

# Healthcare Services: Medical, Pharmacy, Reimbursement, and Coding Policy Alerts

Number 115

February 1, 2026

This is the **February 1, 2026** issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical, Pharmacy, Reimbursement, and Coding policy changes. The Health Plan has a standard process to review all 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 subsequent 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 4/1/2026

<b>Urinary Dysfunction Treatments (Company)</b>  <b>MP180</b>	<b>Policy Updates:</b> Updated to bring configuration in line with criteria. <b>Codes/PA:</b> Changed 0816T-0819T from PA to NMN
<b>New and Emerging Technologies and Other Non-covered Services</b>  <b>MP23</b>	<b>Policy Updates:</b> No recommended changes to criteria <b>Codes/PA:</b> Changed 36 codes from E/I to NMN
<b>Ablative Procedures to Treat Back and Neck Pain</b>  <b>MP21</b>	<b>Policy Updates:</b> <ul style="list-style-type: none"><li>Restored imaging criteria to align with Medicare language (criterion I.C.-D.).</li><li>Updated documentation requirements – now require that diagnostic imaging (MRIs, CTs, etc.) be completed within the past 12 months, not at “onset of symptoms.”</li><li>Updated so that now requirement aligns with language in other back-related medical policies (“Spinal Epidural Steroid Injections; “Spinal Fusion and Decompression Procedures”.)</li></ul> <b>Codes/PA:</b> No changes to codes or PA
<b>Myoelectric Upper Limb Prosthesis (Company)</b>  <b>MP26</b>	<b>Policy Updates:</b> Modified non-covered section for clarity without changes in intent. Added five additional codes to the policy. Replaced part replacement note with new criteria. <b>Codes/PA:</b> <ul style="list-style-type: none"><li>Addition of L7499 and L6646 with no configuration.</li><li>Addition of L7259, L6611, and L6621 with PA.</li></ul>

<b>Deep Brain and Responsive Cortical Stimulation (Company)</b>  <b>MP100</b>	<b>Policy Updates:</b> Removed scale requirement for dystonia and added a requirement that there be no FDA contraindications. <b>Codes/PA:</b> No changes to codes or PA.
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## MEDICARE POLICIES

*Effective 3/1/2026*

<b>New and Emerging Technologies and Other Non-Covered Services</b>  <b>MP220</b>	<b>Policy Updates:</b> <ul style="list-style-type: none"> <li>Updated layout of policy. Instead of "Medicare and Coverage Notes" and "Evidence Summary" rows being separated, they are now combined. This is intended to provide clearer rationale for why a service is not covered.</li> <li>Removed "evidence review date" row from all Table 2 Set tables. CMS requires that we review all policies annually, and this policy meets this requirement.</li> </ul> <b>Codes/PA:</b> <ul style="list-style-type: none"> <li>Removed CPT 87513 (NMN to No PA) as this code is not specific to a single proprietary test but is included in the MolDX Infectious disease LCDs/LCAs.</li> <li>Removed CPT codes 0655T, 95919, 0738T, 0739T, 0748T, 0770T, 0771T, 0772T, 0773T, 0774T, 0776T, 0777T, 0778T, 0779T, 0781T, 0782T, 0373U, 0376U, E1905, 0791T, 0793T, 0393U, 0414U, and 0418U (NMN to No PA) due to low utilization for Medicare Advantage members.</li> <li>No change to other codes or their configuration.</li> </ul>
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*Effective 4/1/2026*

<b>Urinary Dysfunction Treatments (Medicare)</b>  <b>MP231</b>	<b>Policy Updates:</b> Updated to bring configuration in line with criteria. <b>Codes/PA:</b> Changed 0816T-0819T from PA to NMN
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<b>Myoelectric Upper Limb Prostheses</b>  <b>MP374</b>	<p><b>Policy Updates:</b> No changes to policy position. Continue to use Company medical policy criteria due to lack of fully established Medicare coverage criteria for the plan's service area.</p> <p><b>Codes/PA:</b></p> <ul style="list-style-type: none"><li>Added HCPCS codes L7499, L6611, L6621, L7259, and L6646 as potentially related HCPCS codes. HCPCS code L7499 follows unlisted code processes.</li><li>Added PA to L6611, L6621, and L7259, but not to L6646. No change to configuration for codes currently in the policy.</li></ul>
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## CODING POLICIES

*Effective 4/1/26*

<b>Coding Policy 03.0 - Assistant for Surgical Procedures</b>	<p>PHP has noted an increase in insufficient documentation regarding the role and necessity of the assistant surgeon within operative reports. Coding Policy CP 03.0 – “Assistant for Surgical Procedures” requires the primary surgeon to clearly document both the presence of an assistant at surgery and the specific work performed by that assistant.</p> <p>Effective 04/01/26, if operative reports lack clear or adequate documentation describing the assistant’s role in the procedure, the assistant surgeon’s claim will be denied for reimbursement.</p>
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**Here's what's new from the following policy committees:**

## Pharmacy & Therapeutics (P&T) Committee

The December 2025 Oregon Region Pharmacy & Therapeutics Committee meeting was held by consent agenda voting only.

Go-Live Date: Sunday, February 01, 2026, unless otherwise noted

### Special Announcements

1. **Medical drug dose/frequency limits:** Per previous communications, the health plan has implemented claims editing that will assess dose and frequency on drugs administered medically at provider offices and outpatient facilities. Listed below are new limits that will be **effective on March 1, 2026**.

DRUG	HCPCS code, unit	Typical Dose	Dose/Frequency Limit
Keytruda® (pembrolizumab)	J9271, 1mg	400mg	400 every 6 weeks
Tecentriq® (atezolizumab)	J9022, 10mg	1680mg	168 units every 4 weeks
Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs)	J9024, 5mg	1875mg/15ml	375 units every 3 weeks
Jemperli® (dostarlimab-gxly)	J9272, 10mg	1000mg	100 units every 6 weeks
Ocrevus® (ocrelizumab)	J2350, 1mg	600mg	600 units every 6 months
Ocrevus Zunovo® (ocrelizumab and hyaluronidase-ocsq)	J2351, 1mg	920mg	920 units every 6 months
Evenity® (romosozumab-aqqg)	J3111, 1mg	210mg	210 units every 12 months
Tysabri® IV (natalizumab)	J2323, 1mg	300mg	300 units every 4 weeks
Tyruko® IV ( natalizumab-sztn)	Q5134, 1mg	300mg	300 units every 4 weeks

2. **Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors:** Jardiance® (empagliflozin) will be removed from Commercial and Medicaid formularies **effective March 1, 2026**.

- Farxiga® (dapagliflozin) will be the preferred SGLT-2 inhibitor

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## New Drugs and Combinations:

### 1. Aceclidine hcl (Vizz) Droperette

- Indication: For the treatment of presbyopia.
- 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>	N/A	N/A	N/A
<b>Quantity Limit</b>	1 box per 25 days	1 box per 25 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).

