Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 82

May 1, 2023

This is the May 1, 2023 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

The Provider Alert, Prior Authorization Requirements, and Medical policies are all available on ProvLink and through the link above.

NOTE: For Oregon Medicaid requests, services which do not require prior authorization will process against the Prioritized List. To determine which services require prior-authorization, please see the current PHP prior authorization list here.

****EXTERNAL PROVIDER REVIEW OPPORTUNITY****

PHP Medical Policy Committee is seeking feedback from providers to serve as clinical subject matter experts (SMEs) through the policy development and annual review processes. This review process allows providers to offer their expertise and discuss relevant research in their field that will be used to support how these policy decisions are made. This will allow providers an opportunity to offer valuable insight that will help shape policies that affect provider reimbursement and patient care.

If interested, please email us at PHPmedicalpolicyinquiry@providence.org with your name, specialty, and preferred email address.

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 6/1/2023

Thyroid Testing **MP206**	**Policy Updates:** No changes to criteria. Continue to base criteria on Medicare guidance for thyroid testing. **Codes/PA:** Diagnosis codes added to the list of codes that pay with no PA, based on Medicare updates **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Wheelchair and Power Vehicles **MP140**	**Policy Updates:** No change to criteria, but updated Billing Guidelines. **Codes/PA:** Updated configuration for E1028 to allow when billed with select HCPCS codes, otherwise it will continue to deny t07 (not separately payable). No changes to other codes in the policy or their configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 7/1/2023

Cardiac: Disease Risk Screening **MP148**	**Policy Updates:** Changed denial type for criterion II. to "not medically necessary." **Codes/PA:** Changed denial from "investigational" to "not medically necessary" for 81291 and 81493. **OHP:** OHP will follow the Company Policy above
Cardiac: Implantable Loop Recorder **MP76**	**Policy Updates:** Changed denial type for criterion III. to "not medically necessary." **Codes/PA:** No changes to codes or configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Colorectal Cancer Screening **MP106**	**Policy Updates:** Changed denial language in criterion VIII for blood-based biomarker testing from investigational to not medically necessary **Codes/PA:** Set up G0327 to deny as not medically necessary **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: MTHFR **MP311**	**Policy Updates:** Changed denial type for criterion I. to "not medically necessary." **Codes/PA:** Changed denial from "investigational" to "not medically necessary" for the following codes: 0347U, 0348U, 0349U, 0350U, 81291 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Surface Electromyography (sEMG) Testing **MP136**	**Policy Updates:** Changed denial language from investigational to not medically necessary. **Codes/PA:** • Changed denial of 96002 to NMN • Removed denial from S3900. Refer to Coding Policy 22.0 in Billing Guidelines **OHP:** OHP will follow the Company Policy above
Wireless Capsule Endoscopy **MP134**	**Policy Updates:** Change denial type to "not medically necessary" for the following services: colon capsule endoscopy (CPT 91113), magnetically controlled capsule endoscopy (CPT 0651T) and patency capsules. **Codes/PA:** Changed denial from "investigational" to "not medically necessary" for the following codes: 0651T and 91113. **OHP:** OHP will follow the Company Policy above

