

# Healthcare Services Medical & Pharmacy Policy Alerts

Number 83

June 1, 2023

This is the **June 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](mailto:PHPmedicalpolicyinquiry@providence.org) with your name, specialty, and preferred email address.

## MEDICAL POLICY COMMITTEE

**NOTICE: Anesthesia Care with Diagnostic Endoscopy**

*Providence Health Plan has made the decision to remove our PA requirements for all lines of business for anesthesia care with diagnostic endoscopy (CPT codes: 00731, 00732 and 00811). PA configuration and medical policy updates have now been completed.*

### MEDICAL

#### COMPANY POLICIES

Effective 7/1/2023

<p><b>Back: Sacroiliac Joint Fusion or Stabilization</b></p> <p><b>MP24</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>• Added criterion III.A, clarifying which percutaneous SIJ fusion systems are considered medically necessary: “Device is placed across the SI joint (i.e., transfixing device) and intended to promote fusion.”</li> <li>• In criterion IV, added clarification language that devices that do not transfix the SI joint are not medically necessary.</li> <li>• Added 2 figures in Policy Guidelines to illustrate the difference between devices that meet medically necessary criteria vs those that do not</li> <li>• Added Billing guidelines to specify which code should be billed with which percutaneous device.</li> <li>• In Table 1, FDA-Approved devices, created column with type of device/implant and technique.</li> </ul> <p><b>Codes/PA:</b> Added 0809T to deny as not medically necessary.</p>
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	<p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
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Effective 8/1/2023

<p><b>Back: Intradiscal Procedures for Low Back Pain</b></p> <p><b>MP20</b></p>	<p><b>Policy Updates:</b> Changed denial language from investigational to not medically necessary for thermal and non-thermal intradiscal procedures.</p> <p><b>Codes/PA:</b> Changed configuration of codes 22526 and 22527 to deny as not medically necessary</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Chemoresistance and Chemosensitivity Assays</b></p> <p><b>MP121</b></p>	<p><b>Policy Updates:</b> Updated noncoverage from investigational to not medically necessary (NMN)</p> <p><b>Codes/PA:</b> Investigational denial changed to NMN (CPTs: 0083U, 0248U, 0564T, 81535, 81536, 86849)</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Nerve Conduction Studies</b></p> <p><b>MP129</b></p>	<p><b>Policy Updates:</b> Changed denial from investigational to not medically necessary</p> <p><b>Codes/PA:</b> Changed denial for 7 codes to NMN.</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Vectra DA Test for Rheumatoid Arthritis</b></p>	<p><b>Policy Updates:</b> Updated noncoverage from investigational to not medically necessary (NMN).</p> <p><b>Codes/PA:</b> Investigational denial changed to NMN (CPT: 81490)</p>

<p><b>MP120</b></p>	<p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Hysterectomy for Benign Conditions</b></p> <p><b>MP286</b></p>	<p><b>Policy Updates:</b> No changes to criteria.</p> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"> <li>• Request that approved diagnosis codes trigger PA when billed from any position (not just primary) with CPT codes for hysterectomy.</li> <li>• Per Claims review, updated the list of diagnosis codes that require PA:             <ul style="list-style-type: none"> <li>○ <b>Removed:</b> <ul style="list-style-type: none"> <li>▪ D060 – Carcinoma in situ of endocervix</li> <li>▪ N730 - Acute parametritis and pelvic cellulitis</li> <li>▪ N731 - Chronic parametritis and pelvic cellulitis</li> <li>▪ N732 – Unspecified parametritis and pelvic cellulitis</li> <li>▪ N733 – Female acute pelvic peritonitis</li> <li>▪ N836 – Hematosalpinx</li> <li>▪ N837 – Hematoma of broad ligament</li> </ul> </li> <li>○ <b>Added:</b> <ul style="list-style-type: none"> <li>▪ N393 – Stress incontinence</li> <li>▪ N3946 – mixed incontinence</li> </ul> </li> </ul> </li> </ul> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing</b></p> <p><b>MP219</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>• Changed denials from investigational to not medically necessary for criteria III-VI</li> <li>• Added criterion IV, stating that repeat testing for the same germline genetic content is not medically necessary.</li> <li>• Removed Oncomap ExTra from and added Pgxome Prenatal to list of non-covered panels</li> </ul> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"> <li>• Removed code 0329U (will be added to NGS policy)</li> <li>• Codes 0012U-0014U and 0056U termed on 9/30/2022</li> </ul> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>