**Formulary Alternatives:** None

### 2. Brensocatib (Brinsupri) Tablet

- Indication: For the treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age and older.
- 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

Quantity Limit	One tablet per day	One tablet per day	One tablet 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> None			

c. Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Brinsupri
MEDICATION NAME	Brensocatib (Brinsupri)
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, all of the following must be met:</p> <ol style="list-style-type: none"> <li>1. Attestation of diagnosis of non-cystic fibrosis bronchiectasis confirmed by a chest computed tomography (CT) scan</li> <li>2. One of the following:           <ol style="list-style-type: none"> <li>a. For patients 18 years and older, greater than two exacerbations requiring antibiotic treatment in the past 12 months</li> <li>b. For patients 12 to 17 years of age, greater than one exacerbations requiring antibiotic treatment in the past 12 months</li> </ol> </li> </ol> <p>For reauthorization: adequate response to therapy, such as decrease in frequency, severity, or duration of exacerbations</p>
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pulmonologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year

d. Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Brinsupri
MEDICATION NAME	Brinsupri
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A

<b>REQUIRED MEDICAL INFORMATION</b>	<p>For initiation of therapy, all of the following must be met:</p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of non-cystic fibrosis bronchiectasis with physician attestation of a chest computed tomography (CT) scan or physician attestation of a documented chest CT scan.</li> <li>2. One of the following:           <ol style="list-style-type: none"> <li>a. For patients 18 years and older, greater than two exacerbations requiring antibiotic treatment in the past 12 months</li> <li>b. For patients 12 to 17 years of age, greater than one exacerbations requiring antibiotic treatment in the past 12 months</li> </ol> </li> </ol> <p>For reauthorization: adequate response to therapy, such as decrease in frequency, severity, or duration of exacerbations</p>
<b>AGE RESTRICTIONS</b>	N/A
<b>PRESCRIBER RESTRICTIONS</b>	Must be prescribed by, or in consultation with, a pulmonologist
<b>COVERAGE DURATION</b>	Initial authorization and reauthorization will be approved for one year

### 3. Bumetanide (Enbumatyst) Spray

- a. **Indication:** For the treatment of edema associated with congestive heart failure, hepatic, or renal disease.
- b. **Decision:**

	Commercial	Medicaid	Medicare
<b>Formulary Status*</b>	Non-formulary	Non-formulary	Part D: Non-formulary
<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>	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).

**Formulary Alternatives:** bumetanide oral or IV, furosemide oral or IV, torsemide oral or IV

### 4. Cosibelimab-ipdl (Unloxcyt) Vial

- a. **Indication:** For the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
- 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
* 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> pembrolizumab (Keytruda), cemiplimab (Libtayo)			

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

## 5. Dordaviprone hcl (Modeyso) Capsule

a. **Indication:** For the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma (DMG) harboring an H3 K27M mutation with progressive disease following prior 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>	20 capsules per 28 days	20 capsules per 28 days	20 capsules per 28 days
* 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> None			

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

#### 6. Gepirone HCl (Exxua) Tab ER 24h

- a. **Indication:** For the treatment of major depressive disorder (MDD) in adults.
- b. **Decision:**

	Commercial	Medicaid	Medicare
<b>Formulary Status*</b>	Non-formulary	Non-formulary (Covered by DMAP)	Part D: Formulary Part B: N/A
<b>Tier**</b>	N/A	N/A	Specialty
<b>Affordable Care Act Eligible</b>	N/A; Non-Formulary	N/A	N/A
<b>Utilization Management Edits</b>	N/A	N/A	Step Therapy
<b>Quantity Limit</b>	One tablet per day	N/A	One tablet 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).

**Formulary Alternatives:** citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, desvenlafaxine, venlafaxine, vilazodone, trazodone, mirtazapine, bupropion, amitriptyline, amoxapine, clomipramine, desipramine, doxepin, imipramine, nortriptyline, protriptyline, trimipramine

- c. **Prior Authorization Criteria for Medicare Part D:**

PA PROGRAM NAME	Antidepressants Step Therapy
MEDICATION NAME	Exxua (gepirone HCL tablet ER)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	<p>ST applies to new starts only</p> <p>One of the following:</p> <ol style="list-style-type: none"> <li>1) History of paid claims or documented trial (totaling at least two months of therapy) of two different generic selective serotonin reuptake inhibitors (SSRIs), or serotonin-norepinephrine reuptake inhibitors (SNRIs)</li> <li>2) Documented intolerance/contraindication to all formulary generic SSRIs/SNRIs (such as citalopram, sertraline, paroxetine, venlafaxine, duloxetine, escitalopram, fluoxetine, desvenlafaxine and fluvoxamine)</li> </ol>

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

## 7. Gepotidacin mesylate (Blujepa) Tablet

a. **Indication:** For the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus*, and *Enterococcus faecalis*.

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	
<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>	10 tablets per 30 days	10 tablets per 30 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).

**Formulary Alternatives:** fosfomycin, sulfamethoxazole-trimethoprim, nitrofurantoin

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

PA PROGRAM NAME	Antibiotics for Urinary Tract Infections
MEDICATION NAME	gepotidacin tablet, film coated (Blujepa®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	Coverage requires medical rationale for use over the following formulary antibiotics. Acceptable rationale includes, but is not limited to: member has failed or has an intolerance to all other available therapies or susceptibility testing results show a strain of bacteria only susceptible to the requested antibiotic therapy. <ul style="list-style-type: none"> <li>1. Nitrofurantoin monohydrate/macrocystals</li> <li>2. Trimethoprim-sulfamethoxazole, trimethoprim</li> <li>3. Fosfomycin trometamol</li> <li>4. Fluoroquinolones (such as ofloxacin, ciprofloxacin, and levofloxacin)</li> <li>5. <math>\beta</math>-Lactam agents (such as amoxicillin-clavulanate, cefdinir, cefaclor, cefpodoxime-proxetil, cefadroxil, cephalexin, amoxicillin, ampicillin)</li> </ul>
AGE RESTRICTIONS	Ages 12 years and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved for one month. No reauthorization.

#### 8. Imlunestrant tosylate (Inluriyo) Tablet

- a. **Indication:** For the treatment of ER-positive, HER2-negative, ESR1-mutated, advanced or metastatic breast cancer (mBC) in adults with disease progression following at least one line of endocrine therapy (ET).
- 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>	Two tablets per day	Two tablets per day	Two 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).

**Formulary Alternatives:** Orserdu® (elacestrant)

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

**9. Revakinagene taroletel-lwey (Encelto) Implant**

- a. **Indication:** For the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).
- 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>	1 per eye per lifetime	1 per eye per lifetime	1 per eye per lifetime

\* Recommendations for placement may differ between lines of business due to regulatory requirements.

\*\* Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).

**Formulary Alternatives:** N/A

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

PA PROGRAM NAME	Encelto
MEDICATION NAME	Encelto (revakinagene taroletel-lwey)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	<p>For all authorizations the following criteria must be met:</p> <ol style="list-style-type: none"> <li>1. Patient has a diagnosis of macular telangiectasia type 2, in at least one eye, as evidenced by typical fluorescein leakage and at least one (1) other of the following features of disease:           <ol style="list-style-type: none"> <li>a. Hyperpigmentation outside a 500-micron radius from the center of the fovea</li> <li>b. Retinal opacification</li> <li>c. Crystalline deposits</li> <li>d. Right angle vessels</li> <li>e. Inner/outer lamellar cavities</li> </ol> </li> <li>2. IS/OS PR break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm as measured by optical coherence tomography (OCT)</li> <li>3. Best corrected visual acuity (BCVA) of 54 letters or better on Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/80 Snellen equivalent)</li> </ol>

	4. No evidence of neovascular MacTel type 2 or documentation is provided indicating that patient has controlled neovascularization with no subretinal fibrosis 5. Patient has not previously received an Encelto® implant for the requested eye
AGE RESTRICTIONS	Age based on FDA approved label
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an ophthalmologist
COVERAGE DURATION	Authorization will be approved for two months. Prior authorization is limited to one Encelto® treatment per eye per lifetime. Additional implants will not be authorized.

