastatic non-small cell lung cancer (NSCLC) with exon 18 deletions or exon 21 L858R substitution mutations as detected by an FDA-approved test. Lazcluze must |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| | | be used in combination with Rybrevant (amivantamab). Reauthorization requires that the member is tolerating therapy and has experienced a therapeutic response and the Lazcluze continues to be given in combination with Rybrevant. |
| Elagolix and Relugolix-Containing Products – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) and Myfembree (relugolix, estradiol, norethindrone acetate) for uterine fibroids to require trial/failure to one prior treatment to reduce menstrual bleeding or contraindication to all. |
| Empaveli (pegcetacoplan) and Fabhalta (iptacopan) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to account for new indication for Fabhalta (iptacopan): Primary Immunoglobin Nephropathy (IgAN). Criteria requires age of 18 years of age or older, diagnosis based on FDA-approved indication confirmed by biopsy and supported by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g or proteinuria ≥ 1gm/day; and trial/failure/contraindication to a maximally tolerated dose of either an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) and the member has experienced therapeutic failure, contraindication, or intolerance to both Filspari (sparsentan) and Tarpeyo (budesonide). Reauthorization requires that the member has experienced a reduction in the UPCR or proteinuria from baseline. |
| Enspryng (satralizumab-mwge) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Enspryng (satralizumab-mwge) to require presence of one core clinical characteristic of neuromyelitis optica spectrum disorder (NMOSD). |
| Evrysdi (risdiplam) – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE-pecific disclaimer allowing 12 months. |
| Eysuvis – Commercial and Healthcare Reform | TBD | Policy revised to change benefits from guideline to other managed prior |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| | | authorization. Automatic authorization removed. |
| Furoscix (furosemide) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Furoscix (furosemide) to reflect revisions in FDA-approved indications. Previously Furoscix was only indicated for New York Heart Association (NYHA) Class II and Class III chronic heart failure. It is now indicated for all classes of heart failure. Criteria requiring that the member be diagnosed with NYHA Class II or Class III chronic heart failure has been removed; remaining criteria remains as established. |
| Gattex (teduglutide) – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |
| Homozygous Familial Hypercholesterolemia – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE-specific disclaimer allowing 12 months. |
| Livmarli (maralixibat) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Livmarli (maralixibat) to lower the age to 12 months of age or older for progressive familial intrahepatic cholestasis (PFIC), to require Livmarli (maralixibat) 9.5 mg/mL be used for Alagille syndrome and 19 mg/mL be used for PFIC . Quantity limit updated to allow for maximum maintenance dosing criteria per FDA labeling. |
| Lybalvi (olanzapine/samidorphan) – Commercial and Healthcare Reform | 10/17/2024 | Policy for Lybalvi (olanzapine/samidorphan) revised to remove criterion that the member has been counseled on appropriate lifestyle modifications (e.g., diet, exercise) while also using an antipsychotic. |
| Miscellaneous Immunomodulators – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Pomalyst (pomalidomide) to require age based on FDA-approved indication and to remove quantity limitation criteria. Policy revised for Pomalyst (pomalidomide) and Farydak (panobinostat) to require that member has received previous therapies per FDA-approved indication. |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| Nemluvio (nemolizumab-ilto) – Commercial and Healthcare Reform | 10/28/2024 | New policy created for Nemluvio (nemolizumab-ilto) requiring age, diagnosis to FDA-label, specialist, ≥ 10 identifiable nodular lesions, trial/failure/contraindication to one generic corticosteroid, or unable to use. Reauthorization requiring reduction in itch or nodules/lesions from baseline. Dosing must align with submitted weight. Initial authorization of 6 months and reauthorization of 12 months. |
| Palforzia [peanut (Arachis hypogaea) allergen powder-dnfp] – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Palforzia [peanut (Arachis hypogaea) allergen powder-dnfp] to update minimum age to 1 year. Authorization duration updated to 12 months. |
| PCSK9 Inhibitors – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |
| Prevymis (letermovir) Oral Pellets – Commercial and Healthcare Reform | TBD | New policy created for Prevymis (letermovir) oral pellets requiring age, diagnosis based on FDA-approved indication, and trial/failure to Prevymis (letermovir) tablets, unable to swallow tablets, or unable to use Prevymis (letermovir) tablets due to body weight dosing limitations. Limitations of coverage that Prevymis (letermovir) oral pellets is not indicated for treatment of cytomegalovirus. |
| Primary Axillary Hyperhidrosis – Commercial and Healthcare Reform | 10/28/2024 | Policy initial authorization duration updated to 12 months for DE. |
| Primary Biliary Cholangitis – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to add Livdelzi (seladelpar) to require diagnosis and age based on FDA approved indication, therapeutic failure to ursodiol therapy defined as alkaline phosphatase (ALP) levels ≥ 1.67 x upper limit of normal (ULN) or bilirubin levels > 1-2 x ULN or experienced contraindication or intolerance to ursodiol monotherapy and used in combination with ursodiol unless ursodiol is contraindicated or not tolerated. Reauthorization criteria to |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| | | require member experience positive clinical response defined by ALP level < 1.67 x ULN or total bilirubin level < ULN, member requires additional therapy and used in combination with ursodiol unless ursodiol is contraindication or not tolerated. Limitation of coverage includes, Livdelzi (seladelpar) should not be used in decompensated cirrhosis. |
| Pylera (bismuth subcitrate potassium, metronidazole, tetracycline) – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration increased to 14 days. |
| Signifor (pasireotide) – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |
| Thiola and Thiola EC (tiopronin) – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |
| Tyrvaya (varenicline solution) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised for Tyrvaya (varenicline solution) to update step to generic cyclosporine. |
| Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE-specific disclaimer allowing 12 months. |
| Voranigo (vorasidenib) – Commercial and Healthcare Reform | 10/28/2024 | New policy for Voranigo (vorasidenib) requiring diagnosis based on FDA-approved indication. |
| Xermelo (telotristat ethyl) – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE specific disclaimer allowing 12+ months. |
| Xiidra (lifitegrast) – Healthcare Reform | 10/28/2024 | Policy revised for Xiidra (lifitegrast) to update age to 17 years and older. |
| Xiidra (lifitegrast) – Healthcare Reform | TBD | Policy revised for Xiidra (lifitegrast) to add step through ophthalmic generic cyclosporine. |
| Yorvipath (palopegteriparatide) – Commercial and Healthcare Reform | 10/28/2024 | Policy created for Yorvipath (palopegteriparatide) to include an age limit of 18 years of age or older, a diagnosis of hypoparathyroidism, prescriber attestation that the member's |