Genetic Testing: Non-Covered Genetic Panel Tests **MP213**	**Policy Updates:** • Removed any panels that are on another policy from the Table of non-covered genetic panels • Added Proprietary Code column to non-covered table. • Changed denial of genetic panel tests to not medically necessary **Codes/PA:** • Changed denial of all investigational codes to not medically necessary • Removed any codes already addressed on other policies **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Inherited Thrombophilias **MP266**	**Policy Updates:** • Changed denial types where relevant to "not medically necessary." • Added criterion addressing repeat germline testing (criterion V.) • Added criterion addressing factor V Leiden testing for retinal artery occlusion. **Codes/PA:** Changed denial from "investigational" to "not medically necessary" for 81291. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic and Molecular Testing **MP215**	**Policy Updates:** No change to criteria. **Codes/PA:** • Removed PA for HFE testing (CPT 81256) • Removed 0049U; code will be placed on "GT: Myeloproliferative Diseases" policy. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Sleep Disorder Testing **MP60**	**Policy Updates:** • Changed denial type for actigraphy testing from "investigational" to "not medically necessary" • Per consideration, added "maintenance of wakefulness testing" to criteria X.-XIII. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Sleep Oral Appliances **MP46**	**Policy Updates:** Changed denial from "investigational" to "not medically necessary" for non-covered oral appliances used for the treatment of obstructive sleep apnea. **Codes/PA:** Changed denial from "investigational" to "not medically necessary" for the following codes: E0485, K1027, K1001, K1028, K1029. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Genetic Testing: Gene Expression Profile Testing for Breast Cancer **MP47**	**Policy Updates:** Updated non-coverage position from investigational to NMN. **Codes/PA:** • Investigational criteria updated to NMN (0249U, 0295U) • Added 0153U as NMN • PA removed from S3854 (other code needed for claim for all S-codes per Coding Policy). Note added to Billing Guidelines. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Inherited Susceptibility to Colorectal Cancer **MP115**	**Policy Updates:** • Updated non-coverage position from investigational to NMN. • Added *NTHL1, POLE, POLD1* testing option based on NCCN recommendation. • Added NMN language for repeat testing • Added +RNAinsigt for COLONExt test by Ambry Genetics to list of noncovered panels **Codes/PA:** • Investigational criteria updated to NMN **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Hereditary Breast and Ovarian CA **MP143**	**Policy Updates:** • Added +RNAinsight for BreastNext and +RNAinsight for OvaNext by Ambry Genetics to noncovered panels. Changing to NMN 6/1 • Added BARD1 to list of genes associated with Breast Cancer per NCCN guidelines. Also added language as list is not all inclusive. **Codes/PA:** No changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Myeloproliferative Diseases **MP72**	**Policy Updates:** • Changed investigational denials to not medically necessary. • Added NMN criteria for repeat testing. • Moved 0049U from Genetic and Molecular Testing (Company). Will continue to PA. **Codes/PA:** • Non-coverage indications will process as not medically necessary instead of investigational **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Genetic Testing: Reproductive Planning and Prenatal Testing **MP78**	**Policy Updates:** • PA removed from S-code (S3844). Note put in Billing Guidelines that additional codes needed for claim. • Removed criteria for Pre-Implantation Genetic Diagnosis and Screening (PGD and PGS). Code was changed in March 2020 to pay without PA but criteria remained (CPT codes 81228 & 81229). • Added NMN criteria for repeat testing. • Removed PA for HFE testing (CPT 81256) in coordination with Genetic and Molecular Testing (Company) **Codes/PA:** • PA removed from S- code (S3844) as additional code required for claim. • PA removed from 81256 • Removed CPTs 81228 & 81229 (Just from policy, configuration already removed in 2020) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Advanced Diabetes Management Technology **MP 27**	**Policy Updates:** Updated Billing Guideline to replace terminated code K0553 (termed 1/1/2023) with A4238 & A4239 for supply allowance. **Codes/PA:** For A4238 and A4239 added a cumulative limit of 12 per calendar year. No changes to other codes in the policy. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Lower Limb Prosthesis **MP22**	**Policy Updates:** Removal of Knee-Ankle-Foot device (L2006). Addressed on Ankle Foot-Knee Ankle Foot Orthosis (Company). Currently no criteria on policy addressing device. **Codes/PA:** Removed L2006 from policy. Already addressed on Ankle Foot-Knee Ankle Foot Orthosis (Company). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Ankle-Foot/Knee-Ankle-Foot Orthoses **MP293**	**Policy Updates:** Investigational criteria updated to not medically necessary. **Codes/PA:** • Investigational criteria updated to NMN (L2006) • Added L9900 to Billing Guidance- but no change to code configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE

Effective 6/1/23

Wheelchair and Power Vehicles **MP300**	**Policy Updates:** No change to criteria, but updated Billing Guidelines **Codes/PA:** Updated configuration for E1028 to allow when billed with select HCPCS codes, otherwise continue to deny t07 (not separately payable). No changes to other codes in the policy or their configuration.

Effective 7/1/23

Cardiac: Disease Risk Screening **MP132**	**Policy Updates:** No changes to criteria in this Medicare policy, but because the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration
Cardiac: Implantable Loop Recorders **MP343**	**Policy Updates:** No changes to criteria in this Medicare policy, but because the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration
Wireless Capsule Endoscopy **MP308**	**Policy Updates:** No changes to criteria, but did reorganize criteria. Because the Company policy criteria is changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No change to codes or configuration.
Advanced Diabetes Management Technology **MP25**	**Policy Updates:** No change to criteria (some changes were made to "Billing Guidelines" to both this 7/1 version and the previous 6/1 version). **Codes/PA:** Code configuration changes are as follows:

	• Re-added PA to CGM receiver/monitor codes (E2102, E2103). This will be for new provisions or replacements only. Individuals who already have a CGM will be able to keep their current unit and continue to obtain supplies (A4238/A4239). We would not review future CGM requests for these individuals unless they requested a replacement or new unit. • Added a cumulative limit of 12 per calendar year to supply codes (A4238 and A4239). • No changes to other codes in the policy.
Genetic and Molecular Testing **MP317**	**Policy Updates:** No change to criteria. **Codes/PA:** Removed PA from CPT 81256. No code or configuration changes to any other code in the policy. *NOTE: Removal of PA does not guarantee coverage. Medicare expects all services to be medically reasonable and necessary for the indication they are being used for, regardless of the existence of a formal medical policy or PA requirements.*
Sleep Disorder Treatment: Oral and Sleep Position Appliances **MP45**	**Policy Updates:** No change to criteria. **Codes/PA:** Re-added PA to E0486. No changes to other codes or their respective configuration. *NOTE: PA was removed from E0486 as of 5/1/2022 due to the COVID PHE. With the PHE end approaching (5/11/2023), PA will be added back to this service.*

