



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

Number 110

September 1, 2025

This is the September 1, 2025 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: <a href="https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/">https://healthplans.providence.org/provider-information/</a>

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 <a href="mailto:PHPmedicalpolicyinquiry@providence.org">PHPmedicalpolicyinquiry@providence.org</a> with your name, specialty, and preferred email address.





# **MEDICAL POLICY COMMITTEE**

## **MEDICAL**

## **COMPANY POLICIES**

#### Effective 10/1/2025

Serologic Testing and Therapeutic Monitoring for Inflammatory Bowel Disease	Policy Updates: No recommended changes to criteria Codes/PA: Removes PA from CPT 81306, 81335, 84433
MP218	
Advanced Diabetes	Policy Updates: No changes to criteria. Eversense added to device table in "policy
Management	guidelines" section as FDA-approved implantable CGM.
Technology	Codes/PA: Added PA to the following codes for implantable continuous glucose monitors
	(e.g. Eversense) - 0446T, 0447T, 0448T.
MP27	

## Effective 11/1/2025

Blepharoplasty, Blepharoptosis Repair, and Brow Lift	Policy Updates: Updated criteria, splitting out blepharoplasty, blepharoptosis repair, and brow lift into their own criteria. Added documentation requirements in criteria to highlight requirements more clearly.  Codes/PA: No changes to codes or PA
MP101	





Knee Arthroscopy and	Policy Updates:		
Open Procedures	Title changed to include open procedures of the knee.		
Previously: Knee	Added criteria for lysis of adhesions.		
Arthroscopy and Meniscal	Removed criteria that do not have a corresponding CPT code		
Repair	<ul> <li>Removed NSAIDs as required conservative therapy for various procedures</li> </ul>		
•	Codes/PA: No changes to coding or PA. CPT 29870 already requires PA.		
MP 434			
Wheelchair and Power	Policy Updates: No general changes made to criteria. Plan criteria are based on various CMS references, mostly Noridian LCDs. Updated		
Vehicles	Criteria LIV, LXX, and LXXXIII to add clarity as to why each item is considered <b>not</b> medically necessary. Added PA to select codes (details		
	below). Criteria changes are not required as criteria is already provided for these items in the policy currently.		
MP140	Codes/PA: Added PA to the following codes		
	E0986; push-rim activated power assist system for manual wheelchair		
	E1002-E1010 and E1012; power seating systems		
	E1161; manual w/c with tilt-in-space		
	K0005; ultralight manual wheelchair		
	No changes for other codes in the policy.		
Shoulder Arthroscopy and	Policy Updates: Added documentation requirements to mirror requirements of other arthroscopy and arthroplasty policies (e.g.		
Open Procedures	evaluation by physician performing the procedure; imaging for all procedures).		
	Codes/PA: Added 2 codes for chronic rotator cuff tear repair (23412, 23420) to require PA		
MP436			
Genetic Testing for	Policy Updates: Re-added section on NIPT that was previously removed. These criteria will help us assess unlisted codes that come in for		
Reproductive Planning and	non-standard NIPS (beyond trisomies 13, 18, and 21).		
Prenatal Testing	Codes/PA: No changes to codes or PA		
MP78			

## **ARCHIVE**

Effective 9/1/2025





Chiropractic Care	Policy Updates: Archived policy. PHP will use ASH as its alt-care vendor, taking over UM for chiropractic care for commercial Oregon			
MP250	groups on 9/1, with Medicare and Washington commercial groups to follow on 1/1/26. Additional info <a href="here">here</a> . <b>Codes/PA:</b> Removed existing configuration from all codes.			