| Policy Name* | Policy Effective Date** | Updates and/or Approval Criteria |
|---|---|---|
| | | albumin-corrected serum calcium level is 7.8 mg/dL, and the member has established hypoparathyroidism despite treatment with calcium and active forms of vitamin D. Reauthorization of Yorvipath may be approved when the following criterion is met: The prescriber attests improvement in total serum calcium from baseline. |
| Zokinvy (lonafarnib) – Commercial and Healthcare Reform | 10/28/2024 | Initial authorization duration updated to 12 months for DE. |
| Zurzuvae (zuranolone) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to add additional criteria of the needs for prescriber attestation that symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery. |

*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 |
|---|---|---|
| Ampyra (dalfampridine) – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE-specific disclaimer allowing 12 months. |
| Bevespi (glycopyrrolate/formoterol) – Commercial and Healthcare Reform | 10/28/2024 | Policy updated to include when a benefit, reauthorization of Bevespi (glycopyrrolate-formoterol) may be approved when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in symptoms of COPD, the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests that the member has experienced delayed disease progression, or the prescriber attests that the member has experienced a reduction in the number of exacerbations. |
| Brand Cholinesterase Inhibitors – Commercial and Healthcare Reform | TBD | Policy revised to add Zunveyl (benzgalantamine) requiring FDA approved diagnosis and therapeutic failure, intolerance, or contraindication to two plan |

| Policy Name* | Policy Effective Date** | Updates and Automatic Approval Criteria |
|---|---|---|
| | | preferred generic cholinesterase inhibitors (galantamine, rivastigmine, or donepezil). |
| Brand Reliever Inhalers – Commercial and Healthcare Reform | 10/28/2024 | Policy updated to require the member to experience a therapeutic failure or intolerance to all of the following for Airsupra (budesonide and albuterol): an inhaled corticosteroid-formoterol combination product and an inhaled corticosteroid and albuterol product. Reauthorization criteria updated to include the member has experienced therapeutic failure or intolerance to an inhaled corticosteroid-formoterol combination product and an inhaled corticosteroid and albuterol product. |
| Carbidopa/Levodopa – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to add Crexont (carbidopa/levodopa) requiring FDA approved indication and therapeutic failure or intolerance to one of the following: generic carbidopa/levodopa tablets or extended-release tablets. |
| Continuous Glucose Monitoring (CGM) Systems – Commercial and Healthcare Reform | TBD | Policy revised for Eversense, Guardian, and Freestyle Libre systems to require trial/failure/contraindication to plan-preferred Dexcom systems. |
| Cyclobenzaprine, Metaxalone, and Methocarbamol Products – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to add Tanlor (methocarbamol) requiring diagnosis of acute, painful musculoskeletal condition and experienced therapeutic failure or intolerance to three (3) of the following plan-preferred medications: 1) generic cyclobenzaprine 5 or 10 mg, 2) generic methocarbamol 500 mg, 3) generic chlorzoxazone 500 mg, 4) generic orphenadrine or all are contraindicated. |
| Digitized Inhalers – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to include DE specific disclaimer allowing 12+ months. |
| Duaklir (aclidinium bromide and formoterol fumarate) – Commercial and Healthcare Reform | 10/28/2024 | Policy updated to include when a benefit, reauthorization of Duaklir (aclidinium bromide and formoterol fumarate) may be approved when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in symptoms of chronic obstructive pulmonary disease (COPD), the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests that the member has experienced delayed disease progression, or the prescriber attests that the |

