Formulary Updates

Published on February 3, 2023

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for December 2022. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in December 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

Quinapril and Hydrochlorothiazide Tablets USP 20mg/12.5mg by Aurobindo Pharma USA, Inc.: Recall - Detection of N-Nitroso Quinapril Impurity

On October 24, 2022, East Windsor, New Jersey, Aurobindo Pharma USA, Inc. has initiated a voluntary recall of two (2) lots of Quinapril and Hydrochlorothiazide Tablets USP 20mg/12.5mg, to the consumer level from the US market due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril above the proposed interim limit.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall.

Quinapril Tablets by Lupin Pharmaceuticals, Inc.: Recall - Potential Presence of N-Nitroso-Quinapril Impurity

On December 21, 2022, Manufacturer recalled the above product due to the presence of a nitrosamine impurity, N-Nitroso-Quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. To date, Lupin has received no reports of illness that appear to relate to this issue.

Daptomycin for Injection 500 mg/vial and Daptomycin for Injection 350 mg/vial by Accord Healthcare Inc.: Recall – Label Mix-up

On December 22, 2022**,** Durham, North Carolina, Accord Healthcare, Inc. is voluntarily recalling a single lot of Daptomycin for Injection 500 mg/vial, and Daptomycin for Injection 350 mg/vial product contained in cartons imprinted with lot # R2200232 Exp: 01/2025 to the consumer/user level.

Administration of Daptomycin 500 mg/vial, to the population most at risk which are children or patients with renal impairment, there is a reasonable probability that the likelihood of the labeled warnings can potentially be increased if a higher than the intended dose is used which could lead to serious adverse health consequences. If these reactions occur, they may require medical treatment such as hemodialysis and systemic glucocorticoids. To date, Accord has not received any reports of adverse events related to this recall.

06/22/2022 FDA investigating risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia (denosumab)

The U.S Food and Drug Administration is investigating the risk of severe hypocalcemia with serious outcomes in patients with advanced kidney disease on dialysis treated with Prolia (denosumab).

Patients should speak with a health care professional before making changes to their medication regimen. Health care professionals should consider the risk of hypocalcemia with the use of Prolia in patients on dialysis.

Highmark Formulary Update – December 2022

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 are effective January 2023 unless otherwise noted.

Brand Name	Generic Name	Comments
Janssen COVID-19 Vaccine	Janssen COVID-19 Vaccine	Prevention of COVID-19
Lagevrio	Molnupiravir	Mild to moderate COVID-19
Menveo One-Vial Presentation*	[Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]	Prevention of meningococcal disease in patients 10-55 years of age
Novavax COVID-19 Vaccine	Novavax COVID-19 Vaccine	Prevention of COVID-19
Paxlovid	Nirmatrelvir; ritonavir	Mild to moderate COVID-19

* Commercial Comprehensive formulary only

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Omlonti*	Omidenepag isopropyl	latanoprost 0.005% eye drops, timolol maleate drops
Furoscix	Furosemide	Prescriber discretion
Lytgobi	Futibatinib	Prescriber discretion
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol	Riluzole

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..

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
Furoscix	Furosemide
Lytgobi	Futibatinib
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol

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 are effective January 2023 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Janssen COVID-19 vaccine	Janssen COVID-19 vaccine	3	Prevention of COVID-19
Lagevrio	Molnupiravir	3	Mild to moderate COVID-19
Menveo one-vial presentation	[Meningococcal (groups a, c, y, and w-135) oligosaccharide diphtheria crm197 conjugate vaccine]	3	Prevention of meningococcal disease in patients 10-55 years of age
Novavax COVID-19 vaccine	Novavax COVID-19 vaccine	3	Prevention of COVID-19
Paxlovid	Nirmatrelvir; ritonavir	3	Mild to moderate COVID-19
Items listed below were not added to the formulary			
Furoscix	Furosemide	NF	Prescriber discretion
Lytgobi	Futibatinib	NF	Prescriber discretion
Omlonti*	Omidenepag isopropyl	NF	latanoprost 0.005% eye drops, timolol maleate drops
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol	NF	riluzole

