

# Healthcare Services Medical & Pharmacy Policy Alerts

Number 99

October 1, 2024

This is the **October 1, 2024** 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

### MEDICAL

#### COMPANY POLICIES

*Effective 11/1/2024*

<p><b>Serum Iron Studies</b></p> <p><b>MP321</b></p>	<p><b>Policy Updates:</b> No recommended changes to criteria.</p> <p><b>Codes/PA:</b> Code configuration updates based on CMS Lab NCD</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>Gene Expression Profile Testing for Melanoma</b></p> <p><b>MP252</b></p>	<p><b>Policy Updates:</b> Added medical necessity to criterion III. – GEP tests for indeterminate melanocytic neoplasms for cutaneous melanoma (e.g. MyPath melanoma (0090U) or DecisionDx-Melanoma (CPT 0314U)).</p> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"> <li>• Added PA to 0090U and 0314U – two proprietary codes specific to testing of indeterminate neoplasms.</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>

*Effective 12/1/2024*

<p><b>Benign Prostatic Hyperplasia Treatments</b></p> <p><b>MP246</b></p>	<p><b>Policy Updates:</b> Added Prostate Artery Embolization as not medically necessary, criterion X.</p> <p><b>Codes/PA:</b> Added code 37243, currently pairs to PA. Add 5 dx codes to pair to 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>Percutaneous Vertebroplasty and Sacroplasty</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>• Changed title to remove colon.</li> </ul>

<p><b>MP196</b></p> <p><i>Previously: Back: Percutaneous Vertebroplasty and Sacroplasty</i></p>	<ul style="list-style-type: none"> <li>Wrote out criteria, based on CMS LCD for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture</li> <li>Added medical necessity criteria for other indications</li> </ul> <p><b>Codes/PA:</b> Removed pair to pay configuration for medically necessary codes and add 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>Genetic and Molecular Testing</b></p> <p><b>MP215</b></p>	<p><b>Policy Updates:</b> Added the following criteria to medical necessity criteria section: familial Hypercholesterolemia, macrocephaly/overgrowth.</p> <p><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>Wheelchairs and Power Vehicles</b></p> <p><b>MP140</b></p>	<p><b>Policy Updates:</b> Updated criteria used for K0830 and K0831 for all non-Medicare LOBs <b>except</b> OHP/Medicaid.</p> <p><b>Codes/PA:</b> For all non-Medicare LOBs <b>except OHP</b>, removed PA from codes K0830 and K0831 and added NMN denial. PA needs to remain on these codes for OHP as there is an OAR that indicates these codes may be covered for this LOB.</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed</p>

Effective 1/1/2025

<p><b>Total Knee Arthroplasty</b></p> <p><b>MP 418</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>New policy for total knee arthroplasty (TKA) procedures</li> <li>Criteria based on InterQual.</li> <li>Two TKA codes, currently only require PA when billed from an inpatient site of service (27445, 27447). Site of service reviews will continue for these codes but will now require PA regardless of site of service.</li> <li>CAP questionnaire will be available by 1/1.</li> </ul> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"> <li>New PA requirements</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>
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ARCHIVE

Effective 10/1/2024

<p><b>Outpatient Physical Therapy</b></p> <p><b>MP245</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>• Archived medical policy.</li> <li>• Utilization management is performed by EviCore for commercial and ASO LOB, making this policy unnecessary.</li> </ul> <p><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>Viscosupplementation</b></p> <p><b>MP 203</b></p>	<p><b>Policy Updates:</b></p> <ul style="list-style-type: none"> <li>• Archived “Viscosupplementation” medical policy.</li> <li>• Codes were mistakenly configured to deny u21, despite being listed as an excluded benefit in member handbooks.</li> <li>• Configuration has been changed as of 8/1 to deny “not a covered benefit,” instead of u21, to align with member handbooks.</li> <li>• No need for commercial medical policy, since benefit config trumps medical policy.</li> </ul> <p><b>Codes/PA:</b> Coding configuration was updated on 8/1 to change denial type from “not medically necessary” to “not a covered benefit.”</p> <p><b>OHP:</b> These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed</p>

## MEDICARE POLICIES

Effective 10/1/2024

<p><b>Viscosupplementation</b></p> <p><b>MP202</b></p>	<p><b>Policy Updates:</b> Company policy being archived, due to services eligible to be denied as a benefit exclusion, rather than by medical policy oversight. Medicare Advantage doesn’t have a benefit exclusion, so will keep this Medicare policy; however, in lieu of using Company policy criteria, will use the Wisconsin LCD. This is a new approach by the health plan, using an outside Medicare contractor (MAC) LCD; however, this is based on CMS information found in a CMS Final Rule FAQ that states this approach is allowed, when certain</p>
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	<p>requirements are met. This means the plan is required to treat this out-of-area LCD the same as we would any other “internal criteria” source.</p> <p><b>Codes/PA:</b> No change to codes or configuration. Continue current diagnosis code configuration, which allows for knee osteoarthritis (OA), and denies NMN for any other indication.</p>
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Effective 12/1/2024

<p><b>Percutaneous Vertebroplasty and Sacroplasty</b></p> <p><i>Previously: Back: Percutaneous Vertebroplasty and Sacroplasty</i></p> <p><b>MP342</b></p>	<p><b>Policy Updates:</b> No change to criteria. Continue to use Medicare criteria or Company criteria as directed, since not all uses of this procedure are within scope of the LCD. Updated to format and regulatory language. Updated title.</p> <p><b>Codes/PA:</b> For codes with diagnosis code configuration, remove this and replace with PA.</p>
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Effective 1/1/2025