## **MEDICARE POLICIES**

## Effective 10/1/2025

Genetic and Molecular	Policy Updates: Updates include the following:			
Testing	• This policy shares codes with the soon-to-be-archived Serologic Testing for IBD policy. Due to new LCD and coverage for 0286U, which could result in increased utilization, and since 0286U was already part of this policy, criteria has been updated and auto-			
MP317	denial has been removed.			
	<ul> <li>Added general criteria for NGS testing for myeloid malignancies or suspected myeloid malignancies, as well as NGS testing for solid tumors. Relocated tests from the panel table to their respective LCD/LCA.</li> </ul>			
	Codes/PA: Code configuration updates include the following:			
	• Code 81401 - term pair-to-deny configuration, and re-added PA (consistent with other 8140X codes).			
	Code 0286U – termed NMN denial and added PA.			
	No changes to other codes in this policy at this time.			
Respiratory Viral Panels	Policy Updates: Updated "criteria" for code 0563U based on updates to Noridian LCDs for infectious disease testing (L39003, L39001)			
MP255	and companion LCAs (A58726 and A58720, respectively).			
IVIP255	Codes/PA: Added dx code configuration to code 0563U that matches other "Group 6" CPT codes and their diagnosis code set-up (Group			
	6 CPT codes require TWO dx codes, from two different lists, in order to qualify for Medicare coverage). This should be retroactively			
	effective 7/1/2025, for Medicare LOB only. No claim adjustments will be requested			

Effective 11/1/2025





Knee Arthroscopy and Open Procedures Previously: Knee Arthroscopy and Meniscal Repair	Policy Updates: No change to criteria. Will continue to use either the provided Medicare policy OR the internal Company criteria due to lack of fully established Medicare coverage policy or criteria (depending on specific procedure). Change to policy title to align with Company change with the same effective date.  Codes/PA: No change to codes or configuration.
MP435	
Shoulder Arthroscopy and Open Procedures	<b>Policy Updates:</b> No change to criteria. Will continue to use the internal Company criteria due to lack of fully established Medicare coverage policy or criteria.
MP437	Codes/PA: Added CPT 23412, 23420 to policy, and added PA.
Wheelchair and Power Vehicles	Policy Updates: No change to policy. Continue to use Medicare coverage policies and regulations as directed. Will add PA to select codes (details below). Criteria changes are not required as relevant Medicare LCDs are already provided for these items in the policy currently. Codes/PA: Added PA to the following codes:
MP300	E0986; push-rim activated power assist system for manual wheelchair
	<ul> <li>E1002-E1010 and E1012; power seating systems</li> <li>E1161; manual w/c with tilt-in-space</li> </ul>
	K0005; ultralight manual wheelchair
	No changes to other codes in the policy

## **ARCHIVE**

Effective 10/1/2025

Serologic Testing and Therapeutic Monitoring for Inflammatory Bowel Disease	Policy Updates: Archive.  Codes/PA: Several codes are found in multiple Medicare medical policies, so will term policy relationship only for most codes.  Exceptions include:
Disease	<ul> <li>Code 84433 - termed PA and allow to process.</li> <li>Code 81401 - termed pair-to-deny configuration and re-add PA (consistent with other 8140X codes).</li> </ul>
	Code 81401 - termed pair-to-deny configuration and re-add PA (consistent with other 8140X codes).





MP344	Code 0286U - will require configuration updates

## **VENDOR UPDATES**

Effective 11/15/25

Carelon - Cardiology	Interim Update Clinical Review Criteria: PA added to new codes Codes/PA: PA added to C7562 and 0238T
Carelon - Radiology	Interim Update Clinical Review Criteria: PA added to new codes Codes/PA: PA added to 95965 and 95966

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

## Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting August 1, 2025 Go-Live Date: Wednesday, October 01, 2025, unless otherwise noted





#### **Table of Contents:**

- New Drugs and Combinations
- New Indications Monitoring
- Drug Safety Monitoring
- Other Formulary Changes
- Clinical Policy Changes

## **New Drugs and Combinations:**

- 1. Avutometinib capsules; defactinib tablets (Avmapki Fakzynja Co-Pack®)
  - a. **Indication**: For the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) 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	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	1 pack (66 tablets)/28 days	1 pack (66 tablets)/28 days	1 pack (66 tablets)/28 days

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

Formulary Alternatives: N/A

- a. Prior Authorization Criteria for Commercial/Medicaid: Add drug to "Anti-Cancer Medications-Self-Administered" Policy
- b. Prior Authorization Criteria for Medicare Part D: Add drug to "Anti-Cancer Agents" Policy
- 2. Ensartinib capsule (Ensacove®)
  - a. **Indication**: For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor.