Providence Health Plan

Providence Health Assurance

Archive

Effective 5/1/23

Definition: Confined to the Home **MP183**	**Policy Updates:** Archive policy due to lack of use by UM **Codes/PA:** No codes on policy **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Definition: Mobility Assistive Equipment **MP175**	**Policy Updates:** Archive policy due to lack of use by UM **Codes/PA:** No codes on policy **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

REIMBURSEMENT POLICIES

Effective 5/1/2023

Facility Routine Supplies and Services
 	
UM43
	Recommendation: No recommended changes to existing criteria or processes. Updated CMS references and citations.
	Reimbursement Methodology: No changes to reimbursement methodology.
	Relevant References/CMS Guidance:
	• Medicare Benefit Policy Manual, Chapter 1—Inpatient Hospital Services Covered Under Part A, §40.0—Supplies, Appliances, and Equipment
	• Medicare Benefit Policy Manual, Chapter 4—Part B Hospital, §230.2—Coding and Payment for Drug Administration
	• Medicare Claims Processing Manual, Chapter 20—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §210—CWF Crossover Editing for DMEPOS Claims During an Inpatient Stay
	• Medicare General Information, Eligibility, and Entitlement Manual
	  • Chapter 1—General Overview, §60.4—Statutory Obligations of Practitioners and Other Persons
	  • Chapter 4—Physician Certification and Recertification of Services, §10—Certification and Recertification by Physicians for Hospital Services
	  • Chapter 4—Physician Certification and Recertification of Services, §20—Certification for Hospital Services Covered by the Supplementary Medical Insurance Program
	  • Chapter 5—Definitions, §20—Hospital Defined
	• Provider Reimbursement Manual – Part 1, Chapter 22, §2202.4, §2202.6, §2202.8, §2203
	• MLN Matters® Number: MM8959. Implementing the Payment Policies Related to Patient Status from the CMS-1599-F
	• MLN Matters® Number: SE1333. Temporary Instructions for Implementation of Final Rule 1599-F for Part A to Part B Billing of Denied Hospital Inpatient Claims
	• Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
	MLN Matters® Number: 1541573. Medicare DMEPOS Payments While Inpatient

Inpatient Hospital Readmissions **UM54**	**Recommendation:** No recommended changes to existing criteria or processes. Updated CMS references and citations. **Reimbursement Methodology:** No changes to reimbursement methodology. **Relevant References/CMS Guidance:** • Centers for Medicare & Medicaid Services (CMS). Quality Improvement Organization Manual, Chapter 4—Case Review, §4240 – Readmission Review

	• Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual, Chapter 3—Inpatient Hospital Billing, §40.2.5—Repeat Admissions • Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual, Chapter 3—Inpatient Hospital Billing, §40.2.6—Leave of Absence • Centers for Medicare & Medicaid Services (CMS). Hospital Readmission Reduction Program (HRRP) Social Security Administration (SSA). Payment to Hospitals for Inpatient Hospital Services, Title 18, § 1886

Providence Health Plan

Providence Health Assurance

VENDOR UPDATES

eviCore - Clinical Information for Medical Necessity Review	**Changes, effective 4/3/2023:** - No clinically impactful revisions. - Guideline version number and effective date have been updated to reflect this annual review. - Guideline has been up-versioned to V1.0.2023 and is effective immediately.
eviCore - Physical & Occupational (PTOT) Therapy Services	**Changes, effective 5/1/2023:** **PTOT-1.0 Criteria for the Provision of Physical and Occupational Therapy Services** - Added introductory paragraph prior to the definitions that provides a basic explanation of the intent of the guideline. Similar to statement already in use in Speech guidelines. **PTOT-1.1 Definitions** - Editorial updates of definitions for better understanding and readability. Listed in alphabetical order. - Added definitions for: Determination and Episode of Care. - Removed definitions for: Palliative Care and Preventive Care - these terms not used in guideline, so no reason to be in definitions. **PTOT-1.2 Criteria to Determine Medical Necessity for Skilled Physical/Occupational Therapy Care** - Editorial updates for better readability and logical flow of section. - Added new language to guide understanding about dosage (number of visit) decisions. **PTOT-1.3 Rules, Coverage, Benefits and Mandates** - Clarification language regarding hierarchy of national, state and health plan rules/policies in request decisions. **PTOT-2.0 Clinical Considerations** - Minor editorial changes and removal of phrases that are now stated in the dosage language added to PTOT-1.2

	PTOT-2.1 Integumentary Considerations - Minor editorial changes to simplify subsection. Updated references to include more recent supportive literature. **PTOT-2.2 Lymphatic Considerations** - Minor editorial changes to reduce impression of directing care. **PTOT-2.3 Musculoskeletal Considerations** - Minor editorial changes to reduce impression of directing care. - Added references for updated musculoskeletal guidelines. **PTOT-2.4 Neurologic Considerations** - Minor editorial changes to reduce impression of directing care. **PTOT-2.5 Pediatric Neurodevelopmental Considerations** - Minor editorial changes to reduce impression of directing care. **PTOT-2.6 Pelvic Considerations** - Minor editorial changes to reduce impression of directing care. - Updated reference for new post-partum clinical guidelines. **PTOT-2.8 Vestibular Considerations** - Minor editorial changes to reduce impression of directing care. - Added reference to clinical guideline for cervicogenic dizziness.