**10. Rilzabrutinib (Wayrilz) Tablet**

- Indication:** For the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.
- 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>	Two tablets per day	Two tablets 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:** eltrombopag, Mplate®<sup>®</sup>, Doptelet<sup>®</sup>

- Prior Authorization Criteria for Commercial/Medicaid:**

PA PROGRAM NAME	Thrombocytopenia Medications
MEDICATION NAME	Rilzabrutinib tablet (Wayrilz®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

EXCLUSION CRITERIA	Concomitant use with other thrombopoietin receptor agonists (e.g., Mplate®, Promacta®, Nplate®) or with tyrosine kinase inhibitors (e.g., Tavalisse®, Wayrilz®)
REQUIRED MEDICAL INFORMATION	<p>For <b>Immune Thrombocytopenia (ITP)</b>, Alvaiz®, Doptelet®, Nplate®, Promacta®, Tavalisse®, or Wayrilz® may be covered if the following criteria are met:</p> <ul style="list-style-type: none"> <li>a. Diagnosis of chronic immune thrombocytopenia (ITP)</li> <li>b. Platelet count of less than 30,000 cells per microliter</li> <li>c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated:           <ul style="list-style-type: none"> <li>i. Systemic corticosteroids</li> <li>ii. Immune globulin</li> <li>iii. Splenectomy</li> </ul> </li> <li>d. For Alvaiz®, Doptelet®, and Tavalisse®: Inadequate response, intolerance, or contraindication to generic eltrombopag</li> <li>e. For Wayrilz, Inadequate response, intolerance, or contraindication to generic eltrombopag and Doptelet</li> </ul>
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist, hematologist, gastroenterologist or hepatologist.
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year

#### 11. Sulopenem etzadroxil/probenecid (Orlynvah) Tablet

- a. **Indication:** For the treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options.
- 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>	N/A	N/A	N/A
<b>Quantity Limit</b>	10 tablets per 30 days	10 tablets per 30 days	None

\* 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:** fosfomycin, sulfamethoxazole-trimethoprim, nitrofurantoin, amoxicillin-clavulanate, cefdinir, cefaclor, and cefpodoxime-proxetil, ciprofloxacin

## 12. Zongertinib (Hernexeos) Tablet

- a. **Indication:** For the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received 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>	Three tablets per day	Three tablets per day	Three 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).

**Formulary Alternatives:** Enhertu (fam-trastuzumab deruxtecan-nxki) vial

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

## 13. Zopapogene imadenovec-drba (Papzimeos) Vial

- a. **Indication:** For the treatment of adults with recurrent respiratory papillomatosis (RRP).
- 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

Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	4 injections within 12 weeks per lifetime	4 injections within 12 weeks per lifetime	4 injections within 12 weeks per lifetime
* 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:

PA PROGRAM NAME	Papzimeos
MEDICATION NAME	Papzimeos
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	<p>All the following must be met:</p> <ol style="list-style-type: none"> <li>1. Histologically confirmed diagnosis of recurrent respiratory papillomatosis</li> <li>2. Documented HPV serotype 6 or 11</li> <li>3. At least three (3) surgeries in previous 12 months</li> <li>4. Documented laryngotracheal papillomas</li> <li>5. Must have received HPV vaccination if under the age of 46 years.</li> </ol> <p>No reauthorization is allowed.</p>
AGE RESTRICTIONS	Approved for patients 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an otolaryngologist.
COVERAGE DURATION	6 months
QUANTITY LIMIT	One course of therapy (4 vials) per lifetime. Each vial is formulated to contain an extractable dose of $5 \times 10^{11}$ PU in a 1 mL suspension.

**New Indications:**

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database  
 from 8/1/2025–9/30/2025

Therapies with Prior Authorization Policies (Non-oncology)

1. **ACTEMRA (TOCILIZUMAB)**
  - a. New indication approved 8/8/2025:
    - i. Treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult and pediatric patients aged 2 years and older 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).
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid and Medicare Part B policy with new indication.
2. **AJOVY (FREMANEZUMAB-VFRM)**
  - a. New indication approved 8/8/2025:
    - i. The preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more.
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Indication reviewed with December 2025 P&T annual review.
3. **EVKEEZA (EVINACUMAB-DGNB)**
  - a. New indication approved 09/25/2025:
    - i. Adjunct to diet and exercise and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies to reduce LDL-C in adults and pediatric patients, aged 1 year and older, with homozygous familial hypercholesterolemia (HoFH).
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B policy with new indication. No other criteria updates warranted.
4. **OPZELURA (RUXOLITINIB)**
  - a. New indication approved 09/18/2025:
    - i. Mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid policy with new indication. No other criteria updates warranted.
5. **TREMFYA (GUSELKUMAB)**
  - a. New indication approved 09/26/2025:
    - i. Treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis and who are candidates for systemic therapy or phototherapy
    - ii. Treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis.
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid Policy with new indication. No policy updates warranted for Medicare Part D.
6. **VYJUVEK (BEREMAGENE GEPERPAVEC-SVDT)**
  - a. New indication approved 09/12/2025:

- i. Treatment of wounds in adults and pediatric patients ages with dystrophic epidermolysis bullosa (DEB) with mutations in the collagen type VII alpha 1 chain (COL7A1) gene.
- b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B policy with expanded age indication. No other criteria updates warranted.

7. **WEGOVY (SEMAGLUTIDE)**

- a. New indication approved 8/15/2025:
  - i. For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.
- b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Indication reviewed at October 2025 P&T.

Therapies with Prior Authorization Policies (Oncology)

1. **ARZERRA (OFATUMUMAB)**
- a. New indication(s) approved 8/18/25
  - i. For the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.
- 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.

2. **KOSELUGO (SELUMETINIB)**
- a. New indication(s) approved 9/10/25
  - i. Treatment of pediatric patients 1 year old and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)
- 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

1. **VONVENDI (VON WILLEBRAND FACTOR (RECOMBINANT) LYOPHILIZED POWDER FOR SOLUTION)**
- a. New indication approved 9/5/2025:
  - i. Indicated in adult and pediatric patients with (All types of) von Willebrand disease (VWD):
    - a. On-demand treatment and control of bleeding episodes.
    - b. Perioperative management of bleeding.
    - c. For adult patients only: Routine prophylaxis to reduce the frequency of bleeding episodes.
- b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Vaccines

1. **COMIRNATY** (COVID-19 VACCINE, mRNA)
  - a. 2025-2026 formula approved 8/27/2025:
    - i. 10 mcg drug product (2025-2026 Formula): For use in individuals 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19; and
    - ii. 30 mcg drug product (2025-2026 Formula): For use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.
2. **MNEXSPIKE** (COVID-19 VACCINE, mRNA)
  - a. 2025-2026 formula approved 8/27/2025:
    - i. For use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.
3. **NUVAXOVID** (COVID-19 VACCINE, ADJUVANATED)
  - a. 2025-2026 formula approved 8/27/2025:
    - i. For use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
  - b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.
4. **SPIKEVAX** (COVID-19 VACCINE, mRNA)
  - a. 2025-2026 formula approved 8/27/2025:
    - i. For use in individuals who are 65 years of age and older, or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

**RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

## Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database  
from 8/1/2025–9/30/2025

### FDA Drug Safety Communications

1. **Drug Name:** Clozapine
  - a. **Date Posted:** August 27, 2025
  - b. **Safety Alert Title:** FDA removes risk evaluation and mitigation strategy (REMS) program for the antipsychotic drug Clozapine
  - c. **Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dermarite-industries-expands-voluntary-nationwide-recall-due-potential-burkholderia-cepacia>
  - d. **What safety concern is FDA announcing?**