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 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 are effective January 2023 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Janssen COVID-19 Vaccine	Janssen COVID-19 Vaccine	3	Prevention of COVID-19
Lagevrio	Molnupiravir	3	Mild to moderate COVID-19
Menveo One-Vial Presentation	[Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]	3	Prevention of meningococcal disease in patients 10-55 years of age
Novavax COVID-19 Vaccine	Novavax COVID-19 Vaccine	3	Prevention of COVID-19
Paxlovid	Nirmatrelvir; ritonavir	3	Mild to moderate COVID-19
Items listed below were not added to the formulary			
Furoscix	Furosemide	NF	Prescriber discretion
Lytgobi	Futibatinib	NF	Prescriber discretion
Omlonti*	Omidenepag isopropyl	NF	Latanoprost 0.005% eye drops, timolol maleate drops
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol	NF	Riluzole

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)			
Janssen COVID-19 Vaccine	Janssen COVID-19 Vaccine	2	Prevention of COVID-19
Lagevrio	Molnupiravir	2	Mild to moderate COVID-19
Menveo One-Vial Presentation	[Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]	2	Prevention of meningococcal disease in patients 10-55 years of age
Novavax COVID-19 Vaccine	Novavax COVID-19 Vaccine	2	Prevention of COVID-19
Paxlovid	Nirmatrelvir; ritonavir	2	Mild to moderate COVID-19
Items listed below were added to the formulary (Non-Preferred)			
Furoscix*	Furosemide	3	Provider discretion
Lytgobi*	Futibatinib	3	Provider discretion
Omlonti*	Omidenepag isopropyl	3	Latanoprost 0.005% eye drops, timolol maleate drops
Items listed below were not added to the formulary			
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol	NF	Riluzole

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
Furoscix	Furosemide
Lytgobi	Futibatinib
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Anabolic Steroids – Commercial and Healthcare Reform	12/21/2022	Policy revised for Oxandrin (oxandrolone) to update need for weight gain due to

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		extensive surgery or other clear medical necessity of initiate treatment as outlined with clinical documentation. Removed severe illness as an option. Policy also revised trial/failure/contraindication of a non-opioid analgesic drug for bone pain and two prescription drugs to treat osteoporosis or Oxandrin (oxandrolone) is used in addition to a prescription drug for osteoporosis.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	12/21/2022	Policy revised for Cotellic (cobimetinib) requiring age and diagnosis based on FDA-approved expanded indication.
BTK Inhibitors – Commercial and Healthcare Reform	12/21/2022	Policy revised for Imbruvica (ibrutinib) oral suspension for all FDA-approved indications that if the request is for Imbruvica (ibrutinib) oral suspension, the member must have an inability to swallow both Imbruvica (ibrutinib) oral tablets and Imbruvica (ibrutinib) oral capsules.
Cholbam (cholic acid) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Cholbam (cholic acid) to remove "documentation" of diagnosis in criteria.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	12/21/2022	Policy revised for Rinvoq (upadacitinib) for new indication of non-radiographic axial spondyloarthritis (nr-axSpA) to require age, diagnosis based on FDA-approved indication, trial/failure to 2 nonsteroidal anti-inflammatory drugs (NSAIDs) or contraindication to all, and trial/failure of Cimzia (certolizumab). Exception criteria added for select indications to allow other medications in the same or similar class to count towards preferred drug step requirement.
Chronic Inflammatory Diseases – Commercial National Select Formulary	12/21/2022	Policy revised for Rinvoq (upadacitinib) for new indication of non-radiographic axial spondyloarthritis (nr-axSpA) to require age, diagnosis based on FDA-approved indication, trial/failure to 2 nonsteroidal anti-inflammatory drugs (NSAIDs) or contraindication to all, and trial/failure of Cimzia (certolizumab). Exception criteria added for select indications to allow other medications in the same or similar class to