| Policy Name* | Policy Effective Date** | Updates and Automatic Approval Criteria |
|---|---|---|
| | | member has experienced a reduction in the number of exacerbations. |
| Epinephrine Products – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to add Neffy (epinephrine) to policy to require diagnosis based on FDA-approved indication, weight 30 kg or greater, history of severe allergy or anaphylaxis. The member must also not be a candidate for therapy with plan-preferred products generic or authorized generic epinephrine auto injector products and Symjepi prefilled syringe. |
| Evekeo (amphetamine sulfate) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to remove Evekeo ODT (amphetamine sulfate) orally disintegrating tablet since it is off market |
| HIV-1 Therapies – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated for pre-exposure prophylaxis to include DE specific disclaimer allowing 12+ months. |
| Kerendia (finerenone) – Commercial and Healthcare Reform | 10/28/2024 | Policy revised to move kidney function and serum potassium requirements from limitations of coverage to approval criteria. Initial authorization duration updated to 12 months for DE. |
| Non-Preferred Benign Prostatic Hyperplasia (BPH) Therapy – Commercial and Healthcare Reform | TBD | Policy revised to add Tezruly (terazosin) requiring FDA approved diagnosis and therapeutic failure or intolerance to one plan-preferred generic alpha-1 blockers (BPH: alfuzosin, tamsulosin, doxazosin, terazosin; HTN: doxazosin, terazosin) AND inability to swallow capsules. |
| Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Commercial and Healthcare Reform | TBD | Policy revised to include Zituvimet XR (sitagliptin/metformin) extended-release to require T/F of metformin, drug-containing products of linagliptin and drug-containing products of sitagliptin phosphate. |
| Rayos (prednisone) – Commercial and Healthcare Reform | 10/28/2024 | Authorization duration updated to 12 months. |
| Zerviate (cetirizine ophthalmic solution) 0.24% – Commercial and Healthcare Reform | 10/1/2024 | Initial authorization removed; authorization duration updated to 12 months. |

*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 |
|---|---|---|
| Livmarli (maralixibat) 19 mg/mL | 1 bottle (30 mL ) per 30 days | 3 bottles (90 mL ) per 90 days |
| Nemluvio (nemolizumab-ilto) | 1 pen per 28 days | 3 pens per 84 days |
| Prevymis (letermovir) oral pellets | 800 packets per 365 days | 800 packets per 365 days |
| Pylera (bismuth subcitrate; metronidazole; tetracycline) | 168 capsules per 365 days | 168 capsules per 365 days |
| Taltz (ixekizumab) 20 mg/0.25 mL prefilled syringe | 1 prefilled syringe per 28 days | 3 prefilled syringes per 84 days |
| Taltz (ixekizumab) 40 mg/0.5 mL prefilled syringe | 1 prefilled syringe per 28 days | 3 prefilled syringes per 84 days |
| Tremfya (guselkumab) 200 mg/2 mL Syringe and Pen | 1 prefilled syringe/pen (2 mL ) per 28 days | 3 prefilled syringes/pens (6 mL ) per 84 days |
| Yorvipath (palopegteriparatide) | 2 pens per 28 days | 6 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 |
|---|---|---|
| Neffy (epinephrine) | 2 devices per dispensing event | 2 devices 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 |
|---|---|
| Lazcluze (lazertinib) 240 mg | 240 mg: One (1) tablet per day |
| Lazcluze (lazertinib) 80 mg | 80 mg: Two (2) tablets per day" |
| Leqselvi (deuruxolitinib) | 2 tablets per day |
| Livdelzi (seladelpar) | 1 capsule per day |
| Tezruly (terazosin) | 20 mL (20 mg) per day |

| Drug Name | Daily Limit |
|---|---|
| Voranigo (vorasidenib) | 10 mg: 2 tablets per day<br>40 mg: 1 tablet per day |
| Zituvimet XR (sitagliptin and metformin hydrochloride) 50 mg/1,000 mg | 2 tablets per day |
| Zituvimet XR (sitagliptin and metformin hydrochloride) 50 mg/500 mg; 100 mg/1,000 mg | 1 tablet per day |
| Zunveyl (benzgalantamine) | 2 tablets per day |

*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 |
|---|---|---|
| Vaxchora | Cholera Vaccine, Live, Oral | Active immunization against disease caused by Vibrio cholerae serogroup O1. Vaxchora is approved for use in persons 2 through 64 years of age traveling to cholera-affected areas |

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

| Brand Name | Generic Name | Preferred Alternatives |
|---|---|---|
| Crexont | Carbidopa/Levodopa | carbidopa-levodopa |
| Femlyv | Norethindrone Acetate And Ethinyl Estradiol | Finzala, Mibelas 24 Fe, Hailey 24 Fe, Tarina 24 Fe* |
| Neffy | epinephrine | epinephrine auto-injector, EpiPen auto-injector, Symjepi syringe |
| Tezruly | terazosin | terazosin |
| Zituvimet XR 50 mg/1,000 mg, 50 mg/500 mg, 100 mg/1,000 mg | sitagliptin and metformin hydrochloride | Tradjenta, Januvia, Janumet XR |
| Zunveyl | benzgalantamine | donepezil, galantamine, rivastigmine tartrate |
| Zurnai | nalmefene hydrochloride | naloxone syringe |