- i. The U.S. Food and Drug Administration (FDA) removed the risk evaluation and mitigation strategy (REMS) for clozapine (currently marketed as Clozaril, Versacloz, and generics), effective June 13, 2025. Clozapine, an antipsychotic medicine, can cause severe neutropenia (a low level of certain white blood cells), which can lead to serious and fatal infections. The removed REMS required enrollment of prescribers, pharmacies, and patients in a restricted distribution program and reporting of the level of certain white blood cells (i.e., the absolute neutrophil count (ANC)) to mitigate the risk of severe neutropenia.
- ii. Based on FDA's re-evaluation of the Clozapine REMS and on the [November 19, 2024 Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee](#), the Agency determined that the REMS was no longer necessary to ensure the benefits of clozapine outweigh the risk of severe neutropenia. Although there remains a risk of severe neutropenia with clozapine use, clozapine labeling (including a new Medication Guide) is sufficient to mitigate this risk and maintain a positive benefit/risk profile. ANC monitoring can help identify neutropenia early to allow for timely intervention. Therefore, prescribers should continue to monitor patients' ANC according to the monitoring frequencies described in the [prescribing information](#). Eliminating the REMS is expected to improve access to clozapine and decrease the burden on the health care delivery system.

e. **What is FDA doing?**

- i. FDA has removed the REMS for clozapine. As a result, prescribers, pharmacies, and patients are no longer required to participate in the REMS program and report patients' ANC results to the REMS in order for clozapine to be dispensed to the patient.
- ii. Information about severe neutropenia is in the prescribing information for all clozapine medicines, including in a Boxed Warning and a new Medication Guide.
- iii. Severe neutropenia remains a serious, potentially fatal risk that is greatest in the first several months of clozapine treatment. ANC monitoring can help identify neutropenia early to allow for timely intervention. Therefore, FDA recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information.

f. **What should health care professionals do?**

- i. Prescribers of clozapine no longer have to be enrolled in the REMS or to enroll their patients in it. They also do not have to submit absolute neutrophil count (ANC) results to the REMS program. Prescribers should continue to monitor their patients' ANC before starting clozapine and during treatment according to the prescribing information and to counsel patients about the risk of severe neutropenia.
- ii. Pharmacies do not need to be enrolled in the REMS to order clozapine from wholesaler distributors. Pharmacists do not need to verify patient eligibility, including ANC monitoring, before dispensing clozapine to patients.
- iii. Health care professionals should be advised that the risk of neutropenia is generally greatest in the first several months of clozapine treatment and persists at a lower level thereafter. In addition, they should tell their patients to seek medical care if they experience symptoms that may indicate neutropenia.

g. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Leqembi (lecanemab)

- a. **Date Posted:** August 28, 2025
- b. **Safety Alert Title:** FDA to recommend additional, earlier MRI monitoring for patients with Alzheimer's disease taking Leqembi (lecanemab)
- c. **Link to more information:** <https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommend-additional-earlier-mri-monitoring-patients-alzheimers-disease-taking-leqembi-lecanemab>
- d. **What safety concern is FDA announcing?**

- i. The U.S. Food and Drug Administration (FDA) is recommending an additional, earlier magnetic resonance imaging (MRI) monitoring prior to the 3<sup>rd</sup> infusion for patients with Alzheimer's disease taking Leqembi (lecanemab). The earlier monitoring can identify individuals with amyloid-related imaging abnormalities with edema (ARIA-E), which is characterized by brain swelling or fluid buildup. ARIA-E is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur and there have been deaths.
- ii. The Alzheimer's disease community has been aware of ARIA-E associated with Leqembi, and current prescribing information recommends MRI imaging before the 5<sup>th</sup>, 7<sup>th</sup>, and 14<sup>th</sup> infusions. However, after an in-depth analysis of this safety issue, the Agency has determined that an additional monitoring MRI prior to the 3<sup>rd</sup> infusion can potentially help identify ARIA-E events earlier.
- iii. ARIA-E can progress after initial detection on MRI. Identifying patients with ARIA-E can lead health care professionals, patients, and their families to delay or discontinue Leqembi treatment to potentially mitigate these serious and, in some cases, fatal events.

e. **What is FDA doing?**

- i. FDA is requiring the prescribing information of Leqembi (lecanemab) to include an earlier monitoring MRI between the 2<sup>nd</sup> and 3<sup>rd</sup> infusion. This revised language will be in the monitoring schedule (Section 2.3) of the prescribing information.

f. **What should health care professionals do?**

- i. Health care professionals should be aware of the new recommendations and perform monitoring MRIs on patients between the 2nd and 3rd Leqembi infusions. Health care professionals should advise patients (or their caregivers) to immediately contact them if they experience ARIA-E symptoms, such as headache, confusion, dizziness, vision changes, nausea, aphasia, weakness or seizure. In this case, health care professionals should order urgent MRIs.
- ii. If ARIA-E is diagnosed, health care professionals should discuss with patients and caregivers the potential need to delay or discontinue Leqembi treatment. Please refer to dose suspension criteria in the approved USPI in Section 2.3 Table 1. ARIA-E, with or without symptoms, can progress after initial detection on MRI.

g. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

#### Drug Recalls/Market Withdrawals

1. **Drug Name:** DermaKleen, Dermasarra, Kleenfoam, and Pergiene Products
  - a. **Date of Recall:** August 8, 2025
  - b. **Reason for recall:** Contamination with Burkholderia cepacia
  - c. **Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dermarite-industries-issues-voluntary-nationwide-recall-dermakleen-dermasarra-kleenfoam-and>
  - d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
2. **Drug Name:** B. Braun Lactated Ringer's Injection USP 1000 mL and 0.9% NaCl USP 1000 mL injection
  - a. **Date of Recall:** August 19, 2025
  - b. **Reason for recall:** Due to the presence of particulate matter
  - c. **Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-medical-issues-voluntary-nationwide-recall-lactated-ringers-injection-usp-1000-ml-and-09>
  - d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Cyclobenzaprine HCl 10 mg tablet (Unichem Pharmaceuticals)

- Date of Recall:** August 27, 2025
- Reason for recall:** Device & Drug Safety – Mislabel
- Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/unichem-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-cyclobenzaprine-hydrochloride>
- Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** DermaRite Hand Sanitizers, Cleansers, Skin Protectants, Deodorant

- Date of Recall:** August 27, 2025
- Reason for recall:** Potential Burkholderia cepacia contamination
- Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dermarite-industries-expands-voluntary-nationwide-recall-due-potential-burkholderia-cepacia>
- Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Green Lumber Dietary Supplement

- Date of Recall:** August 28, 2025
- Reason for recall:** Undeclared prescription drug, tadalafil, detected
- Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/green-lumber-holding-llc-issues-consumer-alert-counterfeit-products-following-fda-findings#recall-announcement>
- Health Plan Recommendation:** Notify providers via Medical Policy Alert.