<p><b>Total Knee Arthroplasty</b></p> <p><b>MP419</b></p>	<p><b>Policy Updates:</b> New Medicare Advantage medical policy. Medicare criteria are available, and these will be used for Medicare Advantage members (LCD L36577 and LCA A57686).</p> <p><b>Codes/PA:</b> Added PA to CPT codes 27445, 27486 and 27487 for all place of service locations. Will need to update PA for CPT 27447 from inpatient only locations to all locations.</p>
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**ARCHIVE**

Effective 10/1/24

<p><b>Chiropractic Care</b></p> <p><b>MP243</b></p>	<p><b>Policy Updates:</b> Archived.</p> <p><b>Codes/PA:</b> No changes to codes or configuration (no medical policy edits – current edits are Benefits-driven).</p>
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**REIMBURSEMENT POLICIES**

Effective 10/1/24

<p><b>Urine Drug Testing</b></p> <p><b>RP12</b></p>	<p><b>New Reimbursement Policy</b></p> <p><b>Recommendation:</b> Converting Coding Policy 28.0 to a Reimbursement Policy since the policy is primarily a <i>reimbursement</i>-related topic, and is also directly related to a <i>medical</i> policy. This particular policy addresses urine drug testing and will now be under the reimbursement policy team for continued policy management. There is no change to intent, but there are some revisions to wording, formatting, and layout, as well as an added inverse statement, situational examples, and tables.</p> <p><i>NOTE: Consistent with the current Coding Policy, this new Reimbursement Policy applies to non-Medicare and non-Medicaid LOBs only. Medicare and Medicaid LOBS are excluded from the scope of this policy.</i></p> <p><b>Reimbursement Methodology:</b> No change to current reimbursement methodology. Whatever LOBs are subject to this policy today will continue to be subject to this policy.</p> <p><b>Relevant References:</b></p> <ul style="list-style-type: none"> <li>• Providence Health Plan Company Medical Policy "Drug Testing for Therapeutic or Substance Use Monitoring"</li> <li>• Providence Health Plan Clinical Editing System</li> <li>• National Correct Coding Initiative (NCCI) Policy Manual</li> <li>• National Correct Coding Initiative (NCCI) Edits</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>
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Here's what's new from the following policy committees:

Pharmacy & Therapeutics (P&T) Committee  
Oregon Region P&T Committee August 2, 2024  
Pharmacist & Technician Update

Go-Live Date: **Tuesday, October 01, 2024**, unless otherwise noted

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### New Drugs or Combinations

1. Sotatercept-csrk (Winrevair) Kit

1. **Indication:** For the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.
2. **Decision:**

	Commercial	Medicaid	Medicare
<b>Formulary Status*</b>	Formulary	Formulary	Part D: Formulary Part B: Medical
<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>	1 kit/21 days	1 kit/21 days	2 kits/21day

\* 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:** Flolan, Veletri, Remodulin, Tyvaso/DPI, Orenitram, Ventavis, Uptravi, bosentan (Tracleer), ambrisentan (Letairis), Opsumit, Adempas, sildenafil, tadalafil

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

PA PROGRAM NAME	Pulmonary Hypertension
MEDICATION NAME	Winrevair subcutaneous kit 45 mg Winrevair subcutaneous kit 60 mg
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	None
REQUIRED MEDICAL INFORMATION	<p>For patients initiating therapy, the following criteria must be documented:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization as defined by: <ol style="list-style-type: none"> <li>i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest AND</li> <li>ii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)</li> </ol> </li> <li>2. Patient has one of the following: <ol style="list-style-type: none"> <li>i. World Health Organization (WHO) Group 1 classification, pulmonary arterial hypertension (PAH; defined by a pulmonary capillary wedge pressure [PCWP] or left ventricular end diastolic pressure [LVEDP] less than or equal to 15 mmHg) with WHO/New York Heart Association (NYHA) functional class as outlined below: <ol style="list-style-type: none"> <li>a. Flolan®, Veletri®, Tyvaso®, Tyvaso® DPI and Ventavis: Class III or IV</li> <li>b. <b>Winrevair®: Class II or III</b></li> <li>c. All other therapies: Class II, III, or IV</li> </ol> </li> <li>ii. For Adempas® only, WHO Group 4 classification CTEPH with WHO/New York Heart Association (NYHA) functional class II, III, or IV</li> <li>iii. For Tyvaso®/Tyvaso® DPI only, WHO Group 3 classification PH-ILD</li> </ol> </li> <li>3. <b>For Winrevair®:</b> <ol style="list-style-type: none"> <li>i. <b>Patient is currently established on (for at least 90 days) at least two of the following, unless all are not tolerated or contraindicated:</b> <ol style="list-style-type: none"> <li>a. <b>Endothelin receptor antagonist (ERA; such as bosentan, ambrisentan, or macitentan)</b></li> </ol> </li> </ol> </li> </ol>



	<ul style="list-style-type: none"> <li>b. Phosphodiesterase-5 inhibitor (PDE5i; such as Revatio® [sildenafil] or Adcirca® [tadalafil]) OR a soluble guanylate cyclase stimulator (sGC; such as Adempas®)</li> <li>c. Prostacyclin analogue or receptor agonist (such as epoprostenol, Ventavis®, Uptravi®, treprostinil)</li> </ul> <ul style="list-style-type: none"> <li>ii. Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless all are not tolerated or contraindicated</li> <li>iii. Platelet count greater than or equal to 50,000/mm<sup>3</sup></li> </ul> <p>For patients established on therapy:</p> <ul style="list-style-type: none"> <li>1. Documentation of response to therapy such as lack of disease progression, improvement in WHO functional class must be provided.</li> <li>2. Winrevair only: <ul style="list-style-type: none"> <li>i. Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless not tolerated or contraindicated</li> <li>ii. Platelet count greater than or equal to 50,000/mm<sup>3</sup></li> </ul> </li> </ul>
AGE RESTRICTIONS	Winrevair: ages 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist
COVERAGE DURATION	Winrevair: Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months. All others: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

4. Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Pulmonary Antihypertensives
MEDICATION NAME	Winrevair subcutaneous kit 45 mg Winrevair subcutaneous kit 60 mg
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	<p>For initial authorization the following criteria must be documented:</p> <ul style="list-style-type: none"> <li>1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization, as defined by all of the following: <ul style="list-style-type: none"> <li>i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest,</li> <li>ii. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg, AND</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>iii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU),</li> </ul> <p>2. Patient has documentation of one of the following</p> <ul style="list-style-type: none"> <li>i. World Health Organization (WHO) Group 1 classification PAH (or WHO Group 4 classification CTEPH for Adempas® only) with WHO/New York Heart Association (NYHA) functional class II, III, or IV,</li> <li>ii. For Tyvaso® DPI only, pulmonary hypertension associated with interstitial lung disease (WHO Group 3 classification PH-ILD).</li> <li>iii. <b>For Winrevair only: World Health Organization (WHO) Group 1 classification PAH with WHO/New York Heart Association (NYHA) functional class II or III,</b></li> </ul> <p>3. For Opsumit, Uptravi, Tracleer tablets for suspension, patient has had a therapeutic failure to generic bosentan or ambrisentan.</p> <p>4. <b>For Winrevair®:</b></p> <ul style="list-style-type: none"> <li>i. <b>Patient is currently established on two of the following, unless all are not tolerated or contraindicated:</b> <ul style="list-style-type: none"> <li>a. Endothelin receptor antagonist (ERA; such as bosentan, ambrisentan, or macitentan)</li> <li>b. Phosphodiesterase-5 inhibitor (PDE5i; such as Revatio® [sildenafil] or Adcirca® [tadalafil]) OR a soluble guanylate cyclase stimulator (sGC; such as Adempas®)</li> <li>c. Prostacyclin analogue or receptor agonist (such as epoprostenol, Ventavis®, Uptravi®, treprostinil)</li> </ul> </li> <li>ii. <b>Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless all are not tolerated or contraindicated</b></li> <li>iii. <b>Platelet count greater than or equal to 50,000/mm<sup>3</sup></b></li> </ul> <p>Reauthorization requires documentation of response to therapy including lack of disease progression or improvement in WHO functional class <b>and the following drug-specific criteria, if applicable:</b></p> <p>1. <b>Winrevair only:</b></p> <ul style="list-style-type: none"> <li>i. <b>Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless not tolerated or contraindicated</b></li> <li>ii. <b>Platelet count greater than or equal to 50,000/mm<sup>3</sup></b></li> </ul>
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist
COVERAGE DURATION	<b>Winrevair: Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.</b> <b>All others: Authorization will be approved until no longer eligible with the plan.</b>

2. Danicopan (Voydeya) Tablet

- a. **Indication:** For treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).
- b. **Decision:**

	Commercial	Medicaid	Medicare
<b>Formulary Status*</b>	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
<b>Tier**</b>	Tier 6 - Non-Preferred Specialty	N/A	N/A
<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>	Danicopan 150 mg dose pack: six tablets per day Danicopan 200 mg dose pack: six tablets per day	Danicopan 150 mg dose pack: six tablets per day Danicopan 200 mg dose pack: six tablets per day	
* 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> pegcetacoplan (Empaveli)			

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

PA PROGRAM NAME	Complement Inhibitors
MEDICATION NAME	Danicopan (Voydeya) tablet
REQUIRED MEDICAL INFORMATION	<p>For initial authorization for Paroxysmal Nocturnal Hemoglobinuria (PNH):</p> <ol style="list-style-type: none"> <li>1. Documented, confirmed diagnosis of PNH by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (such as red blood cells [RBCs] and white blood cells [WBCs]) demonstrating that the patient’s peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)</li> <li>2. Symptomatic hemolytic PNH defined as lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal and at least one of the following prior to initiating therapy with a complement inhibitor:               <ol style="list-style-type: none"> <li>a. Documented history of thrombosis</li> <li>b. Transfusion dependence (for example, hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)</li> <li>c. Disabling fatigue</li> </ol> </li> </ol>

	<ul style="list-style-type: none"> <li>d. End-organ complications</li> <li>e. Frequent pain paroxysms (for example, dysphagia or abdominal pain)</li> </ul> <p>3. For Soliris and Fabhalta: Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)</p> <p>4. For danicopan (Voydeya): all the following criteria must be met:</p> <ul style="list-style-type: none"> <li>a. Documentation of extravascular hemolysis while on ravulizumab or eculizumab</li> <li>b. Trial and failure, intolerance, or contraindication to pegcetacoplan (Empaveli) OR documentation of medical rationale for not switching to Empaveli therapy</li> <li>c. Documentation that danicopan will be used concomitantly with ravulizumab or eculizumab</li> <li>d. For authorization of danicopan 200 mg dose, must meet one of the following: <ul style="list-style-type: none"> <li>i. Documentation of a hemoglobin (Hgb) level that has not increased by greater than 2 g/dL after at least four weeks of initial therapy with 150 mg three times daily</li> <li>ii. Patient required a transfusion during the previous four weeks</li> </ul> </li> </ul> <p>For reauthorization: Documentation of positive response to therapy</p>
QUANTITY LIMITS	For danicopan (Voydeya): 6 tablets per day

3. Immune globulin,gamma(igg)stwk (Alyglo) Vial

- a. **Indication:** For the treatment of primary humoral immunodeficiency (PI) in adults.
- b. **Decision:**

	Commercial	Medicaid	Medicare
<b>Formulary Status*</b>	Medical	Medical	Part D: Formulary Part B: Medical
<b>Tier**</b>	N/A	N/A	Specialty
<b>Affordable Care Act Eligible</b>	N/A	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).			
<b>Formulary Alternatives: Currently available immune globulin products</b>			

- c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B:** Added to the Immune Gamma Globulin (IGG) policy.