Providence Health Plan

Providence Health Assurance

Here's what's new from the following policy committees:

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting April 7, 2023

Go-Live Date: Thursday, June 01, 2023, unless otherwise noted

Special Announcement - Specialty Drugs Shipped from Pharmacies to Providers/Facilities ("White Bagging") Policy

Providence Health Plan (PHP) created this policy to provide structure for providers/facilities who want to order specialty medications directly from the specialty pharmacy for a particular patient. The clinic/facility will then have their staff admix and administered to the patient, known as "White Bagging".

Instead of the traditional buy and bill method, "White Bagging" may benefit a prescribing provider or facility by:

- Eliminating up-front acquisition costs of drugs and subsequent billing for drugs
- Decreasing administrative burden of ordering, receiving, and storing expensive medications
- Convenient delivery of medication to the prescribing provider's clinic or facility

Participation is voluntary, and a provider/facility can choose which drugs listed in the policy they would like to white bag. The providers that utilize this policy are motivated to bring medications to their patients while keeping their business operations running optimally.

PHP wants providers/facilities to know that this opportunity exists and may benefit their practice. The intent of this policy is to define a process, which medications, and what pharmacies are eligible for white bagging.

Providence Health Plan

Providence Health Assurance

Table of Contents:

New Drugs and Combinations:

1. **Olutasidenib (Rezlidhia) Capsule**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Tibsovo®			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications Policy
   d. **Prior Authorization Criteria for Medicare Part D**: Added to Anti-cancer Agents Program

2. **Adagrasib (Krazati) Tablet**
   a. **Indication**: For the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received at least one prior systemic therapy.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives:			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications policy
   d. **Prior Authorization Criteria for Medicare Part D**: Added to Anti-cancer Agents Program

3. **Lenacapavir sodium (Sunlenca) Tablet and Vial**
   a. **Indication**: For use in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.
   b. **Decision**:

Lenacapavir vial for subcutaneous injection			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	N/A	N/A	N/A

* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: ibalizumab-uiyk (Trogarzo®), fostemsavir (Rukobia®)

Lenacapavir tablets			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: ibalizumab-uiyk (Trogarzo®), fostemsavir (Rukobia®)			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Sunlenca
MEDICATION NAME	Lenacapavir sodium tablet and vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new starts) all the following must be met: 1. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance, intolerance or contraindication to at least two antiretroviral medications in each of at least three following classes: a. Non-nucleoside reverse transcriptase inhibitor b. Nucleoside reverse transcriptase inhibitor c. Protease inhibitor

	d. Integrase strand-transfer inhibitor 2. Documentation current antiretroviral regimen has been stable for at least two months and current viral load is greater than or equal to 400 copies/mL 3. Confirmation that patient will take an optimized background regimen of antiretroviral therapy along with lenacapavir 4. Dose and frequency are in accordance with FDA-approved labeling For patients established on therapy, all the following must be met: 1. Patient is currently receiving treatment with lenacapavir 2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy) of at least 0.5 log10 copies/mL. Note: A decrease in viral load less than 0.5 log10 copies/mL may be considered if there is documentation that a M66I mutation has not occurred. 3. Confirmation that patient will continue to take an optimized background regimen of antiretroviral therapy 4. Dose and frequency are in accordance with FDA-approved labeling
AGE RESTRICTIONS	May be approved for patients aged eighteen years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an infectious disease specialist.
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

4. **Mosunetuzumab-axgb (Lunsumio) Vial**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Indication was approved under accelerated approval based on response rate. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: copanlisib di-hcl (Aliqopa®), tazemetostat (Tazverik®), axicabtagene ciloleucel (Yescarta®), tisagenlecleucel (Kymriah®)

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Add to the Injectable Anti-cancer Medications policy

5. **Pirtobrutinib (Jaypirca) Tablet**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives:			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications policy
   d. **Prior Authorization Criteria for Medicare Part D**: Added to Anti-cancer Agents Program

6. **Fecal microbiota, live-jslm (Rebyota) Enema**
   a. **Indication**: For the prevention of recurrence of *Clostridioides difficile (C. diff)* infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Rebyota® is not indicated for treatment of CDI.
   b. **Decision**:

	Commercial	Medicaid	Medicare

Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**:

PA PROGRAM NAME	Fecal Microbiota (Rebyota®)
MEDICATION NAME	Fecal Microbiota, live-jslm (Rebyota®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization for the prevention of recurrence of *Clostridioides difficile* infection (CDI) requires all the following criteria be met: 1. Confirmed diagnosis of recurrent CDI, defined as two or more recurrences after a primary episode. Episodes must have occurred less than eight weeks after completion of treatment for a previous episode. 2. Positive stool test for *C. difficile* within 30 days before prior authorization request 3. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days)
AGE RESTRICTIONS	Approved for ages 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist
COVERAGE DURATION	Authorization will be approved for one treatment course per primary episode. Subsequent requests must meet initial authorization criteria.