*only pertains to Compass formulary

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

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

- **Performance Formulary**
- **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 |
|---|---|---|
| Vaxchora | Cholera Vaccine, Live, Oral | Active immunization against disease caused by Vibrio cholerae serogroup O1. Vaxchora is approved for use in persons 2 through 64 years of age traveling to cholera-affected areas |

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

| Brand Name | Generic Name | Preferred Alternatives |
|---|---|---|
| | None 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 |
|---|---|---|
| Crexont | carbidopa/levodopa | carbidopa-levodopa |
| Enzeevu | aflibercept-abzv | Avastin, Eylea |
| Epysqli | eculizumab-aagh | Prescriber Discretion |
| Erzofri | paliperidone palmitate | Invega |
| Femlyv | norethindrone acetate and ethinyl estradiol | Kaitlib Fe****, noreth-ethinyl estradiol-iron tablet, chewable 0.8mg-25mcg(24) and 75 mg (4)** Microgestin FE 1/20 (28), Microgestin 1/20 (21)*** |
| Femlyv – applies to Performance** and Venture**** Formularies | norethindrone acetate and ethinyl estradiol | Junel Fe 24, Hailey 24 Fe |
| Leqselvi | deuruxolitinib | Olumiant, Litfulo |

| | | |
|---|---|---|
| Livdelzi | seladelpar | ursodiol tablet |
| Neffy | epinephrine | epinephrine auto-injector, EpiPen auto-injector, Symjepi syringe |
| Nemluvio | nemolizumab-ilto | Dupixent Syringe 300 mg/2 mL ; Dupixent Pen 300 mg/2 mL |
| Pavblu | aflibercept-ayyh | Avastin, Eylea |
| Tezruly | terazosin | terazosin |
| Yorvipath | palopegteriparatide | calcitriol |
| Zituvimet XR 50 mg/1,000 mg, 50 mg/500 mg, 100 mg/1,000 mg | sitagliptin and metformin hydrochloride | Tradjenta, Januvia, Janumet XR |
| Zunveyl | benzgalantamine | donepezil, galantamine, rivastigmine tartrate |
| Zurnai | nalmefene hydrochloride | naloxone syringe |

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form. To access this form for your region, go to the **Provider Resource Center** and choose your region from the top right. Select **Resources & Education** > **Forms** > **Pharmacy Prior Authorization Forms** and then scroll down to the **Prescription Drug Medication Request Form**.

** Only pertains to Medicare Performance Formulary
*** Only pertains to Medicare Fundamental Formulary
**** Only pertains to Medicare Venture Formulary

## C. Additions to the Specialty Tier

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

| Brand Name | Generic Name |
|---|---|
| Lazcluze 240 mg, 80 mg | lazertinib |
| Lymphir | denileukin diftitox-cxdl |
| Niktimvo | axatilimab-csfr |
| Prevymis oral pellets | letermovir |
| Voranigo | vorasidenib |