## Other Formulary Changes:

Drug Name	Recommendation	Policy Name
<b>Eltrombopag choline (Alvaiz) Tablet</b>	New formulation <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-formulary, Prior Authorization, Quantity Limit (1 tablet per day)</li> </ul> <b>Effective: 3/1/2026</b>	Thrombocytopenia Medications
<ul style="list-style-type: none"> <li><b>Cabozantinib s-malate (Cabometyx) Tablet</b></li> <li><b>Acalabrutinib maleate (Calquence) Tablet</b></li> <li><b>Apalutamide (Erleada) Tablet</b></li> <li><b>Lenvatinib mesylate (Lenvima) Capsule</b></li> </ul>	<ul style="list-style-type: none"> <li>Commercial: down tier from Tier 6 to Tier 5</li> </ul> <b>Effective: 1/1/2026</b>	Anti-Cancer Medications - Self-Administered

Drug Name	Recommendation	Policy Name
<b>Tocilizumab-anoh (Avtozma) Vial</b>	New Biosimilar; Line extend as non-preferred biosimilar <ul style="list-style-type: none"> <li>Medical Benefit, Prior Authorization for all lines of business</li> </ul>	Medically Infused Therapeutic Immunomodulators
<b>Docetaxel/albumin, human (Beizray-Albumin) Vial</b>	New formulation; <ul style="list-style-type: none"> <li>Medical Benefit, Prior Authorization for all lines of business</li> </ul>	ANTI-cancer Medications - Medical Benefit
<b>Escitalopram Oxalate Capsule</b>	New formulation (capsule); <ul style="list-style-type: none"> <li>Non-formulary for all lines of business</li> </ul>	N/A
<b>Ibuprofen 300 mg Tablet</b>	New strength; <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>Gemcitabine hcl (Inlexzo) Implant</b>	New formulation; <ul style="list-style-type: none"> <li>Medical Benefit, Prior Authorization for all lines of business</li> </ul>	ANTI-cancer Medications - Medical Benefit
<b>Selumetinib sulfate (Koselugo) Cap Sprink</b>	New formulation (sprinkle capsule); <ul style="list-style-type: none"> <li>Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 mg: 20 capsules per day; 7.5 mg: 12 capsules per day)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (5 mg: 20 capsules per day; 7.5 mg: 12 capsules per day)</li> </ul>	Anti-Cancer Medications - Self-Administered
<b>Carboplatin (Kyxata) Vial</b>	New MedID; <ul style="list-style-type: none"> <li>Medical Benefit, Prior Authorization for all lines of business</li> </ul>	ANTI-cancer Medications - Medical Benefit
<b>Liraglutide (Saxenda) Pen Injctr</b>	First generic drug (Saxenda); <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 3, Prior Authorization, Quantity Limit (0.5 mL per day)</li> <li>Commercial Dynamic: Non- Formulary, Prior Authorization, Quantity Limit (0.5 mL per day)</li> <li>Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (0.5 mL per day)</li> <li>Medicare Part D: Non- Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Weight Management Medications</li> <li>Medicare Part D: N/A</li> </ul>

Drug Name	Recommendation	Policy Name
<b>Natalizumab-sztn (Tyruko) Vial</b>	New biosimilar for Tysabri; <ul style="list-style-type: none"> <li>Medical Benefit, Prior Authorization for all lines of business</li> </ul>	Tysabri
<b>Immune globulin,gamma(igg)dira (Yimmugo) Vial</b>	New formulation; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Medical Benefit, Prior Authorization, Specialty</li> <li>Medicare Part D: Non-Formulary</li> <li>Medicare Part B: Medical Benefit, Prior Authorization</li> </ul>	Immune Gamma Globulin (IGG)
<b>Tizanidine hcl (Zanaflex) Capsule</b>	New strength 8 mg; <ul style="list-style-type: none"> <li>Non-formulary for all lines of business</li> </ul>	N/A
<b>Roflumilast (Zoryve) Cream (G)</b>	New strength (0.05%); <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-formulary, Prior Authorization, Quantity Limit (60 grams per 30 days)</li> <li>Medicare: Non-Formulary</li> </ul>	Topical Agents for Skin Conditions
<b>Nalmefene hcl (Zurnai) Auto Inject</b>	New formulation; <ul style="list-style-type: none"> <li>Commercial/Medicare Part D: Formulary, Tier 4</li> <li>Medicaid: Formulary</li> </ul>	N/A
<b>Ferric citrate (Auryxia) Tablet</b>	Remove from Medicaid formulary	N/A
<b>Galcanezumab-gnlm (Emgality) Pen Injctr</b>	Remove from Medicaid formulary	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists
<ul style="list-style-type: none"> <li><b>Lanthanum carbonate (Fosrenol) Tab Chew; Powd Pack</b></li> <li><b>Sevelamer hcl (Renagel) Tablet</b></li> <li><b>Sevelamer Carbonate Powd Pack</b></li> </ul>	Remove from Medicaid formulary	Phosphate Binders Step Therapy Policy
<b>Prucalopride succinate (Motegrity) Tablet</b>	<ul style="list-style-type: none"> <li>Commercial Standard: Down tier generic to Tier 2, add quantity limit (one tablet per day)</li> <li>Commercial Dynamic: Down tier generic to Tier 3, add quantity limit (one tablet per day)</li> <li>Medicaid: Add generic to formulary, add quantity limit (one tablet per day)</li> </ul> <p><b>Effective: 3/1/2026</b></p>	Constipation Agents

Drug Name	Recommendation	Policy Name
<b>Evolocumab (Repatha Pushtronx) Pushtronx</b>	Drug formulation removed from market; <ul style="list-style-type: none"> <li>Remove from formulary for all lines of business</li> </ul>	N/A
<b>Itraconazole (Sporanox) Capsule; Solution</b>	Commercial Dynamic: Down tier from Tier 4 to Tier 3	Antifungal Agents
<b>Solriamfetol hcl (Sunosi) Tablet</b>	Commercial: Down tier from Tier 4 to Tier 3	Narcolepsy Agents
<ul style="list-style-type: none"> <li><b>Ubrogepant (Ubrelvy) Tablet</b></li> <li><b>Zavegepant hcl (Zavzpret) Spray</b></li> </ul>	<ul style="list-style-type: none"> <li>Commercial: Add to Formulary, Tier 3</li> </ul>	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists – Comm
<b>Pitolisant hcl (Wakix) Tablet</b>	Remove from Commercial formulary	Narcolepsy Agents
<b>Sodium oxybate (Xyrem) Solution</b>	<ul style="list-style-type: none"> <li>Commercial: Remove brand from formulary, and up tier generic to Tier 6</li> </ul>	Narcolepsy Agents
<b>Golimumab (Simponi) injector/syringe</b>	<ul style="list-style-type: none"> <li>Commercial: Add to formulary Tier 5, prior authorization, quantity limit (one dose per 28 days)</li> </ul> <p><b>Effective: 1/1/2026</b></p>	Therapeutic Immunomodulators
<b>Tocilizumab-aazg (Tyenne) Autoinjector/Syringe; Pen Injctr</b>	<ul style="list-style-type: none"> <li>Commercial: Move to Tier 5 from Tier 6</li> </ul> <p><b>Effective: 1/1/2026</b></p>	Therapeutic Immunomodulators
<b>Vonoprazan fumarate (Voquezna) Tablet</b>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Add quantity limit (10 mg: 1 tablet per day; 20 mg: 2 tablets per day)</li> </ul>	N/A
<b>Vonoprazan/amoxicillin (Voquezna Dual Pak) Combo. Pkg</b>	Commercial/Medicaid: Add quantity limit (112 units per 14 days)	N/A
<b>Lubiprostone (Amitiza) capsule</b>	Commercial/Medicaid: Add quantity limit (2 capsules per day)	N/A
<b>Xeljanz (tofacitinib)</b>	Commercial: Move to Tier 5 from Tier 6	Therapeutic Immunomodulators
<ul style="list-style-type: none"> <li><b>Mavenclad (cladribine)</b></li> <li><b>Vumerity (diroximel fumarate)</b></li> </ul>	Commercial: Move to Tier 5 from Tier 6	Multiple Sclerosis Agents
<b>Linzess (linaclotide)</b>	Commercial/Medicaid: Add quantity limit (1 capsule per day)	N/A
<b>Jardiance (empagliflozin)</b>	Commercial/Medicaid: Remove from formulary	N/A
	<b>Effective: 3/1/2026</b>	