4. Melphalan hcl (Hepzato) Vial

- a. **Indication:** For adult patients with uveal melanoma with unresectable hepatic metastases.
- 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	
<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).			
<b>Formulary Alternatives:</b> N/A			

- c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B:** Added to Anti-Cancer Medications - Medical Benefit policy.

5. Nogapendekin alfa inbakic-pmln (Anktiva) Vial

- a. **Indication:** For the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- 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:** N/A

- c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B:** Added to the Anti-Cancer Medications - Medical Benefit policy.

**6. Pemivibart (Pemgarda (EUA)) Vial**

- a. **Indication:** A monoclonal antibody for pre-exposure prophylaxis of COVID-19 for immune compromised individuals.
- b. **Decision:** Informational

**7. Resmetirom (Rezdiffra) Tablet**

- a. **Indication:** For the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).
- b. **Decision:**

	Commercial	Medicaid	Medicare
<b>Formulary Status*</b>	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
<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>	One tablet per day	One tablet per day	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:** None

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

<b>PA PROGRAM NAME</b>	Rezdiffra
------------------------	-----------

MEDICATION NAME	Rezdiffra
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Presence of cirrhosis
REQUIRED MEDICAL INFORMATION	<p>For initial authorization:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH), confirmed by liver biopsy or vibration-controlled transient elastography (such as FibroScan) within the previous six months</li> <li>2. Baseline nonalcoholic fatty liver disease activity score (NAS) taken within previous three months that is at least four (4), with a score of 1 or more for each component</li> <li>3. Fibrosis stage 2 or 3 (F2/F3) by liver biopsy within the previous six months</li> <li>4. Attestation that patient is abstaining from alcohol consumption</li> <li>5. Documentation of all the following:             <ol style="list-style-type: none"> <li>a. For patients with body mass index (BMI) 27 and above: engaged in weight management lifestyle modifications</li> <li>b. For patients with hypertension or hyperlipidemia: patients are currently using guideline directed medication therapy (such as statins and antihypertensives)</li> <li>c. For patients with type 2 diabetes, one of the following:                 <ol style="list-style-type: none"> <li>i. Currently A1c less than 7% (taken within previous six months)</li> <li>ii. A1c 7% or higher and are currently stable on (for at least six months), or have a contraindication to, additional guideline directed medication therapy with all the following:                     <ol style="list-style-type: none"> <li>1) Metformin</li> <li>2) Glucagon-like peptide 1 (GLP-1) receptor agonist</li> <li>3) Sodium-glucose cotransporter-2 (SGLT2) inhibitor.</li> </ol> </li> </ol> </li> </ol> </li> </ol> <p>For reauthorization: Documentation of response to therapy, defined as no worsening of fibrosis score and no worsening of NAS</p>
AGE RESTRICTIONS	May be covered for patients aged 18 year and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist
COVERAGE DURATION	Authorization and reauthorization will be approved for one year

8. **Tovorafenib (Ojemda) Susp Recon and Tablet** reviewed by Jenna Newman, PharmD.

- a. **Indication:** For treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.
- b. **Decision:**

Health Plan Recommendations			
	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>	Suspension: 96 mL/28 days, Tablets: 24/28 days	Suspension: 96 mL/28 days Tablets: 24/28 days	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> dabrafenib (Tafinlar) + trametinib (Mekinist)			

- c. **Prior Authorization Criteria for Commercial/Medicaid:** Added to the Anti-Cancer Medications – Self-Administered policy.
- d. **Prior Authorization Criteria for Medicare Part D:** Added to the Anti-Cancer Agents policy.

### Other Formulary Changes:

DRUG NAME	RECOMMENDATION	POLICY NAME
<b>Eltrombopag choline (Alvaiz) Tablet</b>	New entity; <ul style="list-style-type: none"> <li>• Non-formulary for all lines of business</li> </ul> <b>Effective: 08/01/2024</b>	N/A
<b>Bromfenac Sodium Drops</b>	First generic drug; <ul style="list-style-type: none"> <li>• Non-formulary for all lines of business</li> </ul> <b>Effective: 08/01/2024</b>	N/A
<b>Adalimumab-RYVK (Simlandi) Autoinjkit</b>	Moving to preferred biosimilar for Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (Two injections per 28 days)	Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)
<b>Adalimumab-atto (Amjevita) Auto Injct / Syringe</b>	Change in preferred biosimilar products. Remove Amjevita from Commercial	Therapeutic Immunomodulators (TIMS)