## 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 | TBD | Policy revised to remove Auryxia (ferric citrate) as a target for D vs NonD review. Policy revised to add criteria requiring medical supplies associated with the delivery of insulin be used for the delivery of insulin for Part D coverage. |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | Policy revised to add oral-only renal dialysis drugs that have no other form of administrations to renal dialysis drug review. |
| Administrative Prior Authorizations for Medicare Part D Plans – Medicare | 10/28/2024 | Policy revised to change 'Perforomist (formoterol fumarate)' to say 'formoterol fumarate nebulizer solution products', encompassing formoterol 20MCG/2ML VL-PARILC (formoterol fumarate with PARI LC PLUS nebulizer) as a target for BvD nebulizer review. |
| Amitiza (lubiprostone) – Medicare | TBD | Policy revised for brand Amitiza (lubiprostone) to require trial/failure to generic lubiprostone for a diagnosis of opioid-induced constipation. |
| Blood Glucose Testing Products - Medicare | 10/28/2024 | Policy revised to add Freestyle Libre 3 Sensor Plus as a preferred product. |
| Brand Cholinesterase Inhibitors – Medicare | TBD | Policy revised to add Zunveyl (benzgalantamine) requiring FDA approved diagnosis and therapeutic failure or intolerance to generic galantamine. |
| CDK Inhibitors – Medicare | 10/28/2024 | Policy revised for Kisqali (ribociclib) to remove requirement that the member is a postmenopausal woman or man when used in combination with fulvestrant with disease progression following endocrine-based therapy, based on expanded indication. |
| CGRP Inhibitors and Reyvow – Medicare | TBD | Policy revised to remove age restrictions, remove step through Nurtec (rimegepant) for the incentive and compass formularies, and to add Reyvow (lasmiditan) requiring FDA approved diagnosis, therapeutic failure, intolerance, or contraindication to one generic triptan with reauthorization requiring a reduction in migraine symptoms. |
| Chronic Inflammatory Diseases – Medicare | TBD | Policy revised to add Leqselvi (deuruxolitinib) for alopecia areata to require diagnosis and age based on FDA approved indication, and therapeutic failure or intolerance to one intralesional corticosteroid or high potency topical corticosteroid or contraindication to all. |
| Chronic Inflammatory Diseases – Medicare | 9/1/2024 | Humira (adalimumab) [53457] labeler, Hyrimoz (adalimumab-adaz) [83457] and adalimumab-adbm [82009] labeler moved to non-preferred and require step through 2 preferred adalimumab products. |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| Chronic Inflammatory Diseases – Medicare | TBD | Policy Revised to move Taltz (ixekizumab) to non-preferred and require therapeutic failure or intolerance to 2 preferred biologic products for the indication being requested. Policy revised to update preferred adalimumab products to Humira (adalimumab) [00074] labeler, Cyltezo (adalimumab-adbm) and Yuflyma (adalimumab-aaty). |
| Chronic Inflammatory Diseases – Medicare | 10/28/2024 | Policy revised to update quantity limitations for Taltz (ixekizumab) to include induction therapy and maintenance therapy for pediatric plaque psoriasis per FDA label. Policy revised to add new indication for Tofidence (tocilizumab-bavi) requiring indication of giant cell arteritis, 18 years of age or older, therapeutic failure or intolerance to one systemic corticosteroid or all are contraindicated and therapeutic failure or intolerance to preferred tocilizumab product. Tofidence for treatment of Covid-19 is covered under Medicare Part A. Policy revised for Tremfya (guselkumab) IV/SC for ulcerative colitis to require diagnosis and age based on FDA approved indication, therapeutic failure or intolerance to two preferred biologics for ulcerative colitis, and if requesting Tremfya SC - clinical response/remission achieved after 3 induction doses of Tremfya IV within 3 to 4 months before initiating Tremfya SC. |
| Corlanor (ivabradine) – Medicare | 10/1/2024 | Policy revised for Corlanor (ivabradine) to remove generic step for pediatric patients. |
| Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) – Medicare | 10/28/2024 | Policy revised for Darzalex Faspro (daratumumab and hyaluronidase) to allow for use in multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant, based on expanded indication. |
| Eculizumab Products – Medicare | TBD | Policy revised to add Epysqli (eculizumab-aagh) and Bkmev (eculizumab-aeeb) both for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) requiring diagnosis to FDA label and supported by flow cytometry and laboratory tests, and Atypical Hemolytic Uremic Syndrome (aHUS) with thrombotic |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | microangiopathy supported by low platelet count (thrombocytopenia), Microangiopathic hemolysis, thrombotic microangiopathy, or decreased kidney function. Reauthorization for PNH requires prescriber attestation that patient has achieved hemoglobin stabilization or an increase from baseline, or has experienced a decrease from baseline in number of transfusions, or has decreased from baseline in lactate dehydrogenase (LDH) levels or reduction in hemolysis. Reauthorization for aHUS requires prescriber attestation that patient has achieved hematologic normalization or experiences a decrease in thrombotic microangiopathy (TMA) events. |
| EGFR-Targeting Kinase Inhibitors – Medicare | TBD | Policy revised for Iressa (gefitinib), to require in addition to current criteria, that if the request is for brand Iressa, the member has experienced therapeutic failure or intolerance to generic gefitinib. |
| EGFR-Targeting Kinase Inhibitors – Medicare | 10/28/2024 | Policy revised to include Lazcluze (lazertinib). Approval of coverage of Lazcluze requires the member to meet the following criteria: first-line treatment in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with exon 18 deletions or exon 21 L858R substitution mutations. Lazcluze must be used in combination with Rybrevant (amivantamab). Reauthorization requires that the member is tolerating therapy and has experienced a therapeutic response and the Lazcluze continues to be given in combination with Rybrevant. |