<p><b>NanoKnife System: Irreversible Electroporation (IRE)</b></p> <p><i>Previously All Lines of Business</i></p> <p><b>MP154</b></p>	<p><b>Policy Updates:</b> Changed denial type from “investigational” to “not medically necessary.” Removed Medicare line of business. <b>Codes/PA:</b> Changed denial type from “investigational” to “not medically necessary” for 0600T and 0601T.</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Sleep Disorder Treatment: Positive Airway Pressure</b></p> <p><b>MP56</b></p>	<p><b>Policy Updates:</b> Added medical necessity criteria addressing adaptive servo-ventilation devices (criterion IX). <b>Codes/PA:</b> No changes to codes/PA.</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.</p>
<p><b>Varicose Veins</b></p> <p><b>MP182</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>• Updated criteria for CPT 0524T- KAVS</li> <li>• Removal of PA from S2202. Note in Billing Guidance that additional code is needed.</li> <li>• Changed those with investigational denial to NMN denial.</li> </ul> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"> <li>• Changed E/I to NMN for codes: 0524T,36473, 36474</li> <li>• Removal of PA for S2202. Must process with another code per Coding policy 22.0</li> </ul> <p><b>OHP:</b> OHP will follow the Company Policy above</p>

## MEDICARE

Effective 6/1/23

<p><b>Back: Discography</b></p> <p><b>MP391</b></p>	<p><b>New Medicare Advantage medical policy</b></p> <p><b>Policy Update:</b> New Medicare Advantage medical policy, separating by line of business. No change to criteria, continue to use Company criteria.</p> <p><b>Codes/PA:</b> No changes to codes or configuration.</p>
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Effective 7/1/23

<p><b>Back: Stabilization Devices and Interspinous Spacers</b></p> <p><b>MP392</b></p>	<p><b>New Medicare Advantage medical policy</b></p> <p><b>Policy Update:</b> New Medicare Advantage medical policy, separating by line of business. No change to criteria, continue to use Company criteria.</p> <p><b>Codes/PA:</b> No changes to codes or configuration.</p>
<p><b>Cochlear Implants and Auditory Brainstem Implants</b></p> <p><b>MP189</b></p>	<p><b>Policy Update:</b> Minor changes to the policy.</p> <ul style="list-style-type: none"> <li>• Added note above criteria that policy doesn't apply to BAHA devices.</li> <li>• Replaced decision memo with updated NCD for 2022 cochlear implant coverage changes.</li> <li>• Replaced Company criteria with Medicare references for auditory brainstem implants. This also meant removing Company-related Policy Guideline content.</li> <li>• Since some NCD coverage relies on study or trial participation, added a list of IDE studies to the Policy Guidelines section.</li> <li>• Updated Billing Guidelines.</li> </ul> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"> <li>• Added L9900 to the policy as a relevant code, but no change to current configuration.</li> <li>• Removed L8694 from the policy code table, removed PA for this code (this code is specific to BAHA devices, while the policy excludes BAHA devices).</li> <li>• Added unlisted code 69949, which may be used in place of S2235.</li> <li>• No change to other codes in the policy or their respective configuration.</li> </ul>

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Effective 8/1/23

<p><b>NanoKnife System: Irreversible Electroporation (IRE)</b></p> <p><b>MP393</b></p>	<p><b>New Medicare Advantage medical policy</b></p> <p><b>Policy Update:</b> New Medicare Advantage medical policy, separating by line of business. No change to criteria, continue to use Company criteria.</p> <p><b>Codes/PA:</b> No changes to codes or configuration.</p>
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**REIMBURSEMENT POLICIES**

