Providence Health Plan

Providence Health Assurance

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

Number 114

January 1, 2026

This is the January 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 with your name, specialty, and preferred email address.

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 1/1/2026

Outpatient Surgical Site of Service **MP420**	**Policy Updates:** • Add select hernia repair and laparoscopic cholecystectomy to policy • Remove criterion I.E.4: Outpatient may be medically necessary for patient with the following anesthesia risk factor: "prolonged surgery (> 3 hours)" **Codes/PA:** Add certain hernia repair and lap chole codes to policy

Effective 3/1/2026

Shoulder Arthroscopy and Open Procedures **MP436**	**Policy Updates:** Addition of CPT code. **Codes/PA:** CPT code to be added to policy with PA.
Circulating Tumor Cell and DNA Assays for Cancer Management **MP122**	**Policy Updates:** • Add criteria clarifying that that ctDNA assays are not medically necessary for routine surveillance and may only be repeated when clinically indicated by a change in disease status (e.g. potential new malignancy). • Edit criterion II.C.11, changing hepatobiliary cancer to biliary tract cancer (HBC was added in error initially) **Codes/PA:** No changes to codes or PA

ARCHIVE

Effective 1/1/2026

Leadless Cardiac Pacemakers **MP424**	**Policy Updates:** Archive ASO-only policy due to low utilization. **Codes/PA:** Remove all code configurations – archiving policy.

REIMBURSEMENT POLICIES

Effective 3/1/2026

Treatment Room Revenue Codes Billed with Evaluation and Management Services

As of **March 1, 2026**, the Plan will not reimburse for evaluation and management (E&M) codes or HCPCS clinic visit codes when billed in conjunction with a treatment room revenue code (0761) on hospital claims submitted for Medicare and Commercial members.

Revenue codes are used on hospital bills to inform payers of where the patient was located within the facility when they received the treatment and/or what type of treatment an individual may have received while they were a patient in the facility. The revenue code range 0760-0769 represents "specialty services," and revenue code 0761 specifically is defined as a "Treatment Room." Therefore, revenue code 0761 should be used solely to represent specialty services rendered in a treatment room.

This revenue code should include the appropriate HCPCS code to represent the "specialty service" that was rendered. Evaluation and management (E&M) services do not represent a "specialty service" or procedure. While revenue Code 0761 may be reimbursable when a specific outpatient procedure is carried out in a hospital setting, the reporting of E&M services with revenue code 0761 does not align with the definition of "specialty services," and they will not be allowed if billed together.

Reimbursement Policy 5 – Incident-to Services	Effective March 1, 2026, Reimbursement Policy 5 has been revised to affect incident-to services rendered for members of the commercial plans, we will no longer recognize or accept incident-to billing for claims when services are provided by a certified or licensed provider who is able to bill under their own NPI number. The Company will not recognize or follow Centers for Medicare and Medicaid Services (CMS) "Incident to" reimbursement rules for any licensed and credentialed physician or non-physician provider (NPP) who has been assigned or is waiting for their own National Provider Identification (NPI). Any provider qualified to act in the place of physician or another qualified health care provider without direct supervision and who is eligible to receive their own National Provider Identification (NPI) recognized by the Plan must submit their claims directly to the Plan under their own NPI. This requirement applies even if the NPP or other qualified healthcare provider was supervised when performing the service. NOTE: This rule applies to providers in the process of applying for their own NPI number. Separately reportable "Incident to" services are only eligible for reimbursement under the supervising provider's NPI if the qualified auxiliary office personnel who rendered the services is ineligible to submit claims directly to the Health Plan, and when all "incident-to" requirements are otherwise met.

CODING POLICIES

Effective 1/1/2026

Coding Policy 27.0 – Unlisted Procedure Codes **(REPEAT ARTICLE from Oct 2025)**	In effort to streamline review and improve accuracy, Providence Health Plan (PHP) will require a concise procedure description (maximum of 70 characters) on all claims billing unlisted codes to be reported in: • Box 19 (Additional Claim Information) for professional claims or • Field 80 (Remarks) for facility claims. Effective January 1, 2026, charges for unlisted codes that are missing the name or brief description of the procedure in the appropriate claim form field will be denied. This update to Coding Policy 27.0 (Unlisted Procedure Codes) changing the previous recommendation to a mandatory requirement will be posted on ProvLink on or before the effective date.