<sup>\*\*</sup> 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. **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	100 mg: 2/day; 25 mg: 1/day	100 mg: 2/day; 25 mg: 1/day	100 mg: 2/day; 25 mg: 1/day

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

Formulary Alternatives: cizotinib (Xalkori®), alectinib (Alecensa®), lorlatinib (Lorbrena®), brigatinib (Alunbrig®)

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

### 3. Pivmecillinam tablet (Pivya®)

- a. **Indication**: For the treatment of female patients 18 years of age and older with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of *Escherichia coli (E. Coli)*, *Proteus mirabilis*, and *Staphylococcus saprophyticus*.
- b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Step Therapy	Step Therapy	Step Therapy
<b>Quantity Limit</b>	3 tablets per day	3 tablets per day	3 tablets per day

<sup>\*\*</sup> 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).





- \* 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: nitrofurantoin, fosfomycin, trimethoprim/sulfamethoxazole

#### c. Step Therapy Criteria for Commercial/Medicaid:

STEP THERAPY CRITERIA	Pivmecillinam (Pivya)
MEDICATION NAME	Pivmecillinam (Pivya)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	A trial, contraindication, or intolerance to the use of formulary fosfomycin, sulfamethoxazole-
REQUIRED MEDICAL INFORMATION	trimethoprim, or nitrofurantoin
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or
COVERAGE DURATION	benefit changes

#### d. Step Therapy Criteria for Medicare Part D:

STEP THERAPY CRITERIA	Pivmecillinam (Pivya)	
MEDICATION NAME	Pivmecillinam (Pivya)	
	One of the following: 1) History of paid claim or documented trial of one of the following	
CRITERIA	formulary medications: fosfomycin, sulfamethoxazole-trimethoprim, nitrofurantoin, OR 2.	
CKITEKIA	Documented intolerance/contraindication to all the following formulary medications:	
	fosfomycin, sulfamethoxazole-trimethoprim, nitrofurantoin.	

#### 4. Atrasentan tablet (Vanrafia®)

a. **Indication**: To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) of at least 1.5 g/g.

#### 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	N/A; Non-Formulary	N/A	N/A
Act Eligible			
Utilization	Prior Authorization	Prior Authorization	N/A
Management Edits		Prior Authorization	N/A
<b>Quantity Limit</b>	One tablet per day	One tablet per day	N/A

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

Formulary Alternatives: Filspari, Tarpeyo, Fabhalta

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

PA PROGRAM NAME	Filspari	
MEDICATION NAME	Vanrafia	
EXCLUSION CRITERIA	For sparsentan only: Concurrent therapy with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren	
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met:  1. Diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed by biopsy  2. Patient has been receiving a stable dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB), at a maximally tolerated dose, with statement that ACE or ARB will be discontinued before sparsentan therapy is initiated (discontinuation is not required for atrasentan)  3. Patient is at high risk of disease progression, defined as meeting one of the following criteria (a or b):  a. Proteinuria of more than 1.0 g/day; OR  b. Urine protein-to-creatinine ratio of 1.5 g/g or more  4. eGFR greater than or equal to 30 mL/min1.73m^2  Reauthorization: Documentation of positive response to therapy defined as improvement in proteinuria.	

## 5. Nipocalimab solution (Imaavy®)

- a. **Indication**: For the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
- b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary

<sup>\*\*</sup> 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).