Effective 6/1/2023

<p><b>Ambulatory Surgery Center (ASC) Reimbursement</b></p> <p><b>RP3</b></p>	<p><b>New Reimbursement policy</b></p> <p><b>Recommendation:</b> Converting Coding Policy 74.0 to a Reimbursement Policy since the policy is primarily a reimbursement-related topic. Will now be under the reimbursement policy team for continued policy management.</p> <p><b>Reimbursement Methodology:</b> No change to current reimbursement methodology; continue to follow CMS guidelines for ambulatory surgical centers (ASCs). Limited exceptions may be made for services not allowed by CMS in an ASC, but these are limited to Commercial (non-Medicare and non-Medicaid) plan members only.</p> <p><b>Relevant References/CMS Guidance:</b></p> <ul style="list-style-type: none"> <li>• Local Medicare Contractor (MAC) – Noridian Healthcare Solutions – web page for Ambulatory Surgical Center (ASC)</li> <li>• Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual, Chapter 14 - Ambulatory Surgical Centers, §10.2 - Ambulatory Surgical Center Services on ASC List</li> <li>• Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services</li> <li>• Medicare Ambulatory Surgical Center Payment- Notice of Final Rulemaking with Comment Period (NFRM) (CMS-1772-FC)</li> </ul>
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<p><b>Birth Center Services</b></p> <p><b>RP2</b></p>	<p><b>New Reimbursement policy</b></p> <p><b>Recommendation:</b> Converting Coding Policy 84.0 to a Reimbursement Policy since the policy is primarily a reimbursement-related topic. Will now be under the reimbursement policy team for continued policy management.</p> <p><b>Reimbursement Methodology:</b> No change to current methodology.</p> <p><b>Relevant References/CMS Guidance:</b></p> <ul style="list-style-type: none"> <li>• Under Medicare, Birth Center Services are not eligible to participate in the Medicare program. Therefore, rather than coming from CMS, much of the information comes from other sources, specifically the Oregon Health Authority (OHA) and PHP medical directors.             <ul style="list-style-type: none"> <li>○ Oregon Health Authority, Health Systems Division: Medical Assistance Programs - Chapter 410, Division 130, MEDICAL-SURGICAL SERVICES</li> <li>○ Oregon Health Authority. "Ambulatory Surgical Center and Birth Center Services." Medical-Surgical Services Administrative Rulebook, Chapter 410, Division 130. Effective January 1, 2016. 410-130-0365, pp 40-41.</li> </ul> </li> </ul>

## VENDOR UPDATES

<p><b>Carelon (formerly AIM) Radiology Guidelines</b></p>	<p><b>Annual Update</b></p> <p><b>Changes to current criteria:</b></p> <ul style="list-style-type: none"> <li>• <b><u>Imaging of the Extremities</u></b> <ul style="list-style-type: none"> <li>○ Acute traumatic injuries – not otherwise specified                 <ul style="list-style-type: none"> <li>▪ Added small clarification regarding patients in whom advanced imaging of suspected calcaneal fractures is indicated.</li> </ul> </li> <li>○ Shoulder arthroplasty, presurgical planning                 <ul style="list-style-type: none"> <li>▪ Clarified that MRI should not be used for preoperative assessment of bone stock and bone version.</li> </ul> </li> </ul> </li> <li>• <b><u>Imaging of the Spine</u></b> <ul style="list-style-type: none"> <li>○ Spinal infection                 <ul style="list-style-type: none"> <li>▪ Added criterion for imaging in patients at risk for infection, based on ACR appropriate use criteria.</li> </ul> </li> </ul> </li> </ul>
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- Cervical injury
  - Added language to clarify modality appropriateness
- Radiculopathy
  - Added indication for CT being done as a CT myelogram, based on ACR rating of may be appropriate.
- **Vascular Imaging**
  - Procedure-related Imaging
    - Vascular anatomic delineation prior to surgical and interventional procedures, not otherwise specified
      - Removed to align with added allowances below for Duplex carotid and CTA/MRA neck.
    - Vascular evaluation prior to transcatheter aortic valve implantation/replacement (TAVI/TAVR)
      - Allow CT in addition to CTA for prep TAVR evaluation (contrast-enhanced CT sufficient for evaluation).
  - Brain, Head and Neck
    - Stenosis or occlusion, extracranial carotid arteries
      - Screening: Limitation to preoperative evaluation prior to cardiac surgery .
      - Management: Clarification to allow follow-up per current ACC guidelines (addresses content gap for allowable 9-12 month eval).
  - Chest
    - Pulmonary artery hypertension
      - Clarification of heading indication and allowance for evaluation of suspected PH (any etiology).
  - Abdomen and Pelvis
    - Unexplained hypotension
      - Removal of indication more appropriate for inpatient assessment.
    - Venous thrombosis or occlusion
      - Addition of Duplex ultrasound as a modality option (no content change - allowance currently operationalized in system).
  - Lower Extremity
    - Peripheral arterial disease (PAD)
      - Removal of cilostazol as prerequisite therapy (specialty panel feedback). Addition of baseline evaluation & surveillance indications post endovascular revascularization.
      - Addition of diagnosis/management and unrepaired surveillance scenarios, the latter aligned with SVS guidelines.