Effective 3/1/2026

Coding Policy 4.0.01 (Removal of IUD billed with E/M Services)	Effective March 1, 2026, Coding Policy 4.0.01 has been revised to better support patient care and align with nationally recognized coding standards. The previous restriction denying IUD removal (CPT 58301) when billed with preventive E/M services (CPT 99381–99397) has been removed. When a patient presents for IUD removal, PHP will reimburse CPT code 58301 and deny E/M codes (99202–99499) billed with a primary diagnosis related to IUD removal on the same date of service by the same provider. CPT code 58301 has a 000-day global period, meaning same-day E/M services for the procedure are generally not separately payable. The evaluation required to remove an IUD is included in payment for the procedure itself. Reimbursement may be made for an E/M visit with removal of an IUD if review of chart notes shows the patient did not present solely for IUD removal and there is a significant, separately identifiable E/M visit documented. If the patient presents for IUD removal, and no significant, separately identifiable E/M visit is documented, CPT code 58301 should be billed without an E/M code.
Coding Policies 4.0.05 & 4.0.09 (E/M Services billed with Diagnostic Indirect Laryngoscopy, or Anoscopy)	PHP has updated Procedure Specific Coding Policies 4.0.05 and 4.0.09 to align with standard coding guidelines and Correct Coding Initiative (CCI) edits. Effective March 1, 2026, when E/M services (CPT codes 99202–99499) are billed with diagnostic indirect laryngoscopy (CPT code 31505) or diagnostic anoscopy (CPT code 46600), standard CCI edits will apply. However, appending modifier 25 will not override these CCI edits. CPT codes 31505 and 46600 have a 000-day global period, meaning same-day E/M services for the procedure are generally not separately payable. Reimbursement for the E/M service may be considered on appeal only if the documentation clearly supports that the E/M service was significant and separately identifiable from the laryngoscopy or anoscopy in these cases.
Coding Policy 4.0.30 (E/M Services billed with Simple Control of Anterior Nasal Hemorrhage)	Procedure Specific Coding Policy 4.0.30 has been revised to remove the denial of simple control of nosebleed billed with an E/M effective March 1, 2026. In its place, E/M services (CPT codes 99202-99499) billed with a primary diagnosis of epistaxis (ICD-10-CM code R04.0) on the same date of service as simple control of nasal hemorrhage (CPT code 30901) will be denied, regardless of CCI edits or modifier use. The evaluation required to treat a simple nosebleed is included in payment for the procedure itself. Reimbursement for the E/M service may be considered on appeal only if documentation clearly shows that the E/M meets the criteria for a significant and separately identifiable service.
Coding Policy 4.0.31 (Cerumen Removal)	Effective March 1, 2026, Coding Policy 4.0.31 has been revised to remove the previous restriction denying cerumen removal billed with E/M services. Cerumen removal (CPT codes 69209 and 69210) will only be reimbursed when reported with a diagnosis of impacted cerumen or a specified ear (ICD-10-CM codes H61.21-H61.23). Removing wax that is not impacted does not warrant reporting a separate procedure code; that work would appropriately be reported using an E/M code. Cerumen removal is not reportable in situations where the removal was required for visualization of the ear to address the chief complaint. When the sole reason for the visit is removal of symptomatic impacted cerumen, an E/M service may not be billed in addition to the cerumen removal. E/M services billed with a primary diagnosis of impacted cerumen (ICD-10-CM codes H61.20-H61.23) or otalgia (ICD-10-CM codes H92.01-H92.09) on the same date of service as cerumen removal (codes 69209 or 69210) will be denied, regardless of CCI edits or modifier use.

	The evaluation required to treat impacted cerumen is included in payment for the procedure itself. An E/M service on the same day as removal of impacted cerumen may not be billed unless it is a significant, separately identifiable service. For example: • If pain in the external ear is the only complaint and the removal of impacted cerumen addresses that complaint, only the wax removal is reportable. • If the patient also has symptoms of otitis media requiring further evaluation, then it may be justified to also bill for an E/M service with modifier –25. Reimbursement for the E/M service may be considered on appeal only if documentation clearly shows that the E/M meets the criteria for a significant and separately identifiable service.