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		count towards preferred drug step requirement.
Compounded Medications – Commercial	12/21/2022	Policy revised to extend authorization duration to 3 months and add reauthorization criteria with a 6-month authorization duration when maintenance use of compounds is needed.
Dupixent (dupilumab) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Dupixent (dupilumab) for new indication prurigo nodularis (PN) requiring member to be 18 years of age older and a specialist (dermatologist, allergist, or immunologist) submits attestation that the member has a diagnosis based on FDA-approved indication. Member must also experience therapeutic failure, contraindication, or intolerance to one generic topical corticosteroid, or the prescriber submits documentation topical prescription therapies would not be advisable. Reauthorization to require prescriber attests that the member has experienced a reduction in itch from baseline.
Endari (L-glutamine) – Commercial and Healthcare Reform	12/21/2022	Policy revised to allow for Endari (L-glutamine) to be used in addition to hydroxyurea.
Exservan and Tiglutik (riluzole) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Exservan and Tiglutik (riluzole) to remove all reauthorization criteria.
FGFR Kinase Inhibitors – Commercial and Healthcare Reform	12/21/2022	Policy revised to add Lytgobi (futibatinib) to require age, diagnosis based on FDA-approved indication, disease harboring FGFR2 gene fusions or other rearrangements, and trial/failure to at least one prior therapy. Reauthorization to require attestation that member is tolerating therapy and has experienced disease improvement or delayed disease progression.
Fingolimod – Commercial and Healthcare Reform	12/28/2022	Policy revised for brand Gilenya (fingolimod) to require trial/failure of generic fingolimod for initial and reauthorization. For new starts to brand Gilenya, policy revised to require trial/failure of dimethyl fumarate.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Firdapse (amifampridine) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Firdapse (amifampridine) to include age requirement of 6 years of age or older.
Fumarate Products – Commercial and Healthcare Reform	12/21/2022	Policy revised to require a step through generic fingolimod for new starts to brand Tecfidera, Bafiertam, and Vumerity.
Furoscix (furosemide) – Commercial and Healthcare Reform	01/06/2023	New policy created for Furoscix (furosemide) to require that the following criteria be met for coverage: age and diagnosis based on FDA-approved indication, Furoscix is prescribed by or in consultation with a cardiologist, the prescriber attests that the member has experienced a previous episode of congestion due to fluid overload and has been treated with a parenteral loop diuretic; the member has been receiving an oral loop diuretic as part of their chronic heart failure medication regimen; and treatment with the oral diuretic will be discontinued until patient is transitioned back to oral diuretic maintenance therapy. Reauthorization requires attestation that the member has used Furoscix for a previous episode of congestion due to chronic heart failure, had positive clinical results and avoided hospitalization; the Furoscix must be prescribed by or in consultation with a cardiologist; the member continues to have a diagnosis of heart failure classified as NYHA Class II/III chronic heart failure; the member has been receiving an oral loop diuretic as part of their chronic heart failure medication regimen; and treatment with the oral diuretic will be discontinued until patient is transitioned back to oral diuretic maintenance therapy. Authorization duration is 6 months.
Hereditary Angioedema – Commercial and Healthcare Reform	TBD	Policy revised requiring reauthorization criteria. Provider attests a decrease in frequency of HAE attacks, significant improvement in the severity or duration of attacks. Extended Takhzyro's dosing interval from 2 to 4 weeks based on