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

Pharmacy Operational Policy ORPTCOPS062

Drugs released from 8/8/2025 – 10/24/2025

**INFORMATIONAL ONLY**

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
<b>Thiotepa (Tepylute) Vial</b>	<p><b>Correction from June 2025 P&amp;T:</b>            New strength (100 mg/10ml). Line extend as Medical Benefit for all lines of business</p>	N/A
<b>Dihydroergotamine mesylate (Brekiga) Auto Injct</b>	New formulation or New entity. Line extend with DHE 45 1mg/ml injection; <ul style="list-style-type: none"> <li>Non-Formulary for all lines of business</li> </ul>	N/A
<ul style="list-style-type: none"> <li><b>Apixaban (Eliquis 0.5 mg) Tab Susp</b></li> <li><b>Apixaban (Eliquis Sprinkle 0.15 mg) Cap Sprink</b></li> </ul>	New formulation. Line extend with Eliquis tablet; <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 3</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Formulary, Tier 3, Quantity Limit (2 tablets/cap sprinkles per day)</li> </ul>	N/A
<b>Apixaban (Eliquis 1.5 mg) Tab Susp</b>	New formulation. Line extend with Eliquis tablet; <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 3</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Formulary, Tier 3, Quantity Limit (6 tablets per day)</li> </ul>	N/A
<b>Apixaban (Eliquis 2 mg) Tab Susp</b>	New formulation. Line extend with Eliquis tablet; <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 3</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Formulary, Tier 3, Quantity Limit (8 tablets per day)</li> </ul>	N/A
<b>Fibrinogen (Fibryga) Vial</b>	New strength (2 gm). Line extend with Fibryga 1 gm IV; <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit</li> <li>Medicare Part D: Non-Formulary</li> </ul>	N/A
<b>Glucagon (Gvoke Vialdx) Vial</b>	New formulation. Line extend as medical; <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit</li> <li>Medicare Part D: Non-Formulary</li> </ul>	N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
<ul style="list-style-type: none"> <li><b>Insulin aspart-xjhz (Kirsty) Vial</b></li> <li><b>Insulin aspart-xjhz (Kirsty Pen) Insulin Pen</b></li> </ul>	New formulation. Line extend with insulin aspart biosimilars; <ul style="list-style-type: none"> <li>Non-Formulary for all lines of business</li> </ul>	N/A
<b>Liothyronine sodium (Liomny) Tablet</b>	New MedID. Line extend with liothyronine; <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 2</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Formulary, Tier 2</li> </ul>	N/A
<b>Flurbiprofen (Lurbiro) Tablet</b>	New generic. Line extend with Lurbipro; <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 2</li> <li>Commercial Dynamic: Formulary, Tier 3</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Formulary, Tier 3</li> </ul>	N/A
<b>Denosumab-dssb (Ospomyv) Syringe</b>	New formulation. Prolia biosimilar. Line extend with non-preferred denosumab biosimilars; <ul style="list-style-type: none"> <li></li> </ul>	N/A
<b>Piperacillin sodium/tazobactam (Piperacillin-Tazobactam) Piggyback</b>	New formulation. Line extend with piperacillin sodium/tazobactam sodium; <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit</li> <li>Medicare Part D: Non-Formulary</li> </ul>	N/A
<b>Darunavir/cobicistat (Prezcobix) Tablet</b>	New strength (675 mg-150 mg). Line extend with Prezcobix 800 mg-150 mg tablet; <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 4</li> <li>Medicaid: Formulary</li> <li>Medicare Part D: Formulary, Tier 5, Quantity Limit (1 tablet per day)</li> </ul>	N/A
<b>Lecanemab-irmb (Leqembi IQLIK) Auto Inject</b>	New dosage form (Auto Inject). Line extend with Leqembi 100mg/ml IV; <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	Anti-Amyloid Monoclonal Antibodies
<b>Bevacizumab-nwgd (Jobevne) Vial</b>	New BLA. Line extend as non-preferred biosimilar; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Medical Benefit, Prior Authorization</li> </ul>	Anti-Cancer Medications - Medical Benefit

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
	<ul style="list-style-type: none"> <li>• Medicare Part D: Non-Formulary</li> <li>• Medicare Part B: Medical Benefit, Prior Authorization and Step Therapy</li> </ul>	
<b>Remestemcel-l-rknd (Ryoncil) Kit</b>	<p>New strengths (100 kg- less than 112.5 kg; 112.5 kg-less than 125 kg; 125 kg- less than 137.5 kg; 137.5 kg- less than 150 kg). Line extend with Existing Ryoncil strengths;</p> <ul style="list-style-type: none"> <li>• Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization</li> <li>• Medicare Part D: Non-Formulary</li> </ul>	Anti-Cancer Medications - Medical Benefit
<b>Zanubrutinib (Brukinsa) Tablet</b>	<p>New strength (160 mg). Line extend with Brukinsa 80mg;</p> <ul style="list-style-type: none"> <li>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 tablets per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day), Specialty</li> <li>• Medicare Part D: Formulary, Tier 5, Quantity Limit (2 tablets per day)</li> </ul>	Anti-Cancer Medications - Self-Administered
<b>Dasatinib (Phyrago) Tablet</b>	<p>New MedID. Line extend with Brand Sprycel;</p> <ul style="list-style-type: none"> <li>• Commercial/ Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (20 mg: 3 tablets per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (20 mg: 3 tablets per day), Specialty</li> </ul>	Anti-Cancer Medications - Self-Administered
<b>Dasatinib (Phyrago) Tablet</b>	<p>New MedID. Line extend with Brand Sprycel;</p> <ul style="list-style-type: none"> <li>• Commercial/ Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (20 mg; 50 mg; 70 mg; 80 mg; 100 mg; 140 mg: 1 tablet per day)</li> <li>• Medicaid: Formulary, Prior Authorization, Quantity Limit (20 mg; 50 mg; 70 mg; 80 mg; 100 mg; 140 mg: 1 tablet per day), Specialty</li> </ul>	Anti-Cancer Medications - Self-Administered
<b>Blood-glucose sensor (Dexcom G7 15 Day Sensor)</b>	<p>New preferred diabetic medical supply (PDMS). Line extend with Dexcom G7 10 day sensor;</p>	Continuous Glucose Monitors for Personal Use

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
	<ul style="list-style-type: none"> <li>Commercial Standard: PDMS, Prior Authorization, Quantity Limit (2 each per 30 days)</li> <li>Commercial Dynamic: Formulary, Tier 3, Prior Authorization, Quantity Limit (2 each per 30 days)</li> <li>Medicaid: Formulary, PDMS, Prior Authorization, Quantity Limit (2 each per 30 days)</li> <li>Medicare Part D: Non-Formulary</li> <li>Medicare Part B: PDMS, Prior Authorization, Quantity Limit (2 each per 30 days)</li> </ul>	
<b>Denosumab-dssb (Ospomyv) Syringe</b>	<p>New formulation. Prolia biosimilar. Line extend with non-preferred denosumab biosimilars;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	Denosumab
<b>Pegloticase (Krystexxa) Infus. Btl</b>	<p>New formulation. Line extend with Krystexxa 8mg/ml;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	Krystexxa
<b>Butalbital-acetaminophen-caffeine Tab ER 24h</b>	<p>New Formulation. Line extend with butal-acetcaf 50-325-40mg tabs and caps;</p> <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 2, Prior Authorization</li> <li>Medicaid: Formulary, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Pediatric Analgesics</li> <li>Medicare Part D: N/A</li> </ul>
<b>Treprostinil sodium (Remodulin) Vial</b>	<p>New strength (0.4 mg/ml). Line extend with existing strengths of Remodulin as Medical;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Pulmonary Hypertension</li> <li>Medicare Part D: N/A</li> </ul>