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

Table of Contents:

New Drugs and Combinations:

1. **Aceclidine hcl (Vizz) Droperette**
    a. **Indication**: For the treatment of presbyopia.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	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**
    a. **Indication**: For the treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age and older.
    b. **Decision**:

	Commercial	Medicaid	Medicare

Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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).			
Formulary Alternatives: 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	For initiation of therapy, all of the following must be met: 1. Attestation of diagnosis of non-cystic fibrosis bronchiectasis confirmed by a chest computed tomography (CT) scan 2. One of the following: a. For patients 18 years and older, greater than two exacerbations requiring antibiotic treatment in the past 12 months b. For patients 12 to 17 years of age, greater than one exacerbations requiring antibiotic treatment in the past 12 months For reauthorization: adequate response to therapy, such as decrease in frequency, severity, or duration of exacerbations
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
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all of the following must be met: 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. 2. One of the following: a. For patients 18 years and older, greater than two exacerbations requiring antibiotic treatment in the past 12 months b. For patients 12 to 17 years of age, greater than one exacerbations requiring antibiotic treatment in the past 12 months For reauthorization: adequate response to therapy, such as decrease in frequency, severity, or duration of exacerbations
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

3. **Bumetanide (Enbumyst) Spray**
   a. **Indication**: For the treatment of edema associated with congestive heart failure, hepatic, or renal disease.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: 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
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: 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
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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).
Formulary Alternatives: 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
Formulary Status*	Non-formulary	Non-formulary (Covered by DMAP)	Part D: Formulary Part B: N/A
Tier**	N/A	N/A	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	Step Therapy
Quantity Limit	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	ST applies to new starts only One of the following: 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) 2) Documented intolerance/contraindication to all formulary generic SSRIs/SNRIs (such as citalopram, sertraline, paroxetine, venlafaxine, duloxetine, escitalopram, fluoxetine, desvenlafaxine and fluvoxamine)
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
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	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. 1. Nitrofurantoin monohydrate/macrocrystals 2. Trimethoprim-sulfamethoxazole, trimethoprim 3. Fosfomycin trometamol 4. Fluoroquinolones (such as ofloxacin, ciprofloxacin, and levofloxacin) 5. β-Lactam agents (such as amoxicillin-clavulanate, cefdinir, cefaclor, cefpodoxime-proxetil, cefadroxil, cephalexin, amoxicillin, ampicillin)
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
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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 taroretcel-lwey (Encelto) Implant**
   a. **Indication**: For the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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 taroretcel-lwey)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For all authorizations the following criteria must be met: 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: a. Hyperpigmentation outside a 500-micron radius from the center of the fovea b. Retinal opacification c. Crystalline deposits d. Right angle vessels e. Inner/outer lamellar cavities

	2. IS/OS PR break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm as measured by optical coherence tomography (OCT) 3. Best corrected visual acuity (BCVA) of 54 letters or better on Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/80 Snellen equivalent) 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**
    a. **Indication**: For the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	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, Mulpleta®, Doptelet®			

    c. **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., Mulpleta®, Promacta®, Nplate®) or with tyrosine kinase inhibitors (e.g., Tavalisse®, Wayrilz®)
REQUIRED MEDICAL INFORMATION	For **Immune Thrombocytopenia (ITP),** Alvaiz®, Doptelet®, Nplate®, Promacta®, Tavalisse®, or Wayrilz® may be covered if the following criteria are met**:** a. Diagnosis of chronic immune thrombocytopenia (ITP) b. Platelet count of less than 30,000 cells per microliter c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated: i. Systemic corticosteroids ii. Immune globulin iii. Splenectomy d. For Alvaiz®, Doptelet®, and Tavalisse®: Inadequate response, intolerance, or contraindication to generic eltrombopag e. For Wayrilz, Inadequate response, intolerance, or contraindication to generic eltrombopaq and Doptelet
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 etzadroxl/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
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	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
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A

Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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).			
Formulary Alternatives: 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	All the following must be met: 1. Histologically confirmed diagnosis of recurrent respiratory papillomatosis 2. Documented HPV serotype 6 or 11 3. At least three (3) surgeries in previous 12 months 4. Documented laryngotracheal papillomas 5. Must have received HPV vaccination if under the age of 46 years. No reauthorization is allowed.
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 5×10^11 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

Providence Health Plan

Providence Health Assurance

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 (RECOMBINENT) 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 3rd 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 5th, 7th, and 14th infusions. However, after an in-depth analysis of this safety issue, the Agency has determined that an additional monitoring MRI prior to the 3rd 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 2nd and 3rd 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 Perigiene 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)
    a. **Date of Recall:** August 27, 2025
    b. **Reason for recall:** Device & Drug Safety – Mislabel
    c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/unichem-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-cyclobenzaprine-hydrochloride
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** DermaRite Hand Sanitizers, Cleansers, Skin Protectants, Deodorant
    a. **Date of Recall:** August 27, 2025
    b. **Reason for recall:** Potential Burkholderia cepacia contamination
    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. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Green Lumber Dietary Supplement
    a. **Date of Recall:** August 28, 2025
    b. **Reason for recall:** Undeclared prescription drug, tadalafil, detected
    c. **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
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Eltrombopag choline (Alvaiz) Tablet	New formulation • Commercial/Medicaid: Non-formulary, Prior Authorization, Quantity Limit (1 tablet per day) Effective: 3/1/2026	Thrombocytopenia Medications
• **Cabozantinib s-malate (Cabometyx) Tablet** • **Acalabrutinib maleate (Calquence) Tablet** • **Apalutamide (Erleada) Tablet** • **Lenvatinib mesylate (Lenvima) Capsule**	• Commercial: down tier from Tier 6 to Tier 5 Effective: 1/1/2026	Anti-Cancer Medications - Self-Administered

Drug Name	Recommendation	Policy Name
Tocilizumab-anoh (Avtozma) Vial	New Biosimilar; Line extend as non-preferred bisoimilar • Medical Benefit, Prior Authorization for all lines of business	Medically Infused Therapeutic Immunomodulators
Docetaxel/albumin, human (Beizray-Albumin) Vial	New formulation; • Medical Benefit, Prior Authorization for all lines of business	ANTI-cancer Medications - Medical Benefit
Escitalopram Oxalate Capsule	New formulation (capsule); • Non-formulary for all lines of business	N/A
Ibuprofen 300 mg Tablet	New strength; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations Without Established Benefit • Medicare Part D: N/A
Gemcitabine hcl (Inlexzo) Implant	New formulation; • Medical Benefit, Prior Authorization for all lines of business	ANTI-cancer Medications - Medical Benefit
Selumetinib sulfate (Koselugo) Cap Sprink	New formulation (sprinkle capsule); • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 mg: 20 capsules per day; 7.5 mg; 12 capsules per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (5 mg: 20 capsules per day; 7.5 mg; 12 capsules per day)	Anti-Cancer Medications - Self-Administered
Carboplatin (Kyxata) Vial	New MedID; • Medical Benefit, Prior Authorization for all lines of business	ANTI-cancer Medications - Medical Benefit
Liraglutide (Saxenda) Pen Injctr	First generic drug (Saxenda); • Commercial Standard: Formulary, Tier 3, Prior Authorization, Quantity Limit (0.5 mL per day) • Commercial Dynamic: Non- Formulary, Prior Authorization, Quantity Limit (0.5 mL per day) • Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (0.5 mL per day) • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Weight Management Medications • Medicare Part D: N/A