7. **Ublituximab-xiiy (Briumvi) Vial**
   a. **Indication**: For the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: ofatumumab, dimethyl fumarate, Aubagio®, Gilenya®			

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Revatio® (**sildenafil)
   a. Previous Indication(s):
      a. Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. Studies establishing effectiveness were short-term (12 to 16 weeks) and included predominately patients with NYHA Functional Class II-III symptoms. Etiologies were idiopathic (71%) or associated with connective tissue disease (25%).
   b. New indication approved 01/31/2023:
      a. Treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

2. **Tymlos® (**abaloparatide)
   a. Previous Indication(s):

a. Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy

b. New indication approved 12/19/2022:
   a. Treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The policy was updated as part of annual review and is included in the policy review section of the consent agenda vote.

3. **Vraylar® (cariprazine**)
   a. Previous Indication(s):
      a. Treatment of schizophrenia in adults
      b. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
      c. Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults
   b. New indication approved 12/16/2022:
      a. Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add to the below criteria:

Prior Authorization for Commercial:

PA PROGRAM NAME	Antipsychotics Step Therapy Policy
MEDICATION NAME	Vraylar
COVERED USES	3 - All Medically-Accepted Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	One of the following criteria must be met: a. The patient is currently established on therapy with the requested medication (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy) OR b. All the following indication-specific criteria must be met: i. For adjunctive treatment of major depressive disorder (Rexulti® or Vraylar(R)): 1. Documentation of current use of an antidepressant (for example:, citalopram, sertraline, paroxetine, duloxetine, mirtazapine, venlafaxine) AND

	2. Documented trial, failure, intolerance, or contraindication to quetiapine and aripiprazole
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

4. **Enjaymo®** (sutimlimab-jome)
    a. Previous Indication(s):
        a. To decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).
    b. New indication approved 01/25/2023:
        a. Treatment of hemolysis in adults with cold agglutinin disease (CAD)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

5. **Actemra®** (tocilizumab)
    a. Previous Indication(s):
        a. Rheumatoid Arthritis, Giant Cell Arteritis, Systemic Sclerosis-Associated Interstitial Lung Disease, Polyarticular Juvenile Idiopathic Arthritis, Systemic Juvenile Idiopathic Arthritis, Cytokine Release Syndrome
    b. New indication approved 12/21/2022:
        a. Coronavirus Disease 2019: Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

<u>Therapies with Prior Authorization Policies (Oncology)</u>

6. **Rubraca®** (rucaparib)
    a. New Indication(s) approved 12/21/2022:
        a. For the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

7. **Tukysa®** (tucatinib)
    a. New Indication(s) approved 01/19/2023:

a. In combination with trastuzumab for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

8. **Brukinsa®** (zanubrutinib)
   a. New Indication(s) approved 01/19/2023:
      a. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

9. **Keytruda®** (pembrolizumab)
   a. New Indication(s) approved 01/26/2023:
      a. As a single agent, for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 cm), II, or IIIA NSCLC
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

10. **Xelodanda®** (capecitabine)
    a. New Indication(s) approved 12/14/2022:
       a. Adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.
       b. Treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen.
       c. Treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen
       d. Adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen.
       e. Treatment of patients with advanced or metastatic breast cancer as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated.
       f. Treatment of patients with advanced or metastatic breast cancer in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy.
       g. Perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy
       h. treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

11. **Ibrance®** (palbociclib)
    a. New Indication(s) approved 12/13/2022:
        a. For the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
            1. an aromatase inhibitor as initial endocrine-based therapy or
            2. fulvestrant in patients with disease progression following endocrine therapy
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

12. **Pemfexy®** (pemetrexed)
    a. New Indication(s) approved 12/14/2022:
        a. In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC).
        b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

13. **Bortezomib generic**
    a. New Indication(s) approved 12/09/2022:
        a. Treatment of adult patients with mantle cell lymphoma (requirement to have received at least 1 prior therapy was removed)
        b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

14. **Tecentriq®** (atezolizumab)
    a. New Indication(s) approved 12/09/2022:
        a. For the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS
        b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

Therapies Without Prior Authorization Policies

15. **Cytalux® (**pafolacianine)
    a. Previous Indication(s):
        a. Optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions
    b. New indication(s) approved 12/16/2022:
        a. Optical imaging agent indicated as an adjunct for intraoperative identification of:
            1. Malignant lesions in adult patients with ovarian cancer.
            2. Malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