| Enspryng (satralizumab-mwge) – Medicare | 10/28/2024 | Policy revised for Enspryng (satralizumab-mwge) to remove age restriction. |
| Enspryng (satralizumab-mwge) – Medicare | TBD | Policy revised for Enspryng (satralizumab-mwge) to require presence of one core clinical characteristic of neuromyelitis optica spectrum disorder (NMOSD). |
| Evekeo (amphetamine sulfate) – Medicare | 10/28/2024 | Policy revised to remove age requirements and update mean sleep latency to eight minutes or less for diagnosis of narcolepsy. |
| Fabhalta (iptacopan) – Medicare | 10/28/2024 | Policy revised to account for new indication for Fabhalta (iptacopan): Primary Immunoglobin Nephropathy (IgAN). Criteria requires diagnosis |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | based on FDA-approved indication confirmed by biopsy and supported by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g or proteinuria ≥ 1gm/day; trial/failure/contraindication to a maximally tolerated dose of either an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) and the member has experienced therapeutic failure, contraindication, or intolerance to either Filspari (sparsentan) or Tarpeyo (budesonide). Reauthorization requires that the member has experienced a reduction in the UPCR or proteinuria from baseline. |
| Furoscix (furosemide) – Medicare | 10/28/2024 | Policy revised for Furoscix (furosemide) to reflect revisions in FDA-approved indications. Previously Furoscix was only indicated for New York Heart Association (NYHA) Class II and Class III chronic heart failure. It is now indicated for all classes of heart failure. Criteria requiring that the member be diagnosed with NYHA Class II or Class III chronic heart failure has been removed; remaining criteria remains as established. |
| Hedgehog Pathway Inhibitors – Medicare | 10/28/2024 | Policy revised for Erivedge (vismodegib), Odomzo (sonidegib), and Daurismo (glasdegib) to remove age limitations. |
| Interleukin (IL)-5 Antagonists – Medicare | 10/28/2024 | "Policy revised to include quantity level limits for Fasenra for patients with severe asthma with eosinophilic phenotype in pediatric patients 6 to 11 years of age weighing ≥ 35 kg for 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter and for patients with severe asthma with eosinophilic phenotype in pediatric patients 6 to 11 years of age < 35 kg for 10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter. |
| Methamphetamine – Medicare | 10/28/2024 | Policy revised to remove brand Desoxyn (methamphetamine) since it is excluded from medicare part D. |
| Nemluvio (nemolizumab-ilto) – Medicare | 10/28/2024 | New policy created for Nemluvio (nemolizumab-ilto) requiring diagnosis to FDA-label. Reauthorization requiring reduction in itch or nodules/lesions from baseline. Dosing must |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | align with submitted weight. Initial authorization of 6 months and reauthorization of 12 months. |
| Niktimvo (axatilimab-csfr) – Medicare | TBD | New policy created for Niktimvo (axatilimab-csfr) requiring member to have a diagnosis of chronic graft-versus-host disease (cGVHD), therapeutic failure, or intolerance to at least two (2) lines of systemic therapy, and to weigh at least 40 kg. |
| Opzelura (ruxolitinib) – Medicare | 10/28/2024 | Policy revised for Opzelura (ruxolitinib) to remove age restrictions. |
| Palforzia (peanut (Arachis hypogaea) allergen powder-dnfp) – Medicare | 10/28/2024 | Policy revised for Palforzia [peanut (Arachis hypogaea) allergen powder-dnfp] to update minimum age to 1 year. |
| Prevymis (letermovir) Oral Pellets – Medicare | TBD | New policy created for Prevymis (letermovir) oral pellets requiring age, diagnosis based on FDA-approved indication, and trial/failure to Prevymis (letermovir) tablets, unable to swallow tablets, or unable to use Prevymis (letermovir) tablets due to body weight dosing limitations. |
| Primary Biliary Cholangitis – Medicare | 10/28/2024 | Policy revised to add Livdelzi (seladelpar) to require diagnosis based on FDA approved indication, therapeutic failure, contraindication or intolerance to ursodiol monotherapy and used in combination with ursodiol unless ursodiol is contraindicated or not tolerated. Limitation of coverage includes, Livdelzi (seladelpar) should not be used in decompensated cirrhosis. |
| Programmed Death Receptor Therapies – Medicare | 10/28/2024 | Policy revised for Jemperli (dostarlimab-gxly) to require diagnosis based on expanded FDA-approved indication for endometrial cancer and for Imfinzi (durvalumab) to require diagnosis based on expanded FDA-approved indication for non-small cell lung cancer. |
| Pulmonary Hypertension – Medicare | TBD | Policy revised to remove criteria for Opsynvi (macitentan and tadalafil) for patient to experience therapeutic failure, contraindication, or intolerance to an agent in at least one (1) of the following drug classes: a generic endothelin receptor antagonists (ERA), a generic phosphodiesterase type 5 (PDE5 inhibitor), or a soluble guanylate cyclase (sGC) stimulator. |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| Radicava and Radicava ORS (edaravone) – Medicare | TBD | Policy revised for Radicava (edaravone) and Radicava ORS (edaravone) to trial and fail generic riluzole, is using in combination with riluzole, or not clinically appropriate to use riluzole. For reauthorization, member is experiencing stability or improvement of symptoms from baseline. |
| Rybrevant (amivantamab-vmjw) – Medicare | 10/28/2024 | Policy revised for Rybrevant (amivantamab-vmjw) to require diagnosis based on FDA-approved expanded indication for use in combination with Lazcluze (lazertinib) for non-small cell lung cancer. |
| Saphnelo (anifrolumab-fnia) – Medicare | 10/28/2024 | Policy revised for Saphnelo (anifrolumab-fnia) to remove age restriction. |
| Soliris (eculizumab) – Medicare | 10/28/2024 | Policy revised to remove age limit of 18 years of age or older for generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD). |
| Soliris (eculizumab) – Medicare | TBD | Policy revised to include NMOSD criteria of the member has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD), the prescriber attests that the member is anti-aqaporin-4 (AQP4) antibody positive, the member exhibits one of the following core characteristics of NMOSD: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions |
| Spravato (esketamine) – Medicare | TBD | Policy revised to add additional quantity limit criteria for induction and maintenance dosing for the treatment of treatment-resistant depression. |
| Sprix (ketorolac tromethamine) – Medicare | TBD | Policy created for 01/01/2026 to require prior authorization for the use of Sprix (ketorolac tromethamine). Coverage of Sprix will require a diagnosis of moderate to severe pain and the member must either have documented dysphagia, esophagitis, mucositis, or repeated episodes of nausea/vomiting OR the member has experienced therapeutic failure or intolerance to two (2) of the following generic products, or contraindication to all: diclofenac |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | potassium tablets or diclofenac sodium tablets, ibuprofen tablets or capsules, indomethacin capsules or indomethacin extended-release capsules, meloxicam tablets, nabumetone tablets, naproxen tablets or naproxen sodium tablets or capsules, or ketorolac tablets. For reauthorization, the prescriber attests that the member has experienced positive clinical response to previous Sprix therapy and the Sprix is being used for a new episode of pain, classified as moderate to severe. |
| Talicia (omeprazole, amoxicillin, and rifabutin) – Medicare | TBD | New Policy for Talicia (omeprazole, amoxicillin, rifabutin) to require diagnosis of H. Pylori infection confirmed by invasive techniques (e.g. endoscopic) or non-invasive techniques (e.g. urea breath test, stool antigen), a clarithromycin allergy, prior exposure to macrolide therapy or previous treatment failed to eradicate H. Pylori infection, using all the components of a first line therapy: Lansoprazole or omeprazole, amoxicillin or metronidazole and clarithromycin, and previous treatment with Pylera (bismuth subcitrate, metronidazole, tetracycline) and omeprazole failed to eradicate H. Pylori infections or an allergy, intolerance, or contraindication to any component of Pylera (bismuth subcitrate, metronidazole, tetracycline). Authorization duration of 14 days |
| Tezruly (terazosin) – Medicare | TBD | New policy for Tezruly (terazosin) requiring FDA approved diagnosis and therapeutic failure or intolerance to generic terazosin or doxazosin AND inability to swallow capsules. |
| Ultomiris (ravulizumab-cwvz) – Medicare | 10/28/2024 | Policy revised to update the language to "all" of the following criteria. |
| Ultomiris (ravulizumab-cwvz) – Medicare | TBD | Policy revised to include neuromyelitis optica spectrum disorder (NMOSD) criteria to the member has a diagnosis of NMOSD, the prescriber attests that the member is anti-aqaporin-4 (AQP4) antibody positive, and the member exhibits one of the following core characteristics of NMOSD: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | resonance imaging (MRI) lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions |
| Uplizna (inebilizumab-cdon) – Medicare | TBD | Policy revised to remove age limit of 18 years of age and older. Policy was revised to include neuromyelitis optica spectrum disorder (NMOSD) criteria of the product has been determined to be eligible for coverage under Part D per policy J-0030, the member exhibits one of the following core characteristics of NMOSD: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions |
| Viibryd (vilazodone) and Trintellix (vortioxetine) – Medicare | TBD | New policy created for Viibryd (vilazodone) and Trintellix (vortioxetine) to require a diagnosis of major depressive disorder (MDD) and therapeutic failure, intolerance, or contraindication to one (1) generic antidepressant (e.g., selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant (TCA), monoamine oxidase inhibitor (MAOI). |
| Viibryd (vilazodone) and Trintellix (vortioxetine) – Medicare | TBD | In addition to existing criteria, policy revised to require a therapeutic failure or intolerance to generic vilazodone if the request is for brand Viibryd (vilazodone). |
| Voranigo (vorasidenib) – Medicare | 10/28/2024 | New policy for Voranigo (vorasidenib) requiring diagnosis based on FDA-approved indication. |
| Xiaflex (collagenase clostridium histolyticum) – Medicare | TBD | New policy created for Xiaflex (collagenase clostridium histolyticum) for the two FDA-approved indications: Dupuytren's contracture and Peyronie's disease. For coverage of Xiaflex for Dupuytren's Contracture, the member must have the FDA-approved diagnosis with a palpable cord, the contracture is at least a 20 degree flexion for a metacarpophalangeal (MP) joint contracture or proximal interphalangeal (PIP) joint contracture, the flexion deformity results in functional limitations, no more than 2 cords are injected per treatment visit, and the member will be treated with a maximum of 3 |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | injections per affected cord. For a diagnosis of Peyronie's disease, the member must have the FDA-approved diagnosis with the presence of a palpable plaque, prior to treatment, the member must have a penile curvature deformity of at least 30 degrees but less than 90 degrees OR, if the member has received prior treatment with Xiaflex, the penile curvature deformity is at least 15 degrees, the member has intact erectile function (with or without medication), and the member has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease. |
| Yorvipath (palopegteriparatide) – Medicare | 10/28/2024 | Policy created for Yorvipath (palopegteriparatide) to include a diagnosis of hypoparathyroidism, prescriber attestation that the member's albumin-corrected serum calcium level is 7.8 mg/dL, and the member has established hypoparathyroidism despite treatment with calcium and active forms of vitamin D. Reauthorization of Yorvipath may be approved when the following criterion is met: The prescriber attests improvement in total serum calcium from baseline. |
| Zolinza (vorinostat) – Medicare | 10/28/2024 | Policy revised for Zolinza (vorinostat) to remove age limitation. |
| Zurzuvae (zuranolone) – Medicare | TBD | Policy revised to add additional criteria of the needs for prescriber attestation that symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery. |