	formulary: Non-Formulary, Prior Authorization, Quantity Limit (Two injections per 28 days) <b>Effective: 11/01/2024</b>	
<b>Clomiphene citrate Tablet</b>	<ul style="list-style-type: none"> <li>Commercial: Remove from Formulary, add Prior Authorization</li> <li>Medicaid: Remove from Formulary</li> </ul> <b>Effective: 11/01/2024</b>	<ul style="list-style-type: none"> <li>Commercial: Fertility and Related Medications</li> <li>Medicaid: N/A</li> </ul>
<b>Baclofen Tablet</b>	New strength; <ul style="list-style-type: none"> <li>Non-formulary for all lines of business</li> </ul>	N/A
<b>Valbenazine tosylate (Ingrezza Sprinkle) sprinkle cap</b>	New Formulation <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (One per day)</li> <li>Medicare: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: VMAT2 Inhibitors</li> <li>Medicare: N/A</li> </ul>
<b>Diazepam (Libervant) Film</b>	New formulation; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary</li> <li>Medicare Part D: Formulary, Tier 4, Prior Authorization</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: N/A</li> <li>Medicare Part D: Rescue Medications for Epilepsy</li> </ul>
<b>Macitentan/tadalafil (Opsynvi) Tablet</b>	New combination; <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>Spesolimab-sbzo (Spevigo) Syringe</b>	New strength and formulation (150 mg/ml syringe); <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 mL per 28 days)</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>
<b>Levomilnacipran hcl (Fetzima) Cap SA 24H</b>	Remove from Commercial formulary	N/A
<b>Frovatriptan succinate (Frova) Tablet</b>	Remove from Commercial formulary	N/A
<b>Istradefylline (Nourianz) Tablet</b>	Commercial: Up tier to Tier 6	N/A

	<b>Effective: 09/01/2024</b>	
<b>Ramelteon (Rozerem) Tablet</b>	Commercial Dynamic: Down tier generic to Tier 2	N/A
<b>Vigabatrin (Sabril) Tablet</b>	Commercial: Down tier generic to Tier 5	N/A
<b>Vortioxetine hydrobromide (Trintellix) Tablet</b>	Remove from Commercial formulary <b>Effective: 11/01/2024</b>	Antidepressants Step Therapy Policy
<b>Ubrogepant (Ubrovelvy) Tablet</b>	Add to Medicaid formulary: Formulary, Prior Authorization, Quantity Limit (16 per 30 days)	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists
<b>Ganaxolone (Ztalmy) Oral Susp</b>	Remove from Commercial and Medicaid formularies: Non-Formulary, Prior Authorization, Quantity Limit (37 mL/day)	Medications for Rare Indications
<b>Mirabegron (Mirabegron ER) Tab ER 24H</b>	First generic drug (Myrbetriq). <ul style="list-style-type: none"> <li>Commercial/Medicare Part D: Non/Formulary</li> <li>Medicaid: Formulary, Step Therapy</li> </ul> <b>Effective Date: 5/1/2024</b>	<ul style="list-style-type: none"> <li>Commercial/Medicare Part D: N/A</li> <li>Medicaid: Overactive Bladder Medications Step Therapy Policy</li> </ul>
<b>Topiramate ER capsules (Trokendi XR)</b>	Commercial/Medicaid: Add Quantity Limit (one capsule per day) <b>Effective: 11/01/2024</b>	New Medications and Formulations without Established Benefit
<ul style="list-style-type: none"> <li><b>Votrient capsule and gel</b></li> <li><b>Truvada</b></li> <li><b>Afinitor</b></li> <li><b>Targretin</b></li> <li><b>Kuvan</b></li> <li><b>Provigil</b></li> <li><b>Tobi neb solution</b></li> <li><b>Zoloft</b></li> <li><b>Lexapro</b></li> <li><b>Sutent</b></li> <li><b>Adcirca</b></li> </ul>	Brand Name Formulations to be removed from the Commercial formulary (generics to remain on formulary)  <b>Effective: 11/01/2024</b>	
<b>Abiraterone submicronized (Yonsa)</b>	Remove from Commercial Formulary. Preferred product is generic abiraterone,	Anti-Cancer Medications - Self-Administered

	which will be required prior to coverage of Yonsa <b>Effective: 11/01/2024</b>	
<b>Estrogen Class Review</b> <ul style="list-style-type: none"> <li>• <b>Angeliq® (estradiol/drospirenone tablet)</b></li> <li>• <b>Estradiol 0.06% gel</b></li> <li>• <b>Estradiol 0.1% gel</b></li> <li>• <b>EvaMist® (estradiol transdermal spray)</b></li> <li>• <b>Femring® (estradiol vaginal ring)</b></li> </ul>	Add to formulary: <ul style="list-style-type: none"> <li>• Commercial: Tier 4</li> <li>• Medicaid: Formulary</li> <li>• Medicare: Formulary, Tier 4               <ul style="list-style-type: none"> <li>○ Angeliq® and Femring® are already on formulary</li> </ul> </li> </ul>	N/A
<b>Estradiol/norethindrone (Activella, Mimvey, Fyavolv, Jinteli)</b>	Medicare: Move to Tier 2	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 04/26/2024 – 06/28/2024

**INFORMATIONAL ONLY**

<b>NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS</b>		
<b>Drug Name</b>	<b>Action Taken</b>	<b>Policy Name</b>
<b>Pneumoc 21-val conj-dip crm/pf (Capvaxive) Syringe</b>	New entity. Line extend with other pneumonia vaccines; <ul style="list-style-type: none"> <li>• Commercial: Formulary, Preventive, Quantity Limit (0.5 mL per day)</li> <li>• Medicaid: Medical Benefit, Quantity Limit (0.5 mL per day)</li> <li>• Medicare Part D: Non-Formulary</li> <li>• Medicare Part B: Medical Benefit</li> </ul>	N/A
<b>Fosaprepitant dimeglumine (Focinvez) Vial</b>	New strength. Line extend with Emend (fosaprepitant dimeglumine); <ul style="list-style-type: none"> <li>• Medical Benefit for all lines of business</li> </ul>	N/A
<b>Rsv vaccine, pref, mrna/pf (Mresvia) Syringe</b>	New entity. Line extend with Abrysvo; <ul style="list-style-type: none"> <li>• Commercial: Formulary, Preventive</li> <li>• Medicaid: Formulary</li> </ul>	N/A