There were no drug safety communications reported during this period.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Quinapril 20 and 40 mg tablets
   - **Date of Recall:** 12/21/2022
   - **Reason for recall:** Presence of nitrosamine impurity, N-Nitroso-Quinapril in 4 lots.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-four-lots-quinapril-tablets-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** After Burn® Cream and First Aid Kits containing After Burn Cream
   - **Date of Recall:** 12/27/2022
   - **Reason for recall:** Product is contaminated with Bacillus licheniformis and Bacillus sonorensis.in one lot at the consumer level
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gfa-production-xiamen-co-ltd-issues-voluntary-nationwide-recall-easy-care-first-aidr-burn-cream-and
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Vancomycin Injection

- **Date of Recall:** 12/27/2022
- **Reason for recall:** Presence of Visible Glass Particulates in one lot
- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-one-lot-vancomycin-hydrochloride-injection-usp
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Vancomycin Injection
   - **Date of Recall:** 01/09/2023
   - **Reason for recall:** Product discoloration in three lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/spectrum-laboratory-products-inc-issues-voluntary-worldwide-recall-epinephrine-l-adrenaline-usp-bulk
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Adalimumab-atto (Amjevita) 40 mg/ 0.8 mL Syringe and Auto-injector	New Biosimilar (Humira®) • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1.6 mL per 28 days) • Medicare Part D: Non-Formulary	Therapeutic Immunomodulators (TIMS)
Adalimumab-atto (Amjevita) 20 mg/0.4mL Syringe	New Biosimilar (Humira®) – non-preferred • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (0.8 mL per 28 days) • Medicare Part D: Non-Formulary	Therapeutic Immunomodulators (TIMS)
Cortisone Acetate Tablet	• Non-formulary for all lines of business	N/A
Melphalan hcl-betadex sulfobutyl ether sodium (Evomela) Vial	• Medical Benefit, with Prior Authorization for all lines of business	Injectable Anti-Cancer Medications
Fingolimod lauryl sulfate (Tascenso ODT) UL - Tab Rapdis	• Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Tezepelumab-ekko (Tezspire) Pen Injctr	New Dosage Form (Pen Injctr);	• Commercial/Medicaid: Tezspire

	• Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Non-Formulary	• Medicare Part D: N/A
Levothyroxine sodium (Ermeza) Solution	New formulation (solution); • Non-formulary for all lines of business	N/A
Fluticasone-salmeterol HFA AER AD	First generic (Advair HFA); Non-formulary for all lines of business •	N/A
Osimertinib mesylate (Tagrisso)	Move to Tier 5 from Tier 6 for Commercial	Oral Anti-Cancer Agents
Oxybutynin chloride Syrup	Add to Medicare Part D Formulary, Tier 2	N/A
Ezetimibe-atorvastatin calcium Tablet	New MedID; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Humalog Junior Kwikpen (Insulin Lispro) Rx - Ins Pen HF	Add to Medicaid formulary	N/A
Parathyroid hormone (Natpara) Cartridge	Remove from Commercial and Medicaid formularies (drug will be no longer be manufactured in 2024)	N/A
Prednisolone (Millipred) Solution / Tablet	Remove from Medicaid formulary	N/A
Insulin glulisine (Apidra / Apidra Solostar) Vial / Insulin Pen	Add to Commercial Formulary, Tier 4, Prior Authorization	Non-Preferred Insulins
Testosterone (Axiron) Sol MD PMP	Add to formulary • Commercial Standard: Tier 2 • Commercial Dynamic: Tier 4 • Medicaid: Formulary • Medicare Part D: Tier 4	N/A
Lurasidone Hcl Tablet	First generic (Latuda). Add to formulary and remove step therapy requirement	Antipsychotics Step Therapy Policy

	• Commercial: Formulary, Tier 2, Quantity Limit (1 tablet per day) • Medicare Part D: Formulary, Tier 3, Quantity Limit (1 tablet per day)	
Palbociclib (Ibrance) Capsule/Tablet	Commercial/Medicaid: Add Quantity Limit (21 capsules/tablets per day)	Oral Anti-Cancer Medications
Abemaciclib (Verzenio) Tablet	Commercial/Medicaid: Add Quantity Limit (2 tablets per day)	Oral Anti-Cancer Medications
• **Ribociclib succinate (Kisqali) 200 mg Tablet** • **Ribociclib succinate (Kisqali) 400 mg Tablet** • **Ribociclib succinate (Kisqali) 600 mg Tablet** • **Ribociclib succinate/ letrozole (Kisqali Femara Co-Pack) 200-2.5 mg Tablet** • **Ribociclib succinate/ letrozole (Kisqali Femara Co-Pack) 400-2.5 mg Tablet** • **Ribociclib succinate/ letrozole (Kisqali Femara Co-Pack) 600-2.5 mg Tablet**	• Commercial/Medicaid: Add Quantity Limit (21 tablets per 28 days) • Commercial/Medicaid: Add Quantity Limit (42 tablets per 28 days) • Commercial/Medicaid: Add Quantity Limit (63 tablets per 28 days) • Commercial/Medicaid: Add Quantity Limit (49 tablets per 28 days) • Commercial/Medicaid: Add Quantity Limit (70 tablets per 28 days) • Commercial/Medicaid: Add Quantity Limit (63 tablets per 28 days)	Oral Anti-Cancer Medications
Pramlintide (Symlin)	Remove from Commercial and Medicaid formularies	N/A