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

**2. Updates to Step Therapy**

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| Afrezza (insulin human) – Medicare Incentive | TBD | New policy created for Afrezza (insulin human) to require a diagnosis of diabetes mellitus and in addition, the member has experienced therapeutic failure or intolerance to one of the following preferred rapid-acting insulin products: |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | Humalog product, insulin lispro, Fiasp, Novolog, or insulin aspart. |
| Brand Reliever Inhalers – Medicare | TBD | Policy updated to require the member to experience a therapeutic failure or intolerance to all of the following for Airsupra (budesonide and albuterol): an inhaled corticosteroid-formoterol combination product and an inhaled corticosteroid and albuterol product. |
| Buprenorphine-Naloxone Step Therapy – Medicare | 10/28/2024 | Policy revised to remove Bunavil (buprenorphine/naloxone) from the criteria, since no longer MedD eligible |
| Carbidopa/Levodopa – Medicare | 10/28/2024 | Policy revised to add Crexont (carbidopa/levodopa) requiring FDA approved indication and therapeutic failure or intolerance to one of the following: carbidopa/levodopa tablets or orally disintegrating tablets, extended-release tables, or carbidopa/levodopa/entacapone tablets. |
| Epinephrine Products – Medicare | 10/28/2024 | Policy revised to add Neffy (epinephrine) to policy to require a medically accepted indication and experienced therapeutic failure, contraindication or intolerance to two (2) of the following: generic epinephrine injections, EpiPen or Symjepi. |
| Gonadotropin-releasing Hormone (GnRH) Agonists – Medicare | TBD | Policy revised to add Triptodur (triptorelin) to require diagnosis based on FDA-approved indication supported by early onset of secondary sexual characteristics, elevated basal luteinizing hormone (LH) or leuprolide-stimulated LH levels, and advanced bone age beyond chronological age. Reauthorization to require positive clinical response defined as pre-pubertal slowing or decline or normalization of LH, follicle-stimulating hormone, bone age, estradiol level, or testosterone level. Policy also revised to make leuprolide acetate depot and Lupron Depot (leuprolide acetate for depot) preferred products while making Eligard (leuprolide acetate) a target product. Approval for coverage of Eligard requires a diagnosis of advanced prostate cancer and therapeutic failure, contraindication, or intolerance to leuprolide acetate depot or Lupron Depot. |
| Intravitreal Injections – Medicare | 10/28/2024 | Policy revised for Beovu (brolucizumab-dbll) to clarify step through Avastin (bevacizumab) is |

| Policy Name | Policy Effective Date* | Updates and/or Approval Criteria |
|---|---|---|
| | | only for Neovascular (Wet) Age-Related Macular Degeneration diagnosis and removed quantity limitations. |
| Intravitreal Injections – Medicare | TBD | Policy revised to add Enzeevu (aflibercept-abzv) and Pavblu (aflibercept-ayyh) requiring FDA-approved diagnosis, trial/failure to Avastin (bevacizumab) if diagnosis for Neovascular (Wet) Age-Related Macular Degeneration, and trial/failure to Eylea (aflibercept). |
| Non-Preferred ADHD Step Therapy – Medicare | TBD | Policy revised to remove Evekeo ODT (amphetamine sulfate) orally disintegrating tablet since it is off market |
| Non-Preferred Basal Insulins – Medicare | TBD | Policy revised to remove Rezvoglar (insulin glargine-aglr) and Semglee (insulin glargine-yfgn) as targets. Policy revised to add Levemir requiring diagnosis of diabetes mellitus. For Incentive formulary, therapeutic failure or intolerance to Lantus/Toujeo (insulin glargine) and Tresiba (insulin degludec) is required. For Compass formulary, therapeutic failure an intolerance to Lantus/Toujeo (insulin glargine) is required. |
| Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Medicare | 10/28/2024 | Policy revised to include Zituvimet XR (sitagliptin/metformin) extended-release to require T/F of drug-containing products of linagliptin and drug-containing products of sitagliptin phosphate. |
| Non-Preferred Rapid-Acting Insulins – Medicare Compass | TBD | Policy revised to add Afrezza (human insulin) to require step therapy. Coverage of Afrezza requires that the member has a diagnosis of diabetes mellitus and the member has experienced therapeutic failure of intolerance to one (1) of the following, when utilized for the same age and indication: Humalog product or insulin lispro product. |
| Pancreatic Enzymes – Medicare | TBD | New policy created for Pancreaze (pancrelipase), Pertzye (pancrelipase), and Zenpep (pancrelipase) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to Creon (pancrelipase). |

**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) |
|---|---|
| Erzofri (paliperidone palmitate) | Two (2) single dose cartons containing two packets per 365 days |
| Leqselvi (deuruxolitinib) | 2 tablets per day |
| Livdelzi (seladelpar) | 1 capsule per day |
| Nemluvio (nemolizumab-ilto) | 2 pens per 28 days |
| Tezruly (terazosin) | 20 mL (20 mg) per day |
| Yorvipath (palopegteriparatide) | 2 pens per 28 days |
| Zituvimet XR (sitagliptin and metformin hydrochloride) 50 mg/1,000 mg | 62 tablets per 31 days |
| Zituvimet XR (sitagliptin and metformin hydrochloride) 50 mg/500 mg ; 100 mg/1,000 mg | 31 tablets per 31 days |
| Zunveyl (benzgalantamine) | 62 tablets per 31 days |