<p><b>Tralokinumab-ldrm (Adbry Autoinjector) Auto Injct</b></p>	<ul style="list-style-type: none"> <li>• Medicare Part D: Formulary, Tier 3</li> </ul> <p>New formulation. Line extend with Adbry 150 mg/ml;</p> <ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days)</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: Adbry</li> <li>• Medicare Part D: N/A</li> </ul>
<p><b>Futibatinib (Lytgobi) 12 mg/day Tablet</b></p>	<p>New MedID. Line extend with Lytgobi 4mg tablets;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (3 tablets per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (3 tablets per day)</li> <li>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 tablets per day)</li> </ul>	<p>Anti-Cancer Medications - Self-Administered</p>
<p><b>Futibatinib (Lytgobi) 16 mg/day Tablet</b></p>	<p>New MedID. Line extend with Lytgobi 4mg tablets;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 tablets per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (4 tablets per day)</li> <li>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 tablets per day)</li> </ul>	<p>Anti-Cancer Medications - Self-Administered</p>
<p><b>Futibatinib (Lytgobi) 20 mg/day Tablet</b></p>	<p>New MedID. Line extend with Lytgobi 4mg tablets;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (5 tablets per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (5 tablets per day)</li> </ul>	<p>Anti-Cancer Medications - Self-Administered</p>

	<ul style="list-style-type: none"> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 tablets per day)</li> </ul>	
<b>Asciminib hydrochloride (Scemblix) Tablet</b>	<p>New strength. Line extend with Scemblix 20mg and 40mg;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 tablets per day)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (4 tablets per day)</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 tablets per day)</li> </ul>	Anti-Cancer Medications - Self-Administered
<b>Cenobamate (Xcopri) Tablet</b>	<p>New strength. Line extend with other Xcopri strengths;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 4, Step Therapy, Quantity Limit (1 tablet per day)</li> <li>Medicaid: Formulary, Step Therapy, Quantity Limit (1 tablet per day)</li> <li>Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (1 tablet per day)</li> </ul>	Antiepileptic Medications Step Therapy Policy
<b>Corticotropin (Acthar Selfject) Pen Injctr</b>	<p>New formulation. Line extend with Acthar Gel;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization, Specialty</li> <li>Medicaid: Formulary, Prior Authorization, Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: HP Acthar Gel</li> <li>Medicare Part D: N/A</li> </ul>
<b>Benralizumab (Fasenra) Syringe</b>	<p>New strength. Line extend with other Fasenra subcutaneous syringe: Medical Benefit, with Prior Authorization for all lines of business</p>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Il-5 Inhibitors</li> <li>Medicare Part B: Il-5 Inhibitors Prior Authorization and Step Therapy – Medicare Part B</li> </ul>
<b>Mirikizumab-mrkz (Omvoh) Syringe</b>	<p>New formulation. Line extend with other Omvoh strengths;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days), Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) / Self-Administered Drugs (SADs)</li> <li>Medicare: N/A</li> </ul>

<b>Upadacitinib (Rinvoq LQ) Solution</b>	<p>New formulation. Line extend with Rinvoq tablets;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (12 mL per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (12 mL per day)</li> <li>• Medicare Part D: Formulary, Tier 5, Prior Authorization</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Adalimumab-adbm (Adalimumab-ADB M(CF) Syringe kit</b>	<p>New formulation. Line extend with non-preferred Humira biosimilars;</p> <ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.8 mL per 28 days)</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)</li> <li>• Medicare: N/A</li> </ul>
<b>Alpelisib (Vijoice) Gran Pack</b>	<p>New formulation. Line extend with Vijoice 50mg tablets;</p> <ul style="list-style-type: none"> <li>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 packet per day)</li> <li>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 packet per day)</li> </ul>	Vijoice
<b>Deutetrabenazine (Austedo XR) Tab ER 24H</b>	<p>New strength. Line extend with Austedo XR 12mg &amp; 24mg;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 tablet per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day), Specialty</li> <li>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day)</li> </ul>	VMAT2 Inhibitors

**NEW GENERICS**

Drug Name	Action Taken	Policy Name
<b>Carbinoxamine maleate (Carbinoxamine Maleate ER) sus ER 12H</b>	First generic drug (Karbinal ER). Line extend as generic; Non-Formulary for all lines of business	N/A
<b>Estradiol Gel MD PMP</b>	First generic drug (Estrogel). Line extend as generic; <ul style="list-style-type: none"> <li>Non-Formulary for all lines of business</li> </ul>	N/A
<b>Deflazacort Oral Susp</b>	First generic (Emflaza). Line extend as generic; <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: Agamree, Emflaza</li> <li>Medicare Part D: N/A</li> </ul>
<b>Eribulin Mesylate Vial</b>	First generic drug (Halaven). Line extend as generic; <ul style="list-style-type: none"> <li>Medical Benefit, with Prior Authorization for all lines of business</li> </ul>	Anti-Cancer Medications - Medical Benefit
<b>Liraglutide Pen Injctr</b>	First generic drug (Victoza). Line extend as generic; <ul style="list-style-type: none"> <li>Commercial: Non-Formulary, Prior Authorization, Quantity Limit (9 mL per 30 days)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (9 mL per 30 days)</li> <li>Medicare Part D: Non-Formulary</li> </ul>	GIP and GLP-1 Receptor Agonists