**Codes/PA:** No changes to codes or configuration

**Effective date:** 9/10/2023

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

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### Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting

#### Special Announcement

Tezspire® (tezepelumab-ekko) and Kevzara® (sarilumab) were added to the "Self-Administered Drug policy and will be in effect beginning **July 1, 2023**.

To ensure adequate monitoring and teaching, there is a 60-day transition period for the provider to be able to administer the drug in their office. After the 60-days, the drug is only able to be obtained as a pharmacy benefit through a specialty pharmacy.

Starting July 1st, Tezspire® (Tezepelumab-ekko) and Kevzara® (sarilumab) will not be covered under the member's medical benefit ("incident-to" a healthcare provider visit) unless a prior authorization has been approved. Administration fees associated with these two self-administered drugs will also not be covered.

If you have determined that it is medically necessary for your patient to continue receiving this drug in your office, please submit a prior authorization, including clinical documentation of medical necessity, to the health plan.

### **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.

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**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:**

	<b>Commercial</b>	<b>Medicaid</b>	<b>Medicare</b>
<b>Formulary Status*</b>	Formulary	Formulary	Part D: Formulary Part B: N/A
<b>Tier**</b>	Tier 6 - Non-Preferred Specialty	N/A	Specialty
<b>Affordable Care Act Eligible</b>	No	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	Prior Authorization
<b>Quantity Limit</b>	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
<b>Formulary Status*</b>	Formulary	Formulary	Part D: Formulary Part B: N/A
<b>Tier**</b>	Tier 6 - Non-Preferred Specialty	N/A	Specialty
<b>Affordable Care Act Eligible</b>	No	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	Prior Authorization
<b>Quantity Limit</b>			
<p>* Recommendations for placement may differ between lines of business due to regulatory requirements.</p> <p>** 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).</p>			
<b>Formulary Alternatives:</b>			

- 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
<b>Formulary Status*</b>	Medical	Medical	Part D: Non-formulary Part B: Medical
<b>Tier**</b>	N/A	N/A	N/A
<b>Affordable Care Act Eligible</b>	N/A; Non-Formulary	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	N/A
<b>Quantity Limit</b>	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
<b>Formulary Status*</b>	Formulary	Formulary	Part D: Formulary Part B: N/A
<b>Tier**</b>	Tier 6 - Non-Preferred Specialty	N/A	Specialty
<b>Affordable Care Act Eligible</b>	No	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	N/A
<b>Quantity Limit</b>	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	<p>For initiation of therapy (new starts) all the following must be met:</p> <ol style="list-style-type: none"> <li>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:               <ol style="list-style-type: none"> <li>a. Non-nucleoside reverse transcriptase inhibitor</li> <li>b. Nucleoside reverse transcriptase inhibitor</li> <li>c. Protease inhibitor</li> </ol> </li> </ol>

	<p>d. Integrase strand-transfer inhibitor</p> <ol style="list-style-type: none"> <li>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</li> <li>3. Confirmation that patient will take an optimized background regimen of antiretroviral therapy along with lenacapavir</li> <li>4. Dose and frequency are in accordance with FDA-approved labeling</li> </ol> <p>For patients established on therapy, all the following must be met:</p> <ol style="list-style-type: none"> <li>1. Patient is currently receiving treatment with lenacapavir</li> <li>2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy) of at least 0.5 log<sub>10</sub> copies/mL. Note: A decrease in viral load less than 0.5 log<sub>10</sub> copies/mL may be considered if there is documentation that a M66I mutation has not occurred.</li> <li>3. Confirmation that patient will continue to take an optimized background regimen of antiretroviral therapy</li> <li>4. Dose and frequency are in accordance with FDA-approved labeling</li> </ol>
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
<b>Formulary Status*</b>	Medical	Medical	Part D: Non-formulary Part B: Medical
<b>Tier**</b>	N/A	N/A	N/A
<b>Affordable Care Act Eligible</b>	N/A; Non-Formulary	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	Prior Authorization
<b>Quantity Limit</b>	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
<b>Formulary Status*</b>	Formulary	Formulary	Part D: Formulary Part B: N/A
<b>Tier**</b>	Tier 6 - Non-Preferred Specialty	N/A	Specialty
<b>Affordable Care Act Eligible</b>	No	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	Prior Authorization
<b>Quantity Limit</b>	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