			Part B: Medical
Tier**	N/A	N/A	Specialty
Affordable Care	No	N/A	NI/A
Act Eligible	NO	N/A	N/A
Utilization	Prior Authorization	Drior Authorization	Drior Authorization
Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A

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

Formulary Alternatives: Medically administered: Vyvgart (efgartigimod alfa) and Rystiggo (rozanolixizumab-noli)

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

PA PROGRAM NAME	FcRn Antagonists		
MEDICATION NAME	Nipocalimab (Imaavy)		
PA INDICATION	1 - All FDA-Approved Indications		
INDICATOR			
EXCLUSION CRITERIA	Use in combination with other immunomodulatory biologic therapies, such as rituximab, eculizumab (Soliris®), ravulizumab (Ultomiris®), efgartigimod (Vyvgart®/Vyvgart Hytrulo®), rozanolixizumab (Rystiggo®), zilucoplan (Zilbrysq®)		
REQUIRED MEDICAL INFORMATION	REQUIRED MEDICAL INFORMATION: For initial authorization, must meet all the indication-specific criteria below: Generalized Myasthenia Gravis (gMG):  1. Anti-acetylcholine receptor (anti-AChR) antibody positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive (Rystiggo® and Imaavy only)  2. One of the following:  a. For Vyvgart/Vyvgart Hytrulo  i. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV  ii. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of five or greater b. For Rystiggo:  i. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to Iva  ii. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of three or greater (with 3 or greater points from non-ocular symptoms)  c. For Imaavy:		

<sup>\*\*</sup> 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).





	<ul> <li>i. MGFA Clinical Classification of Class II to IV         <ol> <li>ii. MG-ADL total score of six or greater</li> </ol> </li> <li>3. Failure with treatment of one of the following over the course of at least 12 months, unless intolerance or contraindication to all therapies:         <ol> <li>a. At least TWO immunosuppressive agents (such as azathioprine, methotrexate, cyclosporine, mycophenolate, corticosteroids, tacrolimus, cyclophosphamide, or rituximab)</li> <li>b. ONE immunosuppressive therapy and required at least four infusions/year of either intravenous immunoglobulin (IVIG), or plasmapheresis/plasma exchange (PLEX)</li> </ol> </li> <li>4. Dose and frequency are in accordance with FDA-approved labeling</li> </ul>
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist or rheumatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

#### 6. Efbemalenograstim alfa-vuxw injection (Ryzneuta®)

a. **Indication**: To decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

#### b. **Decision**:

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

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

Formulary Alternatives: Neulasta, Neupogen, biosimilar filgrastim, biosimilar pegfilgrastim

<sup>\*\*</sup> 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).





c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to "Granulocyte Colony Stimulating Factors (G-CSF)" policy as a non-preferred product

#### 7. Telisotuzumab vedotin-tllv injection (Emrelis®)

a. **Indication**: For the treatment of adult patients with locally advanced or metastatic nonsquamous (NSQ) non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (OE) [at least 50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy

#### b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary
Formulary Status	ivieuicai	Wiedical	Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act	N/A; Non-Formulary	21/2	N1/A
Eligible		N/A	N/A
Utilization	Prior Authorization	Duisu Authorization	Prior Authorization
Management Edits	Phor Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A

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

Formulary Alternatives: None

- c. Prior Authorization Criteria for Commercial/Medicaid: Added to "Anti-Cancer Medications Medical benefit" Policy
- d. Prior Authorization Criteria for Medicare Part B: Added to "Anti-Cancer Medications Prior Authorization and Step Therapy Policy Medicare Part B"

#### 8. Deuruxolitinib tablet (Legselvi®)

- a. **Indication**: For the treatment of severe alopecia areata.
- 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

<sup>\*\*</sup> 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).





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

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

Formulary Alternatives: Olumiant, Litfulo (Non-formulary as alopecia areata is a benefit exclusion for most groups)

- c. Prior Authorization Criteria for Commercial/Medicaid: Added to "Therapeutic Immunomodulators" Policy.
- 9. Prademagene zamikeracel cellular sheet (Zevaskyn®)
  - a. Indication: For the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).
  - b. **Decision**:

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

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

**Formulary Alternatives: None** 

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

PA PROGRAM NAME	Medications for Rare Indications
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<sup>\*\*</sup> 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).

<sup>\*\*</sup> 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).





MEDICATION NAME	Prademagene zamikeracel (Zevaskyn)
PA INDICATION	1 - All FDA-Approved Indications
INDICATOR	
EXCLUSION CRITERIA	Concomitant use with Vyjuvek or Filsuvez
REQUIRED MEDICAL INFORMATION	For initial authorization:  1. Diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) with genetic confirmation of mutations in both COL7A1 genes  2. Treatment will be used on partial-thickness RDEB wounds open chronically for at least six months For reauthorization: Must meet initial criteria
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state.
COVERAGE DURATION	Initial and reauthorization is limited to one treatment course. Approval duration will be for 12 weeks.