The formulary status for the following drugs was line extended in accordance with Providence Health Plan Pharmacy Operational Policy ORPTCOPS062

Providence Health Plan

Providence Health Assurance

Drugs released from December, January, and February

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Pegfilgrastim-fpg (Stimufend) Syringe	Biosimilar to Neulasta. Line extend with Neulasta; • Commercial: Formulary, Tier 5 • Medicaid: Formulary, Specialty • Medicare Part D: Non-Formulary This medication is also covered under the medical benefit for all lines of business	N/A
Risankizumab-rzaa (Skyrizi) Wear Injct	New strength (180mg/1.2ml). Line extend with Skyrizi On-Body (360mg/2.4ml); • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2.4 per 56 days) • Medicaid: Non- Formulary, Specialty, Prior Authorization, Quantity Limit (2.4 per 56 days) • Medicare Part D or B?: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators (TIMS)
Pexidartinib hydrochloride (Turalio) Capsule	New strength (125mg). Line extend with Turalio 200mg capsule; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Voxelotor (Oxbryta) Tablet	New strength (300mg). Line extend with Oxbryta;	• Commercial/Medicaid: Oxbryta • Medicare Part D: N/A

	• Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (3 tablets per day) • Medicare Part D: Non-Formulary	
Rotavirus vac,live att, 89-12 Rotarix) Oral Susp	New dosage form (oral susp) and strength (10E6/1.5ml). Line extend with Rotarix Vaccine Suspension (GCN 27017): • Commercial: Preventive, Quantity Limit (1 dose per day / 2 doses per lifetime) • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Bevacizumab-adcd (Vegzelma) Vial	Biosimilar to Avastin. Non-preferred Biosimilar. Line extend with Avastin; • Medical PA for all lines of business	Injectable Anti-Cancer Medications
Lanadelumab-flyo (Takhzyro) Syringe	New Dosage form (syringe) and strength (150mg/ml). Line extend with Takhzyro 300mg/2ml; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 ml per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 ml per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 ml per 28 days)	Prophylactic Hereditary Angioedema Therapy
Apalutamide (Erleada) Tablet	New strength (240mg). Line extend with Erleada 60mg; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications

• **Treprostinil diolamine (Orenitram month 1 titration kt) TB ER DSPK** • **Treprostinil diolamine (Orenitram month 2 titration kt) TB ER DSPK** • **Treprostinil diolamine (Orenitram month 3 titration kt) TB ER DSPK**	New dosage form (TB ER DSPK) and strength. Line extend with Orenitram ER; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pulmonary Arterial Hypertension • Medicare Part D: N/A

New Generics:

Drug Name	Action Taken	Policy Name
Bendamustine hcl Vial	First generic (Treanda). Line extend as generic; • Medical Benefit with Prior Authorization for all of lines business	Injectable Anti-Cancer Medications
Diclofenac potassium Powd Pack	NDA authorized generic (Cambia). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (9 packets per 30 days) • Commercial Dynamic: Formulary, Tier 4, Prior Authorization, Quantity Limit (9 packets per 30 days) • Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (9 packets per 30 days) • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Cambia • Medicare Part D: N/A
Sodium oxybate Solution	First generic (Xyrem). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (18 ml per day) • Medicaid: Non- Formulary, Specialty, Prior Authorization, Quantity Limit (18 ml per day)	Narcolepsy Agents

	• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (18 ml per day)	
Brimonidine Tartrate Gel w/Pump	First generic (Mirvaso). Line extend as generic; • Non-Formulary for all lines of business	N/A
Tasimelteon Capsule	First generic (Hetlioz). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 capsule per day) • Medicaid: Non- Formulary, Specialty, Prior Authorization, Quantity Limit (1 capsule per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 capsule per day)	Hetlioz, Hetlioz LQ
Zolmitriptan (Zomig) 5 mg Tablet	Line extend as generic; • Commercial Standard: Formulary, Tier 2, Quantity Limit (9 tablets per 30 days) • Commercial Dynamic: Formulary, Tier 3, Quantity Limit (9 tablets per 30 days) • Medicaid: Formulary, Quantity Limit (9 tablets per 30 days) • Medicare Part D: Tier 3, Quantity Limit (9 tablets per 30 days)	N/A
Zolmitriptan (Zomig) 2.5 mg Tablet	Line extend as generic; • Commercial Standard: Formulary, Tier 2, Quantity Limit (12 tablets per 30 days) • Commercial Dynamic: Formulary, Tier 3, Quantity Limit (12 tablets per 30 days) • Medicaid: Formulary, Quantity Limit (12 tablets per 30 days)	N/A