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		package insert. Revised Takhzyro's initial authorization from 12 months to 6 months.
Horizant (gabapentin enacarbil) – Commercial and Healthcare Reform	12/21/2022	Policy revised for indication of restless leg syndrome to require trial/failure/contraindication to generic gabapentin and 1 of the following: non-ergot dopamine agonist (pramipexole, ropinirole), dopamine precursor (carbidopa/levodopa, levodopa), benzodiazepines, opioids, or clonidine.
Human Growth Hormone – Commercial and Healthcare Reform	12/21/2022	Policy revised for growth hormone products to remove asking for cause of growth hormone deficiency in pediatrics. Added in limitations of coverage that use of growth hormone is not indicated or recommended in patients with achondroplasia as it can potentially worsen the disproportion seen in these patients. For adults with growth hormone deficiency confirming that use of product is for replacement of endogenous growth hormone.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	12/21/2022	Policy revised for growth hormone products to remove asking for cause of growth hormone deficiency in pediatrics. Added in limitations of coverage that use of growth hormone is not indicated or recommended in patients with achondroplasia as it can potentially worsen the disproportion seen in these patients. For adults with growth hormone deficiency confirming that use of product is for replacement of endogenous growth hormone.
Intranasal Benzodiazepines – Commercial and Healthcare Reform	12/21/2022	Policy revised for Nayzilam (midazolam) and Valtoco (diazepam) to require the member is currently receiving antiepileptic maintenance therapy.
Isturisa (osilodrostat) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Isturisa (osilodrostat) to require a reduction in 24-hour urinary free cortisol levels from baseline and attestation that the member has experienced an improvement in signs and symptoms of Cushing's disease from baseline for reauthorization.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Korlym (mifepristone) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Korlym (mifepristone) to require that it is being prescribed by or in consultation with an endocrinologist.
Lybalvi (olanzapine/samidorphan) – Commercial and Healthcare Reform	12/22/2022	Policy revised for Lybalvi (olanzapine/samidorphan) to require trial/failure/contraindication to two of the generic agents: risperidone, quetiapine, and/or aripiprazole.
Market Watch Programs – Delaware	01/06/2023	Policy revised to add clonidine XR to require trial/failure of clonidine hcl immediate-release tablet. Policy revised to add allopurinol 200 mg to require trial/failure of allopurinol 100 mg and allopurinol 300 mg. Policy revised to add Methocarbamol 1000 mg to require trial/failure of generic cyclobenzaprine 5 mg or 10 mg, and generic methocarbamol 500 mg, and generic chlorzoxazone 500 mg. Policy revised to add penciclovir to require trial/failure of acyclovir, famciclovir, and valacyclovir.
Market Watch Programs – New York, Pennsylvania, and West Virginia	01/06/2023	Policy revised to add clonidine XR to require trial/failure of clonidine hcl immediate-release tablet. Policy revised to add allopurinol 200 mg to require trial/failure of allopurinol 100 mg and allopurinol 300 mg. Policy revised to add Methocarbamol 1000 mg to require trial/failure of generic cyclobenzaprine 5 mg or 10 mg, and generic methocarbamol 500 mg, and generic chlorzoxazone 500 mg. Policy revised to add penciclovir to require trial/failure of acyclovir, famciclovir, and valacyclovir.
Noxafil (Posaconazole) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Noxafil (Posaconazole) delayed-release tablets and oral suspension to require diagnosis based on FDA-approved indication for Aspergillus or Candida infection prophylaxis. Policy revised for Noxafil (Posaconazole) oral suspension to require trial/failure of generic fluconazole for oropharyngeal candidiasis.
Ponvory (ponesimod) – Commercial and Healthcare Reform	TBD	Policy revised to require step through generic dimethyl fumarate and fingolimod for new starts to Ponvory.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Relyvrio (sodium phenylbutyrate and taurorsodiol) – Commercial and Healthcare Reform	12/16/2022	New policy created for Relyvrio (sodium phenylbutyrate and taurorsodiol) requiring members to be 18 years of age or older with a diagnosis of sporadic or familial amyotrophic lateral sclerosis (ALS) defined as "definite" by the revised El Escorial criteria. Members are required to have a baseline forced vital capacity of at least 60% and to not be dependent on tracheostomy. Reauthorization criteria requires the prescriber to attest that the member has experienced stability or improvement in the symptoms of ALS.
RET Kinase Inhibitors – Commercial and Healthcare Reform	12/21/2022	Policy revised for Retevmo (selpercatinib) for expanded indication treatment of adult patients with locally advanced or metastatic solid tumors with RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. Also revised policy to require companion diagnostic testing in non-small-cell lung cancer (NSCLC) and thyroid cancer.
Signifor (pasireotide) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Signifor (pasireotide) to require that it is being prescribed by or consultation with an endocrinologist. Reauthorization revised to require a reduction in 24-hour urinary free cortisol levels from baseline and attestation that the member has experienced an improvement in signs and symptoms of Cushing's disease from baseline.
Talicia (omeprazole/amoxicillin/rifabutin) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Talicia (omeprazole, amoxicillin, and rifabutin) to require that step through Pylera (bismuth subcitrate potassium/metronidazole/tetracycline hydrochloride) is in combination with omeprazole. Removed "penicillin allergy" as an exception to being previously treated with a first-line treatment regimen.
Tarpeyo (budesonide) – Commercial and Healthcare Reform	12/21/2022	Policy revised for Tarpeyo (budesonide) to require reauthorization criteria for diagnosis based on FDA-approved indication, using concurrently or trial/failure of an angiotensin converting enzyme inhibitor or an aldosterone receptor blocker,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		trial/failure/contraindication to systemic corticosteroid, and prescriber attests member requires re-continuation of therapy. Authorization duration revised to 10 months.
Thiola (tiopronin) and Thiola EC (tiopronin) – Commercial and Healthcare Reform	TBD	Policy revised for Thiola (tiopronin) and Thiola EC (tiopronin) to require trial and failure of generic tiopronin if the request is for brand Thiola (tiopronin) or brand Thiola EC (tiopronin) for initial authorization and reauthorization.