New Indications: Deferred to October P&T

**Drug Safety Monitoring:** Deferred to October P&T

## **Other Formulary Changes:**

nui y chunges.				
Drug Name	Recommendation	Policy Name		
Acetaminophen/codeine oral solution	Remove from Commercial formulary			
Aztreonam/avibactam sodium	New combination;	N/A		
(Emblaveo) Vial	• Commercial/Medicaid/Medicare Part B:			
	Medical Benefit			
	<ul> <li>Medicare Part D: Non-Formulary</li> </ul>			
Bisoprolol fumarate Tablet	New strength (2.5 mg);	N/A		
	<ul> <li>Non-formulary for all lines of business</li> </ul>			
Buprenorphine hcl/naloxone hcl	I Medicaid: Add all strengths to	N/A		
(Zubsolv) Tab Subl	Formulary with Quantity Limits as			
	follows:			
	o 11.4-2.9 mg: 1 tablet per day			
	o 8.6-2.1 mg: 2 tablets per day (no			
	change)			
	<ul> <li>All other strengths: 3 tablets per</li> </ul>			
	day			





Drug Name	Recommendation	Policy Name
Buspirone hcl	New dosage form (capsule);	Commercial: New Medications and
	Commercial: Non-Formulary, Prior	Formulations without Established
	Authorization	Benefit
	Medicaid/Medicare Part D: Non-	Medicaid/Medicare Part D: N/A
	Formulary	
Clesrovimab-cfor (Enflonsia) Syringe	New RSV Vaccine. Line extend with other	
	RSV vaccines	
Discostilla de li co (XV la c XVD) mala ED	Medical Benefit for all lines of business  Compatible for a Lynn con T PA T	M. E. C. v. F. D. v. I. E. C. v.
Diazoxide choline (Vykat XR) Tab ER	Correction from June 2025 P&T:	Medications For Rare Indications
24h	Commercial/Medicaid: Non-Formulary      with Prior Authorization	
Diflunisal (Dolobid) Tablet	with Prior Authorization	N/A
Diffuffisal (Dolobid) Tablet	New strength (375 mg);	N/A
Eculizumab-aagh (Epysli) Vial	Non-formulary for all lines of business     New BLA; New non-preferred biosimilar for	Complement Inhibitors
Eculizuman-aagn (Epysii) viai	Soliris.	Complement inhibitors
	• Commercial/Medicaid/Medicare Part B:	
	Medical Benefit, Prior Authorization	
	Medicare Part D: Non-Formulary	
Eculizumab-aeeb (Bkemv) Vial	New BLA; New preferred biosimilar for	Complement Inhibitors
Zeunzumus uees (Zhemv) van	Soliris.	compressione manageore
	• Commercial/Medicaid/Medicare Part B:	
	Medical Benefit, Prior Authorization	
	Medicare Part D: Non-Formulary	
Emgality (galcanezumab-gnlm)	Remove from Medicaid formulary to align	Calcitonin Gene-Related Peptide (CGRP)
syringe and pen injector	with Oregon Health Authority preferred	Receptor Antagonists
	drug list	
Eszopiclone tablet	Remove from Medicaid formulary to align	Insomnia Agents- Medicaid
	with Oregon Health Authority preferred	
	drug list	
Fentanyl citrate products (lozenge, effervescent tablets, nasal spray, etc.)	Remove from Commercial/Medicaid	Fentanyl citrate (policy to be retired)
Hemiclor (chlorthalidone) 12.5 mg	formularies, as products are now obsolete  New Strength. Non-formulary for all lines of	N/A
tablet	business	N/A
Ibuprofen/acetaminophen	New strength;	N/A
(Combogesic) Tablet	<ul> <li>Non-formulary for all lines of business</li> </ul>	11/11
Jubbonti (denosumab-bbdz) syringe	New preferred biosimilar for Prolia. Medical	N/A
o appoint (denosuman bbdz) syringe	benefit for all lines of business	11/11
Losartan potassium (Arbli) Oral Susp	New formulation;	N/A
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Drug Name	Recommendation	Policy Name
	Non-formulary for all lines of business	
Melatonin tablets and 1 mg/mL liquid	Require PA for adults 19 years and above	Insomnia Agents- Medicaid
Merilog (insulin aspart-szjj)	New biosimilar for Novolog. Non-formulary	N/A
	for all lines of business	
Rilpivirine hcl (Edurant Ped) Tab	New dosage form;	N/A
Susp	<ul> <li>Commercial: Formulary, Tier 4,</li> </ul>	
	Quantity Limit (6 tablets per day)	
	• Medicaid: Formulary, Quantity Limit (6	
	tablets per day)	
	• Medicare Part D: Formulary, Tier 5	
Sunosi (solreiamfetol)	Change tier for Commercial: Formulary, Tier	Narcolepsy Agents
	5 (from Tier 4), Prior Authorization,	
	Quantity Limit (one tablet per day)	
Teriparatide (Bonsity) Pen Injctr	New MedID; New brand-name product.	Osteoanabolic Agents
	Non-formulary for all lines of business	
Ustekinumab-aekn syringe	New biosimilar for Selarsdi. Non-preferred.	Therapeutic Immunomodulators
	Commercial/Medicaid: Non-Formulary,	
	Prior Authorization, Quantity Limit	
	( one injection per 84 days)	
Y47 1 2 4 12 4 1	Medicare: Non-Formulary	
Wakix (pitolisant)	Remove from Commercial formularies	Narcolepsy Agents
Wyost (denosumab-bbdz) vial	New preferred biosimilar for Xgeva. Medical	N/A
	benefit for all lines of business	
Xyrem (sodium oxybates)	Remove brand-name formulation from the	Narcolepsy Agents
	Commercial formulary. Move generic	
	formulation to Tier 6 (from Tier 5)	