	• Medicare Part D: Formulary, Tier 3, Quantity Limit (12 tablets per 30 days)	
Dichlorphenamide Tablet	First generic drug (Keveyis). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Medications For Rare Indications • Medicare Part D: N/A

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists	Nurtec ODT® was added as a preferred medication for both acute and prophylactic treatment of migraines. To limit medication overuse headaches, acute-use CGRPs will not be covered in combination with other abortive medications (e.g. triptans, ergotamine preparations)
Continuous Glucose Monitors for Personal Use - Medicare Part B	This policy was split from the Commercial/Medicaid policy, as the Centers for Medicaid and Medicare Services (CMS) has different requirements [based on the Local Coverage Determination (LCD) L33822]
Continuous Glucose Monitors for Personal Use	Criteria for use in diabetes were updated to align with the American Diabetes Association (ADA) Standards of Care 2023. Patients using any insulin therapy will be eligible for coverage. Additionally, criteria were added to allow coverage in cases of severe post-bariatric hypoglycemia. Medicare Part B was removed from this policy and will have a separate policy due to CMS requirements.
Enzyme Replacement Therapy	Brienura® added to Enzyme Replacement Therapy Policy and language updated for initial authorizations and reauthorizations to initiation of therapy (new starts) and reauthorizations/patients established on requested therapy.
GnRH Antagonists	Clarified diagnosis of endometriosis must be confirmed.
• **Hepatitis C - Direct Acting Antivirals – Medicaid** • **Hepatitis C - Direct Acting Antivirals**	Criteria were added for use of Mavyret® for patients undergoing heart transplant with viremic donor heart
Kerendia	Updated criteria to define adequate trial of prerequisite therapy.
Medical Nutrition – Comm	Criteria for coverage of Relizorb® and an exclusion for coverage of oral thickening agents was added to the policy. The policy was also updated for operational efficiency;

	certain diagnosis codes will be set up to automatically pay when the claim is submitted due to low risk of inappropriate utilization (such as head and neck cancer).
Medical Nutrition – Medicaid	Criteria for coverage of Relizorb® was added to the policy. The policy was also updated for operational efficiency; certain diagnosis codes will be set up to automatically pay when the claim is submitted due to low risk of inappropriate utilization (such as head and neck cancer).
Medical Nutrition - Medicare Part B	Added exclusion of oral administration of enteral nutrition due to CMS requirements. The policy was also updated for operational efficiency; certain diagnosis codes will be set up to automatically pay when the claim is submitted due to low risk of inappropriate utilization (such as head and neck cancer).
Osteoanabolic Agents	Updated policy criteria for teriparatide to align with new indication for males.
Pituitary Disorder Therapies **Somatostatin Analogs – Medicare Part B**	Added carcinoid syndromes as a covered condition.
Self-Administered Drug (SAD) Exclusion Clinical Policy	Including the word "exclusion" in the policy title was causing confusion, so removed. Several drugs are being removed from the policy as the health plan does not see medical administration of these therapies. Two drugs were added to this policy: 1) tezepelumab-ekko (Tezspire®) and 2) sarilumab (Kevzara®)
SGLT-2 Inhibitors – Medicaid	Simplified criteria significantly to align with the Oregon Health Authority coverage criteria. These agents will be covered for patients with a trial of metformin (for type 2 diabetes) or for other FDA-approved indication.
Strensiq	Added criteria to confirm dosing is within the FDA approved labeled dose.
Tepezza - Medicare Part B	This policy was split from the Commercial/Medicaid policy as it is considered a Medicare Part B Step Therapy program.
Tepezza	Updated criteria to align with the updated recommendations from the American Thyroid Association and the European Thyroid Association Consensus Statement. Updates include trial and failure criteria and criteria to confirm dosing.
Testosterone Replacement Therapy (TRT) - Medicare Part B	Updated criteria to align with Medicare local coverage determination (LCD) 36539. Specifically added criteria to confirm presence of symptoms in setting of low testosterone and reauthorization criteria ensuring ongoing monitoring of hormone levels.
Testosterone Replacement Therapy (TRT)	Policy trial and failure criteria updated to require oral testosterone product Kyzatrex® for requests for other oral products.
Tolvaptan	Prescriber restrictions updated to include cardiologist and endocrinologist.
Voxzogo	Added exclusion criteria (person must be ambulatory and stand without assistance) to reauthorization.

Weight Maintenance Medications	This policy is for Commercial groups that have elected to cover weight maintenance medications. It was updated to remove requirement for enrollment in a weight loss program, raise the body mass index (BMI) cutoffs for treatment, and provide additional BMI considerations for race/ethnicity and pediatric patients.

RETIRED POLICIES	
Policy Name	**Summary of Change**
Brineura	Combined with Enzyme Replacement policy
• **Galafold** • **Myalept** • **Xuriden**	Combined with Medications for Rare Indications policy
Hectorol, Zemplar Step Therapy Policy	Due to low utilization and low risk for overutilization
Millipred	Due low utilization
Natpara	Due to low utilization and drug is being discontinued in 2024
SymlinPen	Due low utilization