<b>Formulary Status*</b>	Medical	Medical	Part D: Non-formulary Part B: Medical
<b>Tier**</b>	N/A	N/A	N/A
<b>Affordable Care Act Eligible</b>	No	N/A	N/A
<b>Utilization Management Edits</b>	Prior Authorization	Prior Authorization	Prior Authorization
<b>Quantity Limit</b>	N/A	N/A	N/A
<p>* Recommendations for placement may differ between lines of business due to regulatory requirements.</p> <p>** 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).</p>			
<b>Formulary Alternatives:</b> 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	<p>Initial authorization for the prevention of recurrence of <i>Clostridioides difficile</i> infection (CDI) requires all the following criteria be met:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Positive stool test for <i>C. difficile</i> within 30 days before prior authorization request</li> <li>3. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days)</li> </ol>
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
<b>Formulary Status*</b>	Medical	Medical	Part D: Non-formulary Part B: Medical
<b>Tier**</b>	N/A	N/A	N/A
<b>Affordable Care Act Eligible</b>	No	N/A	N/A
<b>Utilization Management Edits</b>	N/A	N/A	N/A
<b>Quantity Limit</b>	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).			
<b>Formulary Alternatives:</b> ofatumumab, dimethyl fumarate, Aubagio®, Gilenya®			

New Indications:

<p><u>Therapies with Prior Authorization Policies (Non-oncology)</u></p> <p>1. <b>Revatio®</b> (sildenafil)</p> <ul style="list-style-type: none"> <li>a. Previous Indication(s): <ul style="list-style-type: none"> <li>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%).</li> </ul> </li> <li>b. New indication approved 01/31/2023: <ul style="list-style-type: none"> <li>a. Treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.</li> </ul> </li> <li>c. <b>RECOMMENDATION:</b> Inform prescribers via Medical Policy Alert. Update policy with new indication.</li> </ul> <p>2. <b>Tymlos®</b> (abaloparatide)</p> <ul style="list-style-type: none"> <li>a. Previous Indication(s):</li> </ul>
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- 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	<p>One of the following criteria must be met:</p> <ul style="list-style-type: none"> <li>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</li> <li>b. All the following indication-specific criteria must be met:           <ul style="list-style-type: none"> <li>i. For adjunctive treatment of major depressive disorder (Rexulti® or Vraylar(R)):               <ul style="list-style-type: none"> <li>1. Documentation of current use of an antidepressant (for example:, citalopram, sertraline, paroxetine, duloxetine, mirtazapine, venlafaxine) AND</li> </ul> </li> </ul> </li> </ul>

	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.

Therapies with Prior Authorization Policies (Oncology)

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  $\geq$ 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
<b>Adalimumab-atto (Amjevita) 40 mg/ 0.8 mL Syringe and Auto-injector</b>	New Biosimilar (Humira®) <ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1.6 mL per 28 days)</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Adalimumab-atto (Amjevita) 20 mg/0.4mL Syringe</b>	New Biosimilar (Humira®) – non-preferred <ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (0.8 mL per 28 days)</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Cortisone Acetate Tablet</b>	<ul style="list-style-type: none"> <li>• Non-formulary for all lines of business</li> </ul>	N/A
<b>Melphalan hcl-betadex sulfobutyl ether sodium (Evomela) Vial</b>	<ul style="list-style-type: none"> <li>• Medical Benefit, with Prior Authorization for all lines of business</li> </ul>	Injectable Anti-Cancer Medications
<b>Fingolimod lauryl sulfate (Tascenso ODT) UL - Tab Rapdis</b>	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Prior Authorization</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: New Medications and Formulations without Established Benefit</li> <li>• Medicare Part D: N/A</li> </ul>
<b>Tezepelumab-ekko (Tezspire) Pen Injctr</b>	New Dosage Form (Pen Injctr);	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: Tezspire</li> </ul>