*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
Carafate (sucralfate) Oral Suspension – Commercial and Healthcare Reform	12/21/2022	Policy revised for Carafate (sucralfate) oral suspension to add reauthorization criteria requiring positive clinical response to therapy and attestation that additional courses of treatment are required.
Carafate (sucralfate) Oral Suspension – Commercial and Healthcare Reform	TBD	Policy revised for Carafate (sucralfate) oral suspension to require trial/failure of generic sucralfate oral suspension if the request is for brand Carafate oral suspension.
Cyclobenzaprine, Metaxalone, and Methocarbamol Products – Commercial and Healthcare Reform	01/19/2023	Policy revised to add criteria for Methocarbamol 1000 mg. The member must have a diagnosis of an 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 tablets, 2) generic methocarbamol 500 mg, 3) generic chlorzoxazone 500 mg, 4) generic orphenadrine tablets, or contraindication to all four (4) medications. In addition, references to methocarbamol as a qualifying drug was changed to methocarbamol 500 mg throughout the policy.
Gout Therapies – Commercial and Healthcare Reform	01/19/2023	Policy revised to add allopurinol 200 mg requiring diagnosis and therapeutic failure or intolerance to generic allopurinol 100 mg or generic allopurinol 300 mg. For other criteria in the policy requiring therapeutic failure or intolerance through generic allopurinol, it was specified that the therapeutic

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		failure or intolerance was to generic allopurinol 100 mg or generic allopurinol 300 mg.
Immediate-Release Opioid Management – Commercial and Healthcare Reform	12/21/2022	Policy revised to remove all quantity limits since all the quantity limits are included in Policies J-0646 (Commercial) and J-0645 (Healthcare Reform). Also, added RoxyBond (oxycodone IR), an abuse deterrent product that was re-introduced into the market.
Intraocular Pressure Reducing Agents – Commercial and Healthcare Reform	TBD	Policy revised to add Omlonti (omidenepag isopropyl) requiring age, diagnosis based on FDA-approved indication, trial/failure/contraindication to latanoprost and an additional generic ophthalmic alternative that lowers IOP including prostaglandin analogs (excluding latanoprost), ophthalmic beta-blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, ophthalmic cholinergic agonists, or combination products of these classes. Reauthorization criteria that the member has experienced a positive clinical response to therapy. Authorization duration of 12 months.
Nexiclon (clonidine) XR – Commercial and Healthcare Reform	12/13/2022	Policy revised to add clonidine Hcl ER to require age, diagnosis based on FDA-approved indication, and trial/failure of clonidine Hcl immediate-release tablet.
Non-preferred Atypical Antipsychotic Medications – Healthcare Reform Essential	12/21/2022	Policy revised for Saphris (asenapine) requiring age, diagnosis based on FDA-approved indication, trial, failure, or contraindication to two (2) plan-preferred antipsychotics, and if the request is for brand Saphris, the member has experienced therapeutic failure or intolerance to generic asenapine sublingual tablets.
Saphris (asenapine) – Commercial and Healthcare Reform	04/01/2023	Policy revised for Saphris (asenapine) to specify that the criteria apply to brand-only Saphris (asenapine) and to allow for a diagnosis of either bipolar I disorder or bipolar II disorder. The Commercial and Healthcare Reform versions of the policy were combined into one policy.
Tazarotene Products – Commercial and Healthcare Reform	01/19/2023	Policy revised to add generic tazarotene gel as a target requiring diagnosis based on FDA-approved indication, and trial/failure to generic tazarotene cream. For acne vulgaris, trial/failure/contraindication to two plan-preferred topical agents: adapalene,