Drug Name	Recommendation	Policy Name
Natalizumab-sztn (Tyruko) Vial	New biosimilar for Tysabri; • Medical Benefit, Prior Authorization for all lines of business	Tysabri
Immune globulin,gamma(igg)dira (Yimmugo) Vial	New formulation; • Commercial/Medicaid: Medical Benefit, Prior Authorization, Specialty • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Immune Gamma Globulin (IGG)
Tizanidine hcl (Zanaflex) Capsule	New strength 8 mg; • Non-formulary for all lines of business	N/A
Roflumilast (Zoryve) Cream (G)	New strength (0.05%); • Commercial/Medicaid: Non-formulary, Prior Authorization, Quantity Limit (60 grams per 30 days) • Medicare: Non-Formulary	Topical Agents for Skin Conditions
Nalmefene hcl (Zurnai) Auto Injct	New formulation; • Commercial/Medicare Part D: Formulary, Tier 4 • Medicaid: Formulary	N/A
Ferric citrate (Auryxia) Tablet	Remove from Medicaid formulary	N/A
Galcanezumab-gnlm (Emgality) Pen Injctr	Remove from Medicaid formulary	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists
• **Lanthanum carbonate (Fosrenol) Tab Chew; Powd Pack** • **Sevelamer hcl (Renagel) Tablet** • **Sevelamer Carbonate Powd Pack**	Remove from Medicaid formulary	Phosphate Binders Step Therapy Policy
Prucalopride succinate (Motegrity) Tablet	• Commercial Standard: Down tier generic to Tier 2, add quantity limit (one tablet per day) • Commercial Dynamic: Down tier generic to Tier 3, add quantity limit (one tablet per day) • Medicaid: Add generic to formulary, add quantity limit (one tablet per day) Effective: 3/1/2026	Constipation Agents

Drug Name	Recommendation	Policy Name
Evolocumab (Repatha Pushtronx) Pushtronx	Drug formulation removed from market; • Remove from formulary for all lines of business	N/A
Itraconazole (Sporanox) Capsule; Solution	Commercial Dynamic: Down tier from Tier 4 to Tier 3	Antifungal Agents
Solriamfetol hcl (Sunosi) Tablet	Commercial: Down tier from Tier 4 to Tier 3	Narcolepsy Agents
• **Ubrogepant (Ubrelvy) Tablet** • **Zavegepant hcl (Zavzpret) Spray**	• Commercial: Add to Formulary, Tier 3	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists – Comm
Pitolisant hcl (Wakix) Tablet	Remove from Commercial formulary	Narcolepsy Agents
Sodium oxybate (Xyrem) Solution	• Commercial: Remove brand from formulary, and up tier generic to Tier 6	Narcolepsy Agents
Golimumab (Simponi) injector/syringe	• Commercial: Add to formulary Tier 5, prior authorization, quantity limit (one dose per 28 days) Effective: 1/1/2026	Therapeutic Immunomodulators
Tocilizumab-aazg (Tyenne) Autoinjector/Syringe; Pen Injctr	• Commercial: Move to Tier 5 from Tier 6 Effective: 1/1/2026	Therapeutic Immunomodulators
Vonoprazan fumarate (Voquezna) Tablet	• Commercial/Medicaid: Add quantity limit (10 mg: 1 tablet per day; 20 mg: 2 tablets per day)	N/A
Vonoprazan/amoxicillin (Voquezna Dual Pak) Combo. Pkg	Commercial/Medicaid: Add quantity limit (112 units per 14 days)	N/A
Lubiprostone (Amitiza) capsule	Commercial/Medicaid: Add quantity limit (2 capsules per day)	N/A
Xeljanz (tofacitinib)	Commercial: Move to Tier 5 from Tier 6	Therapeutic Immunomodulators
• **Mavenclad (cladribine)** • **Vumerity (diroximel fumarate)**	Commercial: Move to Tier 5 from Tier 6	Multiple Sclerosis Agents
Linzess (linaclotide)	Commercial/Medicaid: Add quantity limit (1 capsule per day)	N/A
Jardiance (empagliflozin)	Commercial/Medicaid: Remove from formulary Effective: 3/1/2026	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 8/8/2025 – 10/24/2025