	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Medicare Part D: N/A</li> </ul>
<b>Levothyroxine sodium (Ermeza) Solution</b>	New formulation (solution); <ul style="list-style-type: none"> <li>Non-formulary for all lines of business</li> </ul>	N/A
<b>Fluticasone-salmeterol HFA AER AD</b>	First generic (Advair HFA); Non-formulary for all lines of business <ul style="list-style-type: none"> <li></li> </ul>	N/A
<b>Osimertinib mesylate (Tagrisso)</b>	Move to Tier 5 from Tier 6 for Commercial	Oral Anti-Cancer Agents
<b>Oxybutynin chloride Syrup</b>	Add to Medicare Part D Formulary, Tier 2	N/A
<b>Ezetimibe-atorvastatin calcium Tablet</b>	New MedID; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: New Medications and Formulations without Established Benefit</li> <li>Medicare Part D: N/A</li> </ul>
<b>Humalog Junior Kwikpen (Insulin Lispro) Rx - Ins Pen HF</b>	Add to Medicaid formulary	N/A
<b>Parathyroid hormone (Natpara) Cartridge</b>	Remove from Commercial and Medicaid formularies (drug will be no longer be manufactured in 2024)	N/A
<b>Prednisolone (Millipred) Solution / Tablet</b>	Remove from Medicaid formulary	N/A
<b>Insulin glulisine (Apidra / Apidra Solostar) Vial / Insulin Pen</b>	Add to Commercial Formulary, Tier 4, Prior Authorization	Non-Preferred Insulins
<b>Testosterone (Axiron) Sol MD PMP</b>	Add to formulary <ul style="list-style-type: none"> <li>Commercial Standard: Tier 2</li> <li>Commercial Dynamic: Tier 4</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Tier 4</li> </ul>	N/A
<b>Lurasidone Hcl Tablet</b>	First generic (Latuda). Add to formulary and remove step therapy requirement	Antipsychotics Step Therapy Policy

	<ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 2, Quantity Limit (1 tablet per day)</li> <li>Medicare Part D: Formulary, Tier 3, Quantity Limit (1 tablet per day)</li> </ul>	
<b>Palbociclib (Ibrance) Capsule/Tablet</b>	Commercial/Medicaid: Add Quantity Limit (21 capsules/tablets per day)	Oral Anti-Cancer Medications
<b>Abemaciclib (Verzenio) Tablet</b>	Commercial/Medicaid: Add Quantity Limit (2 tablets per day)	Oral Anti-Cancer Medications
<ul style="list-style-type: none"> <li><b>Ribociclib succinate (Kisqali) 200 mg Tablet</b></li> <li><b>Ribociclib succinate (Kisqali) 400 mg Tablet</b></li> <li><b>Ribociclib succinate (Kisqali) 600 mg Tablet</b></li> <li><b>Ribociclib succinate/ letrozole (Kisqali Femara Co-Pack) 200-2.5 mg Tablet</b></li> <li><b>Ribociclib succinate/ letrozole (Kisqali Femara Co-Pack) 400-2.5 mg Tablet</b></li> <li><b>Ribociclib succinate/ letrozole (Kisqali Femara Co-Pack) 600-2.5 mg Tablet</b></li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Add Quantity Limit (21 tablets per 28 days)</li> <li>Commercial/Medicaid: Add Quantity Limit (42 tablets per 28 days)</li> <li>Commercial/Medicaid: Add Quantity Limit (63 tablets per 28 days)</li> <li>Commercial/Medicaid: Add Quantity Limit (49 tablets per 28 days)</li> <li>Commercial/Medicaid: Add Quantity Limit (70 tablets per 28 days)</li> <li>Commercial/Medicaid: Add Quantity Limit (63 tablets per 28 days)</li> </ul>	Oral Anti-Cancer Medications
<b>Pramlintide (Symlin)</b>	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

Drugs released from December, January, and February

**INFORMATIONAL ONLY**

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
<b>Pegfilgrastim-fpg (Stimufend) Syringe</b>	<p>Biosimilar to Neulasta. Line extend with Neulasta;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 5</li> <li>Medicaid: Formulary, Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul> <p>This medication is also covered under the medical benefit for all lines of business</p>	N/A
<b>Risankizumab-rzaa (Skyrizi) Wear Injct</b>	<p>New strength (180mg/1.2ml). Line extend with Skyrizi On-Body (360mg/2.4ml);</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2.4 per 56 days)</li> <li>Medicaid: Non- Formulary, Specialty, Prior Authorization, Quantity Limit (2.4 per 56 days)</li> <li>Medicare Part D or B?: Formulary, Tier 5, Prior Authorization</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Pexidartinib hydrochloride (Turalio) Capsule</b>	<p>New strength (125mg). Line extend with Turalio 200mg capsule;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization</li> <li>Medicaid: Formulary, Specialty, Prior Authorization</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization</li> </ul>	Oral Anti-Cancer Medications
<b>Voxelotor (Oxbryta) Tablet</b>	<p>New strength (300mg). Line extend with Oxbryta;</p>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Oxbryta</li> <li>Medicare Part D: N/A</li> </ul>