## Clinical Policy Changes:

### 1. Major Changes:

POLICY NAME	SUMMARY OF CHANGE
<b>Addyi</b>	Combined Addyi and Vyleesi into one policy, "Medications for Female Sexual Interest/Arousal Dysfunction." <ul style="list-style-type: none"> <li>Addyi: Added requirement for 6 months of diagnosis, quantity limit of one per day i</li> <li>Vyleesi: change quantity limit to 1.2 per 28 days,</li> <li>Decreased initial authorization to two months</li> </ul>

<b>Antiepileptic Medications Step Therapy Policy</b>	Updated quantity limit for Briviact to align with maximum dosing per FDA labeling
<b>Antipsychotics</b>	Added quantity limits
<b>Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists</b>	Added criteria to acute migraine indication to require evaluation of medication overuse headache and exclude concomitant use of CGRPs indicated for acute migraine. Added reauthorization criteria for cluster headache.
<b>Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Medicaid</b>	Updated prophylactic therapy trial and failure prerequisite drugs to allow a trial of three drugs from any class as outlined to align with the Oregon Health Authority (OHA). For acute migraines, added criteria to evaluate for medication overuse headache and require use of preferred acute CGRP (Ubrelyv) to align with OHA. Added criteria to exclude use of dual prophylactic CGRP therapy or dual acute migraine CGRP therapy due to lack of safety and efficacy data. Prescriber restrictions were updated to clarify intent of requiring a specialist consultation on initial review.
<b>Dupixent</b>	<p>Atopic Dermatitis:</p> <ul style="list-style-type: none"> <li>• Updated to allow as first line for patients with body surface area greater than 40%,</li> <li>• Require trial and failure of a topical corticosteroid and topical calcineurin inhibitor for body surface area of 10-40% with allowance to waive calcineurin if an oral immunosuppressant was tried,</li> </ul> <p>Asthma:</p> <ul style="list-style-type: none"> <li>• Updated diagnostic criteria</li> <li>• Decrease requirement for stable oral corticosteroid for steroid-dependence to four weeks,</li> </ul> <p>Reauthorization for Asthma and Nasal Polyps requires combination with standard maintenance therapy,            Coverage Duration for Atopic Dermatitis reauthorization extended to long-term</p>
<b>Dupixent - Medicaid</b>	<p>Split policy from Commercial policy</p> <p>Asthma:</p> <ul style="list-style-type: none"> <li>• Updated diagnostic criteria to align with OHA</li> <li>• Decrease requirement for stable oral corticosteroid for steroid-dependence to four weeks,</li> <li>• Align tried and failed therapy to adherence for 12 months</li> <li>• Reauthorization for asthma requires combination with maintenance therapy</li> </ul> <p>Atopic Dermatitis:</p>



	<ul style="list-style-type: none"> <li>Added allowance for EPSDT (under 21 only needs to show the condition significantly impacts life and does not need to meet severity criteria)</li> <li>Reauthorization increased to long-term</li> </ul> <p>Nasal polyps: aligned criteria with OHA for trial and failure of two courses of intranasal steroids for at least 12 to 26 weeks each</p> <p>Esophagitis: remove requirement for symptoms and weight;</p> <p>Prurigo Nodularis:</p> <ul style="list-style-type: none"> <li>Remove requirement for itching for six weeks</li> <li>Add EPSDT allowance</li> </ul>
<b>Epidiolex</b>	Decreased trial criteria to one instead of two for Medicaid, for Lennox-Gastaut syndrome to align with OHA criteria
<b>Fintepla</b>	Added criteria requiring therapy to be adjunct based on guideline recommendations and OHA policy. Added criteria required echocardiogram screening for initial and reauthorization per package insert black box warning and to align with OHA. For Medicaid only: reduced prerequisite therapy criteria to one drug to align with OHA
<b>Firdapse</b>	Added criteria requiring baseline assessment of function to align with other insurers and OHA, updated reauthorization criteria to require improvement from baseline validated assessment scale
<b>Formulary and Quantity Limit Exceptions</b>	Criteria for brand name medications with formulary, generic alternatives were added to this policy.
<b>Infusion Therapy Site of Care</b>	Several drugs were added to this policy that can be self-administered.
<b>Insomnia Agents - Medicaid</b>	Prior authorization removed from flurazepam as no utilization of this drug. It will be reviewed as a non-formulary medication.
<b>Krystexxa</b>	Add requirement for combination with methotrexate, increase duration of authorization from six months to 12 months for both initial and reauthorization
<b>Long-Acting Opioids</b>	Allowed for waiver of prerequisite therapy with long-acting morphine sulfate therapy for patients with metastatic cancer. Clarified requirement regarding prior short-acting opioid use. Added requirement for naloxone prescription.
<b>Long-Acting Stimulant Medications Quantity Limit</b>	Add allowance for patients aging into a maximum dose
<b>Maximum Allowable Opioid Dose</b>	Updated coverage duration for chronic pain for initial authorization and reauthorization to both be one year.