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Thiotepa (Tepylute) Vial	Correction from June 2025 P&T: New strength (100 mg/10ml). Line extend as Medical Benefit for all lines of business	N/A
Dihydroergotamine mesylate (Brekiya) Auto Injct	New formulation or New entity. Line extend with DHE 45 1mg/ml injection; • Non-Formulary for all lines of business	N/A
• **Apixaban (Eliquis 0.5 mg) Tab Susp** • **Apixaban (Eliquis Sprinkle 0.15 mg) Cap Sprink**	New formulation. Line extend with Eliquis tablet; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3, Quantity Limit (2 tablets/cap sprinkles per day)	N/A
Apixaban (Eliquis 1.5 mg) Tab Susp	New formulation. Line extend with Eliquis tablet; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3, Quantity Limit (6 tablets per day)	N/A
Apixaban (Eliquis 2 mg) Tab Susp	New formulation. Line extend with Eliquis tablet; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3, Quantity Limit (8 tablets per day)	N/A
Fibrinogen (Fibryga) Vial	New strength (2 gm). Line extend with Fibryga 1 gm IV; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Glucagon (Gvoke Vialdx) Vial	New formulation. Line extend as medical; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
• **Insulin aspart-xjhz (Kirsty) Vial** • **Insulin aspart-xjhz (Kirsty Pen) Insuln Pen**	New formulation. Line extend with insulin aspart biosimilars; • Non-Formulary for all lines of business	N/A
Liothyronine sodium (Liomny) Tablet	New MedID. Line extend with liothyronine; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Flurbiprofen (Lurbiro) Tablet	New generic. Line extend with Lurbipr; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Denosumab-dssb (Ospomyv) Syringe	New formulation. Prolia biosimilar. Line extend with non-preferred denosumab biosimilars; •	N/A
Piperacillin sodium/tazobactam (Piperacillin-Tazobactam) Piggyback	New formulation. Line extend with piperacillin sodium/tazobactam sodium; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Darunavir/cobicistat (Prezcobix) Tablet	New strength (675 mg-150 mg). Line extend with Prezcobix 800 mg-150 mg tablet; • Commercial: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5, Quantity Limit (1 tablet per day)	N/A
Lecanemab-irmb (Leqembi IQLIK) Auto Injct	New dosage form (Auto Inject). Line extend with Leqembi 100mg/ml IV; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Anti-Amyloid Monoclonal Antibodies
Bevacizumab-nwgd (Jobevne) Vial	New BLA. Line extend as non-preferred biosimilar; • Commercial/Medicaid: Medical Benefit, Prior Authorization	Anti-Cancer Medications - Medical Benefit

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization and Step Therapy	
Remestemcel-l-rknd (Ryoncil) Kit	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; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Anti-Cancer Medications - Medical Benefit
Zanubrutinib (Brukinsa) Tablet	New strength (160 mg). Line extend with Brukinsa 80mg; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day), Specialty • Medicare Part D: Formulary, Tier 5, Quantity Limit (2 tablets per day)	Anti-Cancer Medications - Self-Administered
Dasatinib (Phyrago) Tablet	New MedID. Line extend with Brand Sprycel; • Commercial/ Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (20 mg: 3 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (20 mg: 3 tablets per day), Specialty	Anti-Cancer Medications - Self-Administered
Dasatinib (Phyrago) Tablet	New MedID. Line extend with Brand Sprycel; • 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) • Medicaid: Formulary, Prior Authorization, Quantity Limit (20 mg; 50 mg; 70 mg; 80 mg; 100 mg; 140 mg: 1 tablet per day), Specialty	Anti-Cancer Medications - Self-Administered
Blood-glucose sensor (Dexcom G7 15 Day Sensor)	New preferred diabetic medical supply (PDMS). Line extend with Dexcom G7 10 day sensor;	Continuous Glucose Monitors for Personal Use