	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (3 tablets per day)</li> <li>Medicare Part D: Non-Formulary</li> </ul>	
<b>Rotavirus vac, live att, 89-12 Rotarix) Oral Susp</b>	<p>New dosage form (oral susp) and strength (10E6/1.5ml). Line extend with Rotarix Vaccine Suspension (GCN 27017):</p> <ul style="list-style-type: none"> <li>Commercial: Preventive, Quantity Limit (1 dose per day / 2 doses per lifetime)</li> <li>Medicaid: Non-Formulary</li> <li>Medicare Part D: Formulary, Tier 3</li> </ul>	N/A
<b>Bevacizumab-adcd (Vegzelma) Vial</b>	<p>Biosimilar to Avastin. Non-preferred Biosimilar. Line extend with Avastin;</p> <ul style="list-style-type: none"> <li>Medical PA for all lines of business</li> </ul>	Injectable Anti-Cancer Medications
<b>Lanadelumab-flyo (Takhzyro) Syringe</b>	<p>New Dosage form (syringe) and strength (150mg/ml). Line extend with Takhzyro 300mg/2ml;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 ml per 28 days)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (2 ml per 28 days)</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 ml per 28 days)</li> </ul>	Prophylactic Hereditary Angioedema Therapy
<b>Apalutamide (Erleada) Tablet</b>	<p>New strength (240mg). Line extend with Erleada 60mg;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization</li> <li>Medicaid: Formulary, Prior Authorization, Specialty</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization</li> </ul>	Oral Anti-Cancer Medications

<ul style="list-style-type: none"> <li>• <b>Treprostinil diolamine (Orenitram month 1 titration kt) TB ER DSPK</b></li> <li>• <b>Treprostinil diolamine (Orenitram month 2 titration kt) TB ER DSPK</b></li> <li>• <b>Treprostinil diolamine (Orenitram month 3 titration kt) TB ER DSPK</b></li> </ul>	<p>New dosage form (TB ER DSPK) and strength. Line extend with Orenitram ER;</p> <ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: Pulmonary Arterial Hypertension</li> <li>• Medicare Part D: N/A</li> </ul>
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### New Generics:

Drug Name	Action Taken	Policy Name
<b>Bendamustine hcl Vial</b>	<p>First generic (Treanda). Line extend as generic;</p> <ul style="list-style-type: none"> <li>• Medical Benefit with Prior Authorization for all of lines business</li> </ul>	Injectable Anti-Cancer Medications
<b>Diclofenac potassium Powd Pack</b>	<p>NDA authorized generic (Cambia). Line extend as generic;</p> <ul style="list-style-type: none"> <li>• Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (9 packets per 30 days)</li> <li>• Commercial Dynamic: Formulary, Tier 4, Prior Authorization, Quantity Limit (9 packets per 30 days)</li> <li>• Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (9 packets per 30 days)</li> <li>• Medicare Part D: Non- Formulary</li> </ul>	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: Cambia</li> <li>• Medicare Part D: N/A</li> </ul>
<b>Sodium oxybate Solution</b>	<p>First generic (Xyrem). Line extend as generic;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (18 ml per day)</li> <li>• Medicaid: Non- Formulary, Specialty, Prior Authorization, Quantity Limit (18 ml per day)</li> </ul>	Narcolepsy Agents