<b>Narcolepsy Agents</b>	Updated indication for Wakix for excessive daytime sleepiness (EDS) in pediatric patients six years and older. Added Wakix as a prerequisite for coverage of oxybate salts for children with EDS in narcolepsy. Added prerequisite therapy requirements for patients with cataplexy
<b>Nuedexta</b>	Added exclusion of complete atrioventricular block without implanted pacemaker/high risk of atrioventricular block to align with package insert
<b>Pediatric Analgesics</b>	Removing all non-formulary medications as no utilization. Review will default to non-formulary review process.
<b>Qudexy XR, Trokendi XR</b>	Move Trokendi to New Medications and Formulations Without Established Benefit policy; Add Quantity Limit of one per day to Qudexy and Trokendi
<b>Reyvow</b>	Combined Cambia and Reyvow into "Acute migraine Medications policy", added reauthorization criteria;
<b>Spinraza</b>	Combined Spinraza, Evrysdi and Zolgensma into one policy, "Therapies for spinal muscular atrophy". Updated reauthorization for Spinraza/Evrysdi to "established on therapy".
<b>Spravato</b>	Remove some exclusion criteria
<b>Strensiq</b>	Removed criteria for patients 18 years and older at time of request and age specific criteria on reauthorization to align with package label. Expanded prescriber restrictions to include any specialist in the area of perinatal or juvenile onset hypophosphatasia.
<ul style="list-style-type: none"> <li>• <b>Tepezza</b></li> <li>• <b>Tepezza Prior Authorization and Step Therapy Policy - Medicare Part B</b></li> </ul>	Removed requirement for clinical activity score for active disease
<b>Therapeutic Immunomodulators (TIMS) – Commercial</b>	Preferred adalimumab biosimilar products were updated, as Simlandi® will replace Amjevita® as one of the preferred products. Tocilizumab-aazg (Tyenne®), a new biosimilar product, will be covered in parity with the innovator product Actemra®.
<b>Topical Agents for Skin Conditions - Medicaid</b>	Change to align with OHA criteria
<b>Triptan Quantity Limit</b>	Changed some quantity limits. Added combination with other acute migraine medications as exclusion criteria, reauthorization requires documentation that increased quantity is still necessary
<b>VMAT2 Inhibitors</b>	Update to quantity limits to reflect newly available dosage strengths, removed exclusion criteria that was a boxed warning only when used in Huntington's disease, updated reauthorization duration to reflect long-term use of these medications.

2. **Deferred Policies** - The following policies reviews are being deferred, to October 2024 ORPTC, for further evaluation:

POLICY NAME	
Anti-Amyloid Monoclonal Antibodies	Botulinum Toxin
Anti-Amyloid Monoclonal Antibodies - Medicaid	Botulinum Toxin Prior Authorization Policy - Medicare Part B
Anti-Amyloid Monoclonal Antibodies Prior Authorization and Step Therapy Policy - Medicare Part B	

3. **Minor Change:**

POLICY NAME		
Diacomit	Medically Administered Multiple Sclerosis Agents	Savella
Elevidys	Medically Administered Multiple Sclerosis Agents Prior Authorization and Step Therapy Policy – Medicare Part B	Tysabri
Exon-Skipping Therapies for Duchenne Muscular Dystrophy	Multiple Sclerosis Agents	Tysabri – Medicare Part B
Fentanyl Citrate	Neupro Step Therapy Policy	Vyepti - Medicare Part B
Hetlioz, Hetlioz LQ	Non-Preferred Fumarate Products	Zeposia
Lemtrada	Nuplazid	Zeposia – Medicaid
Lemtrada Prior Authorization and Step Therapy Policy - Medicare Part B	Radicava, Radicava ORS	

4. **Retired Policies:**

POLICY NAME	SUMMARY OF CHANGE
<b>Antidepressants Step Therapy Policy</b>	Drugs will be removed from the formulary. Criteria from "Formulary and Quantity Limit Exception" policy will apply
<b>Brand Over Generic</b>	Criteria will be combined with the "Formulary and Quantity Limit Exception" policy.
<b>Cambia</b>	Policy combined with Reyvow on new "Acute Migraine Medications" policy
<b>Evrysdi</b>	Combined Spinraza, Evrysdi and Zolgensma into one policy, "Therapies for spinal muscular atrophy".
<b>Ketorolac Intramuscular Injection</b>	Utilization and safety concerns will be assessed with quantity limits.
<b>Non-Preferred Triptan Therapy</b>	Drugs will be removed from the formulary. Criteria from "Formulary and Quantity Limit Exception" policy will apply

<b>Nourianz</b>	Low risk of inappropriate utilization
<b>Qalsody</b>	Moved to “Medications for Rare Indications” policy
<b>Relyvrio</b>	Drug no longer available on the market to new patients
<b>Rescue Medications for Epilepsy</b>	Low risk of inappropriate utilization
<b>Sabril</b>	Low risk of inappropriate utilization
<b>Skysona</b>	Moved to “Medications for Rare Indications” policy
<b>Spevigo</b>	Moved to “Medications for Rare Indications” policy
<b>Vyleesi</b>	Combining with Addyi in the “Medications for Female Sexual Interest/Arousal Disorder” policy
<b>Zolgensma</b>	Combined Spinraza, Evrysdi and Zolgensma into one policy, "Therapies for spinal muscular atrophy".
<b>Ztalmy</b>	Moved to “Medications for Rare Indications” policy

**PHP Operational Policies: [Go-live September 1, 2024](#)**

POLICY NAME	
Authorized and Appropriate Systems User Access Policy	Maintenance Medications for 90-day Supply Policy - Medicaid
Charter and Conflict of Interest Review Policy	Part D Explanation of Benefits Policy
Drugs Available only via Limited Access Policy	Pharmaceutical Product Review Policy
Expedited Coverage Determination and Timeframes Policy - Medicare	Pharmacy Desk Procedures Policy
Failure to Provide Timely Notice on Coverage Determinations Policy	PHP Operational Policies
FDA Approved Devices-Emollients and Dermatological Products Policy	Post Claim Adjudication, Return to Stock, and Unclaimed Prescriptions
Formulary and Quantity Limit Exceptions	Standard Coverage Determination Timeframes Policy
Formulary Status Line Extension Policy	Urgent and Emergency Supply of Medications Policy - Commercial
Infusion Therapy Site of Care Policy	Urgent-Emergency Supply of Medications Policy - Medicare Medicaid