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial Standard: PDMS, Prior Authorization, Quantity Limit (2 each per 30 days) • Commercial Dynamic: Formulary, Tier 3, Prior Authorization, Quantity Limit (2 each per 30 days) • Medicaid: Formulary, PDMS, Prior Authorization, Quantity Limit (2 each per 30 days) • Medicare Part D: Non-Formulary • Medicare Part B: PDMS, Prior Authorization, Quantity Limit (2 each per 30 days)	
Denosumab-dssb (Ospomyv) Syringe	New formulation. Prolia biosimilar. Line extend with non-preferred denosumab biosimilars; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Denosumab
Pegloticase (Krystexxa) Infus. Btl	New formulation. Line extend with Krystexxa 8mg/ml; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Krystexxa
Butalbital-acetaminophen-caffeine Tab ER 24h	New Formulation. Line extend with butal-ace-caf 50-325-40mg tabs and caps; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pediatric Analgesics • Medicare Part D: N/A
Treprostinil sodium (Remodulin) Vial	New strength (0.4 mg/ml). Line extend with existing strengths of Remodulin as Medical; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pulmonary Hypertension • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Apremilast (Otezla XR) Tab ER 24h	New formulation. Line extend with Otezla immediate release; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 tablet per day), Specialty	Therapeutic Immunomodulators (TIMS)
Apremilast (Otezla XR) TB TBER DP	New formulation. Line extend with Otezla immediate release; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (41 tablets per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (41 tablets per 28 days)	Therapeutic Immunomodulators (TIMS)
Ustekinumab-ttwe (Pyzchiva Autoinjector) Auto Injct	New formulation. Line extend with non-preferred Stelara biosimilar; • 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 • Medicare Part D: Non-Formulary	Therapeutic Immunomodulators (TIMS)
Ustekinumab-aekn (Selarsdi) Vial	New formulation. Line extend with Selarsdi 45mg/0.5ml syringe; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.5 mL per 84 days), Specialty • Medicare Part D: Non-Formulary	Therapeutic Immunomodulators (TIMS)
Avatrombopag maleate (Doptelet Sprinkle) Cap Sprink	New formulation. Line extend with Doptelet tablet; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 capsules per day) • Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (2 capsules per day), Specialty	• Commercial/Medicaid: Thrombocytopenia Medications • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Non- Formulary	

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Amphetamine ER ODT TAB RAP BP	First generic drug (Adzenys XR-ODT). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Quantity Limit (1 tablet per day)	N/A
Carbidopa/levodopa (Carbidopa-Levodopa ER) Capsule ER	First generic drug (Rytary). Line extend with brand Rytary capsule; • Non-Formulary for all lines of business	N/A
Clemastine fumarate (Clemsza) Tablet	New MedID. Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicaid Part D: Non-Formulary	N/A
Iron sucrose complex (Iron Sucrose) Vial	First generic drug (Venofer). Line extend as medical; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Clomiphene citrate (Milophene) Tablet	First generic. Line extend with clomiphene citrate; • Non-Formulary for all lines of business	N/A
Everolimus 2 mg & 5 mg Tab Susp	First generic drug (Afinitor Disperz). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day)	Anti-Cancer Medications - Self-Administered
Everolimus 3 mg Tab Susp	First generic drug (Afinitor Disperz). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty	Anti-Cancer Medications - Self-Administered

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (3 tablets per day)	
Deflazacort (Jaythari) Tablet	New MedID. Line extend with generic deflazacort; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (6 mg: 2 tablets per day; 18 mg: 1 tablet per day) Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy • Medicare Part D: N/A
Deflazacort (Jaythari) 30 mg; 36 mg Tablet	• Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy • Medicare Part D: N/A
Glycerol phenylbutyrate Liquid	First generic drug (Ravicti). Line extend with Ravicti 1.1 gm/mL; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Non- Formulary	Medications For Rare Indications
Gabapentin ER 450 mg; 750 mg; 900 mg Tab ER 24h	New generic for Gralise ER. Line extend as generic; • Commercial/Medicaid: Non- Formulary, Prior Authorization • Medicare Part D: Non- Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Bosentan Tab Susp	New generic drug. Line extend with brand Tracleer; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pulmonary Hypertension • Medicare Part D: N/A
Pilocarpine hcl Drops	First generic drug (Vuity). Line extend as generic; • Commercial/Medicaid: Non- Formulary, Prior Authorization	• Commercial/Medicaid: Qlosi, Vuity • Medicare Part D: N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Non- Formulary	
Progesterone, micronized (Progesterone) Insert	First generic. Line extend with Brand Endometrin; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Dynamic: Formulary, Tier 3, Prior Authorization • Medicaid/Medicare Part D: Non-Formulary	• Commercial: Vaginal Progesterone Formulations • Medicaid/Medicare Part D: N/A