	<ul style="list-style-type: none"> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (18 ml per day)</li> </ul>	
<b>Brimonidine Tartrate Gel w/Pump</b>	<p>First generic (Mirvaso). Line extend as generic;</p> <ul style="list-style-type: none"> <li>Non-Formulary for all lines of business</li> </ul>	N/A
<b>Tasimelteon Capsule</b>	<p>First generic (Hetlioz). Line extend as generic;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 capsule per day)</li> <li>Medicaid: Non- Formulary, Specialty, Prior Authorization, Quantity Limit (1 capsule per day)</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 capsule per day)</li> </ul>	Hetlioz, Hetlioz LQ
<b>Zolmitriptan (Zomig) 5 mg Tablet</b>	<p>Line extend as generic;</p> <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 2, Quantity Limit (9 tablets per 30 days)</li> <li>Commercial Dynamic: Formulary, Tier 3, Quantity Limit (9 tablets per 30 days)</li> <li>Medicaid: Formulary, Quantity Limit (9 tablets per 30 days)</li> <li>Medicare Part D: Tier 3, Quantity Limit (9 tablets per 30 days)</li> </ul>	N/A
<b>Zolmitriptan (Zomig) 2.5 mg Tablet</b>	<p>Line extend as generic;</p> <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 2, Quantity Limit (12 tablets per 30 days)</li> <li>Commercial Dynamic: Formulary, Tier 3, Quantity Limit (12 tablets per 30 days)</li> <li>Medicaid: Formulary, Quantity Limit (12 tablets per 30 days)</li> </ul>	N/A

	<ul style="list-style-type: none"> <li>Medicare Part D: Formulary, Tier 3, Quantity Limit (12 tablets per 30 days)</li> </ul>	
<b>Dichlorphenamide Tablet</b>	<p>First generic drug (Keveyis). Line extend as generic;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Medications For Rare Indications</li> <li>Medicare Part D: N/A</li> </ul>

### Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	Summary of Change
<b>Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists</b>	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)
<b>Continuous Glucose Monitors for Personal Use - Medicare Part B</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]
<b>Continuous Glucose Monitors for Personal Use</b>	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.
<b>Enzyme Replacement Therapy</b>	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.
<b>GnRH Antagonists</b>	Clarified diagnosis of endometriosis must be confirmed.
<ul style="list-style-type: none"> <li><b>Hepatitis C - Direct Acting Antivirals – Medicaid</b></li> <li><b>Hepatitis C - Direct Acting Antivirals</b></li> </ul>	Criteria were added for use of Mavyret® for patients undergoing heart transplant with viremic donor heart
<b>Kerendia</b>	Updated criteria to define adequate trial of prerequisite therapy.
<b>Medical Nutrition – Comm</b>	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).
<b>Medical Nutrition – Medicaid</b>	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).
<b>Medical Nutrition - Medicare Part B</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).
<b>Osteoanabolic Agents</b>	Updated policy criteria for teriparatide to align with new indication for males.
<b>Pituitary Disorder Therapies</b>	
<b>Somatostatin Analogs – Medicare Part B</b>	Added carcinoid syndromes as a covered condition.
<b>Self-Administered Drug (SAD) Exclusion Clinical Policy</b>	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®)
<b>SGLT-2 Inhibitors – Medicaid</b>	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.
<b>Strensiq</b>	Added criteria to confirm dosing is within the FDA approved labeled dose.
<b>Tepezza - Medicare Part B</b>	This policy was split from the Commercial/Medicaid policy as it is considered a Medicare Part B Step Therapy program.
<b>Tepezza</b>	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.
<b>Testosterone Replacement Therapy (TRT) - Medicare Part B</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.
<b>Testosterone Replacement Therapy (TRT)</b>	Policy trial and failure criteria updated to require oral testosterone product Kyzatrex® for requests for other oral products.
<b>Tolvaptan</b>	Prescriber restrictions updated to include cardiologist and endocrinologist.
<b>Voxzogo</b>	Added exclusion criteria (person must be ambulatory and stand without assistance) to reauthorization.



<b>Weight Maintenance Medications</b>	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.
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<b>RETIRED POLICIES</b>	
<b>Policy Name</b>	<b>Summary of Change</b>
<b>Brineura</b>	Combined with Enzyme Replacement policy
<ul style="list-style-type: none"> <li>• Galafold</li> <li>• Myalept</li> <li>• Xuriden</li> </ul>	Combined with Medications for Rare Indications policy
<b>Hectorol, Zemplar Step Therapy Policy</b>	Due to low utilization and low risk for overutilization
<b>Millipred</b>	Due low utilization
<b>Natpara</b>	Due to low utilization and drug is being discontinued in 2024
<b>SymlinPen</b>	Due low utilization