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
<b>Apremilast (Otezla XR) Tab ER 24h</b>	<p>New formulation. Line extend with Otezla immediate release;</p> <ul style="list-style-type: none"> <li>Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day)</li> <li>Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 tablet per day), Specialty</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Apremilast (Otezla XR) TB TBER DP</b>	<p>New formulation. Line extend with Otezla immediate release;</p> <ul style="list-style-type: none"> <li>Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (41 tablets per 28 days)</li> <li>Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (41 tablets per 28 days)</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Ustekinumab-ttwe (Pyzchiva Autoinjector) Auto Injct</b>	<p>New formulation. Line extend with non-preferred Stelara biosimilar;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (90 mg/mL: 1 mL per 84 days; 45 mg/0.5 mL: 0.5 mL per 84 days), Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Ustekinumab-aekn (Selarsdi) Vial</b>	<p>New formulation. Line extend with Selarsdi 45mg/0.5ml syringe;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.5 mL per 84 days), Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul>	Therapeutic Immunomodulators (TIMS)
<b>Avatrombopag maleate (Doptelet Sprinkle) Cap Sprink</b>	<p>New formulation. Line extend with Doptelet tablet;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 capsules per day)</li> <li>Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (2 capsules per day), Specialty</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Thrombocytopenia Medications</li> <li>Medicare Part D: N/A</li> </ul>

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	Action Taken	Policy Name
	<ul style="list-style-type: none"> <li>Medicare Part D: Non- Formulary</li> </ul>	

NEW GENERICS		
Drug Name	Action Taken	Policy Name
<b>Amphetamine ER ODT TAB RAP BP</b>	First generic drug (Adzenys XR-ODT). Line extend as generic; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Quantity Limit (1 tablet per day)</li> </ul>	N/A
<b>Carbidopa/levodopa (Carbidopa-Levodopa ER) Capsule ER</b>	First generic drug (Rytary). Line extend with brand Rytary capsule; <ul style="list-style-type: none"> <li>Non-Formulary for all lines of business</li> </ul>	N/A
<b>Clemastine fumarate (Clemsza) Tablet</b>	New MedID. Line extend as generic; <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 2</li> <li>Commercial Dynamic: Formulary, Tier 4</li> <li>Medicaid: Formulary</li> <li>Medicaid Part D: Non-Formulary</li> </ul>	N/A
<b>Iron sucrose complex (Iron Sucrose) Vial</b>	First generic drug (Venofer). Line extend as medical; <ul style="list-style-type: none"> <li>Commercial/Medicaid/Medicare Part B: Medical Benefit</li> <li>Medicare Part D: Non-Formulary</li> </ul>	N/A
<b>Clomiphene citrate (Milophene) Tablet</b>	First generic. Line extend with clomiphene citrate; <ul style="list-style-type: none"> <li>Non-Formulary for all lines of business</li> </ul>	N/A
<b>Everolimus 2 mg &amp; 5 mg Tab Susp</b>	First generic drug (Afinitor Disperz). Line extend as generic; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day)</li> </ul>	Anti-Cancer Medications - Self-Administered
<b>Everolimus 3 mg Tab Susp</b>	First generic drug (Afinitor Disperz). Line extend as generic; <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty</li> </ul>	Anti-Cancer Medications - Self-Administered

NEW GENERICS		
Drug Name	Action Taken	Policy Name
	<ul style="list-style-type: none"> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (3 tablets per day)</li> </ul>	
<b>Deflazacort (Jaythari) Tablet</b>	<p>New MedID. Line extend with generic deflazacort;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (6 mg: 2 tablets per day; 18 mg: 1 tablet per day) Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy</li> <li>Medicare Part D: N/A</li> </ul>
<b>Deflazacort (Jaythari) 30 mg; 36 mg Tablet</b>	<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: Corticosteroids for Duchenne Muscular Dystrophy</li> <li>Medicare Part D: N/A</li> </ul>
<b>Glycerol phenylbutyrate Liquid</b>	<p>First generic drug (Ravicti). Line extend with Ravicti 1.1 gm/mL;</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: Non- Formulary</li> </ul>	Medications For Rare Indications
<b>Gabapentin ER 450 mg; 750 mg; 900 mg Tab ER 24h</b>	<p>New generic for Gralise ER. Line extend as generic;</p> <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>Bosentan Tab Susp</b>	<p>New generic drug. Line extend with brand Tracleer;</p> <ul style="list-style-type: none"> <li>Commercial: Formulary, Tier 5, Prior Authorization</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: Pulmonary Hypertension</li> <li>Medicare Part D: N/A</li> </ul>
<b>Pilocarpine hcl Drops</b>	<p>First generic drug (Vuity). Line extend as generic;</p> <ul style="list-style-type: none"> <li>Commercial/Medicaid: Non- Formulary, Prior Authorization</li> </ul>	<ul style="list-style-type: none"> <li>Commercial/Medicaid: Qlosi, Vuity</li> <li>Medicare Part D: N/A</li> </ul>

NEW GENERICS		
Drug Name	Action Taken	Policy Name
<b>Progesterone, micronized (Progesterone) Insert</b>	<ul style="list-style-type: none"> <li>Medicare Part D: Non- Formulary</li> </ul> <p>First generic. Line extend with Brand Endometrin;</p> <ul style="list-style-type: none"> <li>Commercial Standard: Formulary, Tier 2, Prior Authorization</li> <li>Commercial Dynamic: Formulary, Tier 3, Prior Authorization</li> <li>Medicaid/Medicare Part D: Non-Formulary</li> </ul>	<ul style="list-style-type: none"> <li>Commercial: Vaginal Progesterone Formulations</li> <li>Medicaid/Medicare Part D: N/A</li> </ul>

## Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	Summary of Change
<ul style="list-style-type: none"> <li><b>Adakveo</b></li> <li><b>Adakveo Prior Authorization and Step Therapy Policy - Medicare Part B</b></li> </ul>	Clarified definition of pain crisis. Added quantity limit and updated position statement with new evidence.
<b>Albendazole, Emverm</b>	Added a step through albendazole for Emverm® (mebendazole), added a quantity limit for Emverm®.
<b>Antifungal Agents</b>	Removed prior authorization requirements for itraconazole and therefore removed itraconazole from criteria, removed requirement for Vivjoa® that patient must have been assigned female at birth.
<b>Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Commercial</b>	For migraine prophylaxis, removed trial and failure of generic prophylactic medications (e.g. beta-blockers, antidepressants) as clinical guidelines (American Headache Society 2024) now recommend CGRP antagonists as a first line approach for migraine prevention. Updated Nurtec quantity limit to allow for prophylaxis every other day dosing. For episodic cluster headaches, added additional options for prerequisite medications and removed duration of trial. Updated initial authorization to one year.
<b>CGRP Receptor Antagonists - Medicaid</b>	Updated duration of prerequisite trial and failure to eight weeks and updated criteria for combination therapy with Botox® to align with Oregon Health Authority. Updated Nurtec® quantity limit to allow for prophylaxis every other day dosing. Updated initial authorization to one year.