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
• **Adakveo** • **Adakveo Prior Authorization and Step Therapy Policy - Medicare Part B**	Clarified definition of pain crisis. Added quantity limit and updated position statement with new evidence.
Albendazole, Emverm	Added a step through albendazole for Emverm® (mebendazole), added a quantity limit for Emverm®.
Antifungal Agents	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.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Commercial	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.
CGRP Receptor Antagonists - Medicaid	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**
CGRP Receptor Antagonists Prior Authorization and Step Therapy Policy - Medicare Part 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.
Cholestatic Pruritus Agents	Exclusion criteria of confcurrent 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.
Complement Inhibitors	Updated criteria for c3 glomerulopathy to require Empaveli® for Fabhalta®. Added requirement of use of biosimilar Epysqli® (eculizumab-aagh) for Neuromyelitis Optica Spectrum Disorder (NMOSD) before coverage of Soliris®/Bkemv®.
Complement Inhibitors Prior Authorization and Step Therapy Policy - Medicare Part B	Added requirement of use of biosimilar Epysqli® (eculizumab-aagh) for Neuromyelitis Optica Spectrum Disorder (NMOSD) before coverage of Soliris®/Bkemv®
Constipation Agents	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.
Constipation Agents - Medicaid	Updated criteria to align with the Oregon Health Authority: • Added prescriber restrictions • Updated trial and failure criteria. If patient does not meet trial and failure criteria, will allow for medical rationale for not using preferred agents • Added criteria requiring FDA indication for those eligible for Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) review, • Added quantity limits for all drugs on policy
Hemophilia Prophylactic Agents	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.
• **Hepatitis C - Direct Acting Antivirals** • **Hepatitis C - Direct Acting Antivirals - Medicaid**	Added criterion to address treatment failure or retreatment due to non-compliance and added quantity limits which are already in place.
Infusion Therapy Site of Care	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**
	Bomyntra®/Conexxence® (denosumab-bnht), Jubonti®/Wyost® (denosumab-bbdz), Osenvelt®/Stoboclo® (denosumab-bmwo), Prolia/Xgeva (denosumab)
• **Jesduvroq, Vafseo** • **Jesduvroq, Vafseo Prior Authorization and Step Therapy Policy - Medicare Part B**	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
Livtencity	Quantity limit updated to twelve tablets per day to reflect package insert updates.
• **Medically Infused Therapeutic Immunomodulators (TIMs) – Comm** • **Medically Infused TIMs Prior Authorization and Step Therapy Policy - Medicare Part B**	Updated for new indications for Tremfya (psoriasis/psoriatic arthritis)
Narcolepsy Agents	Updated specific requirements for diagnostic criteria, prerequisite step therapy medications, and duration of approval.
• **PCSK9 Inhibitors – Commercial** • **PCSK9 Inhibitors – Medicaid**	Added criteria for new indication of primary prevention in patients with hyperlipidemia at high-risk of MACE.
Phosphate Binders Step Therapy Policy	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.
• **Prevymis** • **Prevymis Prior Authorization and Step Therapy Policy - Medicare Part B**	Clarified definition of cytomegalovirus (CMV) positive in clinical criteria by adding verbiage in regards to donor and recipient.
• **Reblozyl, Rytelo** • **Reblozyl, Rytelo Prior Authorization and Step Therapy Policy - Medicare Part B**	Updated criteria for myelodysplastic syndrome to align with National Comprehensive Cancer Network guidelines. Added language for medical drug quantity limits.
Rezdiffra	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.
Self-Administered Drugs (SAD)	Added the following drugs: Dawnzera® (donidalorsen), Forzinity® (elamipretide), Otulfi® (ustekinumab-aauz), Stariemza® (ustekinumab-hmny), Yesintek® (ustekinumab-kfce), and Imdulsa® (ustekinumab-srlf)
TIMS – Commercial	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**
TIMS – Medicaid	Updated indications for Tremfya® and Simponi®. Updated preferred biosimilar products for adalimumab and ustekinumab
Thrombocytopenia Medications	For immune thrombocytopenia, require trial/failure of generic eltrombopag before coverage of other policy drugs. Added criteria for Chemotherapy-Induced Thrombocytopenia (CIT)
Topical Agents for Skin Conditions – Medicaid	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**
Hemlibra	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.
Pyrukynd	Policy retired, and Pyrukynd added to Medications for Rare Indications policy.
Ryplazim	Policy retired, and Ryplazim added to Medications for Rare Indications policy.

Providence Health Plan

Providence Health Assurance