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		clindamycin +/- benzoyl peroxide, erythromycin, tretinoin, or sulfacetamide. For plaque psoriasis, trial/failure/contraindication to one topical corticosteroid. Reauthorization of positive clinical response to therapy. Authorization duration of 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
Imbruvica (ibrutinib) oral suspension	Two (2) bottles (216 mL) per 20 days	Six (6) bottles (648 mL) per 60 days
Lagevrio (molnupiravir)	40 capsules per 180 days	40 capsules per 180 days
Lytgobi (futibatinib)	4 packs per 28 days	12 packs per 84 days
Ozempic (semaglutide) 2 mg/3 mL (0.68 mg/mL)*	1 pen per 21 days	3 pens per 63 days
Paxlovid (nirmatrelvir; ritonavir)	• 30 tablet carton: 30 tablets (1 carton of 5 blister cards) per 180 days. • 20 tablet carton: 20 tablets (1 carton of 5 blister cards) per 180 days	• 30 tablet carton: 30 tablets (1 carton of 5 blister cards) per 180 days • 20 tablet carton: 20 tablets (1 carton of 5 blister cards) per 180 days
Prevymis (letermovir)	112 tablets per 365 days	112 tablets per 365 days
RoxyBond (oxycodone IR)	180 tablets per 25 days	540 tablets per 75 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
Omlonti (omidenepag isopropyl)*	Two (2.5 mL) bottles	Four (2.5 mL bottles)
Furoscix (furosemide)	Two (2) kits (prefilled cartridge co-packaged with single-use on-body infusor)	Two (2) kits (prefilled cartridge co-packaged with single-use on-body infusor)

*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
Relyvrio (sodium phenylbutyrate; sodium taurursodiol)	2 packets per day
Turalio (pexidartinib hydrochloride) 125 mg capsules*	4 capsules per day
Allopurinol 200 mg	4 tablets per day

*Effective date to be determined.

**Quantity per Duration (QD) rule also applies to this medication (refer to Table 1).
Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

Requests for coverage of select medications exceeding the defined quantity level limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on member's benefit design.

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Incentive Formulary

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

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
Lagevrio	Molnupiravir	Mild to moderate COVID-19
Menveo One-Vial Presentation	[Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]	Prevention of meningococcal disease in patients 10-55 years of age
Paxlovid	nirmatrelvir; ritonavir	Mild to moderate COVID-19

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

Brand Name	Generic Name	Preferred Alternatives
Omlonti	Omidenepag isopropyl	Latanoprost 0.005% eye drops, timolol maleate 0.25% eye drops

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

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

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

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

Brand Name	Generic Name	Comments
Lagevrio	Molnupiravir	Mild to moderate COVID-19

Brand Name	Generic Name	Comments
Menveo One-Vial Presentation	[Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]	Prevention of meningococcal disease in patients 10-55 years of age
Paxlovid	Nirmatrelvir; ritonavir	Mild to moderate COVID-19

Table 2. Non-Preferred Products

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
Omlonti	Omidenepag isopropyl	Latanoprost 0.005% eye drops, timolol maleate 0.25% eye drops

*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
Furoscix	Furosemide
Imjudo	Tremelimumab-actl
Lytgobi	Futibatinib
Pedmark	Sodium thiosulfate
Relyvrio	Sodium phenylbutyrate; sodium taurursodiol
Rolvedon	Eflapegrastim-xnst
Tecvayli	Teclistamab-cqyv
Vegzelma	Bevacizumab-adcd