MAJOR CHANGES	
Policy Name	Summary of Change
<b>CGRP Receptor Antagonists Prior Authorization and Step Therapy Policy - Medicare Part B</b>	Removed trial and failure of generic prophylactic medications (e.g., beta-blockers, antidepressants) as clinical guidelines (American Headache Society 2024) now recommend CGRP antagonists as a first line approach for migraine prevention. Updated initial authorization to one year.
<b>Cholestatic Pruritus Agents</b>	Exclusion criteria of concurrent use with any other ileal bile acid transporter (IBAT) therapy, exclusion criteria for genes for progressive familial intrahepatic cholestasis (PFIC) moved to criteria, documentation of mutation for Alagille Syndrome (ALGS) added, and quantity limits updated for Livmarli and Bylvay made as max dose differs by indication.
<b>Complement Inhibitors</b>	Updated criteria for c3 glomerulopathy to require Empaveli® for Fabhalta®. Added requirement of use of biosimilar Ephysql® (eculizumab-aagh) for Neuromyelitis Optica Spectrum Disorder (NMOSD) before coverage of Soliris®/Bkemv®.
<b>Complement Inhibitors Prior Authorization and Step Therapy Policy - Medicare Part B</b>	Added requirement of use of biosimilar Ephysql® (eculizumab-aagh) for Neuromyelitis Optica Spectrum Disorder (NMOSD) before coverage of Soliris®/Bkemv®
<b>Constipation Agents</b>	Added quantity limits for all drugs on policy. As generic prucalopride (Motegrity) is now available, removed prior authorization requirements for this drug and added as a trial and failure option for chronic idiopathic constipation. Removed requirement of trial and failure of lubiprostone for females for IBS-C due to operational burden and health equity principles.
<b>Constipation Agents - Medicaid</b>	Updated criteria to align with the Oregon Health Authority: <ul style="list-style-type: none"> <li>Added prescriber restrictions</li> <li>Updated trial and failure criteria. If patient does not meet trial and failure criteria, will allow for medical rationale for not using preferred agents</li> <li>Added criteria requiring FDA indication for those eligible for Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) review,</li> <li>Added quantity limits for all drugs on policy</li> </ul>
<b>Hemophilia Prophylactic Agents</b>	Updated criteria for Alhemo® (concizumab) to include updated indication for patients without inhibitors. Added exclusion for use with factor therapies. Removed weight restrictions as not in package insert.
<ul style="list-style-type: none"> <li><b>Hepatitis C - Direct Acting Antivirals</b></li> <li><b>Hepatitis C - Direct Acting Antivirals - Medicaid</b></li> </ul>	Added criterion to address treatment failure or retreatment due to non-compliance and added quantity limits which are already in place.
<b>Infusion Therapy Site of Care</b>	Added Ontruzant® (trastuzumab-dttb), Riabni (rituximab-arrx), and Rituxan (rituximab) allowing 2 doses within 60 days transition. Removed the following drugs:

MAJOR CHANGES	
Policy Name	Summary of Change
	Bomynta®/Conexxence® (denosumab-bnht), Jubonti®/Wyost® (denosumab-bbdz), Osenvelt®/Stoboclo® (denosumab-bmwo), Prolia/Xgeva (denosumab)
<ul style="list-style-type: none"> <li><b>Jesduvroq, Vafseo</b></li> <li><b>Jesduvroq, Vafseo Prior Authorization and Step Therapy Policy - Medicare Part B</b></li> </ul>	Jesduvroq® is no longer available on the market, so was removed from the policy and changed policy name to Vafseo. Added exclusion for combo with erythropoiesis-stimulating agents, and reduced coverage duration to six months for initial authorization
<b>Livtency</b>	Quantity limit updated to twelve tablets per day to reflect package insert updates.
<ul style="list-style-type: none"> <li><b>Medically Infused Therapeutic Immunomodulators (TIMs) – Comm</b></li> <li><b>Medically Infused TIMs Prior Authorization and Step Therapy Policy - Medicare Part B</b></li> </ul>	Updated for new indications for Tremfya (psoriasis/psoriatic arthritis)
<b>Narcolepsy Agents</b>	Updated specific requirements for diagnostic criteria, prerequisite step therapy medications, and duration of approval.
<ul style="list-style-type: none"> <li><b>PCSK9 Inhibitors – Commercial</b></li> <li><b>PCSK9 Inhibitors – Medicaid</b></li> </ul>	Added criteria for new indication of primary prevention in patients with hyperlipidemia at high-risk of MACE.
<b>Phosphate Binders Step Therapy Policy</b>	Removed Medicaid from policy as drugs are not on the Oregon Health Authority Preferred Drug List; medications will be reviewed as a non-formulary request.
<ul style="list-style-type: none"> <li><b>Prevymis</b></li> <li><b>Prevymis Prior Authorization and Step Therapy Policy - Medicare Part B</b></li> </ul>	Clarified definition of cytomegalovirus (CMV) positive in clinical criteria by adding verbiage in regards to donor and recipient.
<ul style="list-style-type: none"> <li><b>Reblozyl, Rytelo</b></li> <li><b>Reblozyl, Rytelo Prior Authorization and Step Therapy Policy - Medicare Part B</b></li> </ul>	Updated criteria for myelodysplastic syndrome to align with National Comprehensive Cancer Network guidelines. Added language for medical drug quantity limits.
<b>Rezdiffra</b>	Updated Medical Dysfunction-Associated Steatohepatitis (MASH) diagnostic criteria to no longer require liver biopsy; non-invasive confirmation of fibrosis score is permitted. Clarified other criteria to align with semaglutide (Wegovy®) criteria previously approved by P&T.
<b>Self-Administered Drugs (SAD)</b>	Added the following drugs: Dawnzera® (donidalorsen), Forzinity® (elamipretide), Otulfi® (ustekinumab-aauz), Stariemza® (ustekinumab-hmny), Yesintek® (ustekinumab-kfce), and Imdulsa® (ustekinumab-srlf)
<b>TIMS – Commercial</b>	Updated indications for Tremfya® and Simponi®. Updated prerequisite therapy requirements for Rinvoq® for Crohn's disease and ulcerative colitis.

MAJOR CHANGES	
Policy Name	Summary of Change
<b>TIMS – Medicaid</b>	Updated indications for Tremfya® and Simponi®. Updated preferred biosimilar products for adalimumab and ustekinumab
<b>Thrombocytopenia Medications</b>	For immune thrombocytopenia, require trial/failure of generic eltrombopag before coverage of other policy drugs. Added criteria for Chemotherapy-Induced Thrombocytopenia (CIT)
<b>Topical Agents for Skin Conditions – Medicaid</b>	Added criteria for atopic dermatitis for adults with severe disease to align with Oregon Health Authority.

DEFERRED POLICIES	
The following policies reviews are being deferred, to February 2026 ORPTC, for further evaluation	
Acute Hereditary Angioedema Therapy	Prophylactic Hereditary Angioedema Therapy
Acute Hereditary Angioedema Prior Authorization and Step Therapy Policy - Medicare Part	Prophylactic Hereditary Angioedema Prior Authorization and Step Therapy Policy – Medicare Part B
Primary Biliary Cholangitis Agents	

RETIRED POLICIES	
Policy Name	Summary of Change
<b>Hemlibra</b>	Retired policy and added to Hemophilia Prophylactic Agents Policy. Simplified diagnostic criteria to just require diagnosis of hemophilia A so that we can prefer Hemlibra over the three other agents on the policy.
<b>Pyrukynd</b>	Policy retired, and Pyrukynd added to Medications for Rare Indications policy.
<b>Ryplazim</b>	Policy retired, and Ryplazim added to Medications for Rare Indications policy.