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Anabolic Steroids – Medicare	01/01/2024	Policy revised for Oxandrin (oxandrolone) to update need for weight gain due to extensive surgery or other clear medical necessity of initiate treatment.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Policy also revised trial/failure/contraindication of a non-opioid analgesic drug for bone pain and one prescription drug to treat osteoporosis or Oxandrin (oxandrolone) is used in addition to a prescription drug for osteoporosis.
Apomorphine Products – Medicare	01/01/2023	Policy revised to conform with CMS requirements. For approval of Apokyn or Kynmobi (apomorphine), the member must have experienced therapeutic failure, contraindication, or intolerance to 1 of the following medications: ropinirole, pramipexole, entacapone, selegiline, or rasagiline. Previously, member had to experience therapeutic failure, contraindication, or intolerance to two (2) of the medications. The rest of the criteria remains unchanged.
Atypical Antipsychotics – Medicare	01/01/2024	Policy revised for Rexulti (brexpiprazole), Caplyta (lumateperone), and Vraylar (cariprazine) in the treatment of schizophrenia, removed the word "formulary" from the criterion, the member has experienced a therapeutic failure, contraindication, or intolerance to 1 other formulary generic atypical antipsychotic. For Rexulti (brexpiprazole) in the treatment of Major Depressive Disorder (MDD), added the word "generic" to the criterion, the member has experienced therapeutic failure, contraindication, or intolerance to 1 other generic agent in addition to the agent currently being used for the treatment of MDD. For Vraylar (cariprazine) in the treatment of Bipolar Disorder I, removed the word "formulary" from the criterion, the member has experienced therapeutic failure, contraindication, or intolerance to one other formulary generic antipsychotic.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	12/21/2022	Policy revised for Cotellic (cobimetinib) requiring diagnosis based on FDA-approved expanded indication.
BTK Inhibitors – Medicare	12/21/2022	Policy revised for Imbruvica (ibrutinib) oral suspension for all FDA-approved indications that if the request is for Imbruvica (ibrutinib) oral suspension, the member has an inability to swallow both Imbruvica (ibrutinib) oral tablets and Imbruvica (ibrutinib) oral capsules.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Cholbam (cholic acid) – Medicare	12/21/2022	Policy revised for Cholbam (cholic acid) to add member is using Cholbam as adjunctive treatment (which is filed).
Exservan and Tiglutik (riluzole) – Medicare	12/21/2022	Policy revised for Exservan and Tiglutik (riluzole) to remove all reauthorization criteria.
FGFR Kinase Inhibitors – Medicare	01/01/2023	Policy revised to add Lytgobi (futibatinib) to require age, diagnosis based on FDA-approved indication, disease harboring FGFR2 gene fusions or other rearrangements, and trial/failure to at least one prior therapy.
Fingolimod – Medicare	01/01/2023	Policy revised for brand Gilenya (fingolimod) to require trial/failure of generic fingolimod.
Furoscix (furosemide) – Medicare	TBD	New policy created for Furoscix (furosemide) to require that the following criteria be met for coverage: Diagnosis of New York Heart Association (NYHA) Class II/III chronic heart failure; member has been receiving oral furosemide, or another oral loop diuretic (bumetanide, torsemide) as part of their chronic heart failure medication regimen; the prescriber attests that treatment with oral diuretics will replace the use of Furoscix as soon as practical. Authorization duration of 6 months.
Imjudo (tremelimumab-actl) – Medicare	12/16/2022	Policy created for Imjudo (tremelimumab-actl) requiring diagnoses, concomitant therapy, and genomic mutations based on FDA-approved indication.
Intranasal Benzodiazepines – Medicare	01/01/2023	Policy revised for Nayzilam (midazolam) and Valtoco (diazepam) to remove step through diazepam rectal gel.
Intranasal Benzodiazepines – Medicare	01/01/2024	Policy revised for Nayzilam (midazolam) and Valtoco (diazepam) to require the member is currently receiving antiepileptic maintenance therapy.
Kalydeco (ivacaftor) – Medicare	12/21/2022	Policy revised for Kalydeco (ivacaftor) to remove age limitations.
Nourianz (istradefylline) – Medicare	01/01/2023	Policy revised to conform with CMS requirements. For approval of Nourianz (istradefylline), the member must have experienced therapeutic failure, contraindication, or intolerance to 1 of the following medications: ropinirole, pramipexole, entacapone, selegiline, or rasagiline. Previously, member had to experience therapeutic failure, contraindication,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		or intolerance to two (2) of the medications. The rest of the criteria remains unchanged.
Pedmark (sodium thiosulfate) – Medicare	TBD	New policy for Pedmark (sodium thiosulfate) requiring age, diagnosis based on FDA-approved indication, and current use of cisplatin. Reauthorization criteria requiring age, lack of ototoxicity with previous Pedmark use, diagnosis, and current use of cisplatin.
Programmed Death Receptor Therapies – Medicare	12/21/2022	Policy revised for Imfinzi (durvalumab) to require diagnosis based on FDA-approved expanded indication.
Pulmonary Hypertension – Medicare	12/14/2022	Policy revised for Tyvaso (Treprostinil) and Tyvaso DPI (Treprostinil) to remove the requirement that the member is a non-smoker or is engaged in smoking cessation.
Relyvrio (sodium phenylbutyrate and taurorsodiol) - Medicare	12/16/2022	New policy created for Relyvrio (sodium phenylbutyrate and taurorsodiol) requiring members to have a diagnosis of amyotrophic lateral sclerosis (ALS).
Repository Corticotropin Injections – Medicare	01/01/2023	Policy revised for Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel (repository corticotropin injection) to remove specific requirements for maintenance therapy.
RET Kinase Inhibitors – Medicare	12/22/2022	Policy revised for Retevmo (selpercatinib) for expanded indication treatment of adult patients with locally advanced or metastatic solid tumors with RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. Also revised policy to require companion diagnostic testing in non-small cell lung cancer (NSCLC) and thyroid cancer.
Secuado (asenapine) – Medicare	01/01/2024	New policy created for Secuado (asenapine) to require diagnosis, therapeutic failure, or intolerance to generic asenapine sublingual tablets and one of the following: olanzapine, quetiapine, or risperidone.
Tarpeyo (budesonide) – Medicare	01/01/2024	Policy revised for Tarpeyo (budesonide) to require reauthorization criteria for diagnosis based on FDA-approved indication and using concurrently or trial/failure of an angiotensin converting enzyme inhibitor or an aldosterone receptor blocker, and member requires re-continuation of therapy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Tarpeyo (budesonide) – Medicare	12/21/2022	Policy revised for Tarpeyo (budesonide) to revise authorization duration to 10 months.
Tecentriq (atezolizumab) – Medicare	12/21/2022	Policy revised for Tecentriq (atezolizumab) to remove age requirement for metastatic non-small cell lung cancer.
Tecvayli (teclistamab-cqyv) – Medicare	12/16/2022	New policy created for Tecvayli (teclistamab-cqyv) requiring members to have a diagnosis of relapsed or refractory multiple myeloma (RRMM). Members are required to have received at least four (4) prior therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
Thiola and Thiola EC (tiopronin) – Medicare	01/01/2024	Policy revised for Thiola (tiopronin) and Thiola EC (tiopronin) to require trial and failure of generic tiopronin if the request is for brand Thiola (tiopronin) or brand Thiola EC (tiopronin).
Wakix (pitolisant) – Medicare	12/21/2022	Policy revised for indication of narcolepsy without cataplexy to remove criteria requiring significant concern for drug diversion.

*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
Intraocular Pressure Reduction Agents – Medicare	12/14/2022	Policy revised to add Omlonti (omidenepag isopropyl) requiring age, diagnosis based on FDA-approved indication, trial/failure/contraindication to latanoprost, and an additional generic ophthalmic alternative that lowers Intraocular Pressure (IOP) including prostaglandin analogs (excluding latanoprost), ophthalmic beta-blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, ophthalmic cholinergic agonists, or combination products of these classes.
Nexiclon (clonidine) XR – Medicare	TBD	Policy revised to add clonidine Hcl ER to require diagnosis based on FDA-approved indication, and trial/failure of clonidine Hcl immediate-release tablet.

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

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)
Allopurinol 200 mg	4 tablets per day	4 tablets per day
Furoscix (furosemide)	8 kits (prefilled cartridge co-packaged with single-use on-body infusor) per 30 days	24 kits (prefilled cartridge co-packaged with single-use on-body infusor) per 90 days
Lytgobi (futibatinib)	• 12 mg daily dose pack: 3 tablets per day • 16 mg daily dose pack: 4 tablets per day • 20 mg daily dose pack: 5 tablets per day	• 12 mg daily dose pack: 3 tablets per day • 16 mg daily dose pack: 4 tablets per day • 20 mg daily dose pack: 5 tablets per day
Omlonti (omidenepag isopropyl)	2 (2.5 mL) bottles per 30 days	4 (2.5 mL bottles) per 90 days
Ozempic (semaglutide) 2 mg/3 mL (0.68 mg/mL)	3 mL (1 pen) per 28 Days	9 mL (3 pens) per 84 days
Relyvrio (sodium phenylbutyrate; sodium taurursodiol)	2 packets per day	2 packets per day
Turalio (pexidartinib hydrochloride) 125 mg capsules	4 capsules per day	4 capsules per day

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