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

#### **INFORMATIONAL ONLY**

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS			
Drug Name	Action Taken	Policy Name	
Dapsone Gel (Gram)	New Strength. Line extend with existing strengths;  • Commercial Standard: Formulary, Tier 2	N/A	





	Commercial Dynamic: Formulary, Tier 4	
	Medicaid: Non-Formulary	
	<ul> <li>Medicare Part D: Non-Formulary</li> </ul>	
Nirmatrelvir/ritonavir (Paxlovid) Tab	New strength (150-100 mg). Line extend	N/A
DS PK	with Paxlovid;	
	• Commercial/Medicare Part D:	
	Formulary, Tier 3	
	Medicaid: Formulary	
Thiotepa (Tepylute) Vial	New strength (15 mg/1.5ml; 100 mg/10 ml).	Anti-Cancer Medications - Medical Benefit
	Line extend with thiotepa;	
	<ul> <li>Medical Benefit, Prior Authorization for</li> </ul>	
	all lines of business	
Zolbetuximab-clzb (Vyloy) Vial	New strength (300 mg). Line extend with	Anti-Cancer Medications - Medical Benefit
	Vyloy 100mg vial;	
	<ul> <li>Medical Benefit, Prior Authorization for</li> </ul>	
	all lines of business	
Maralixibat chloride (Livmarli) Tablet	New dosage form (tablet). Line extend with	Cholestatic Pruritus Agents
	Livmarli solution;	
	<ul> <li>Commercial/Medicaid: Non-Formulary,</li> </ul>	
	Prior Authorization, Quantity Limit (2	
	tablets per day)	
	<ul> <li>Medicare Part D: Non-Formulary, FDA</li> </ul>	
	Max (2 tablets per day)	

NEW GENERICS				
Drug Name	Action Taken	Policy Name		
Emtricita/rilpivirine/tenof df (Complera) Tablet	First generic drug (Complera). Line extend as generic;	N/A		
	Commercial Standard: Formulary, Tier 2			
	Commercial Dynamic: Formulary, Tier 3			
	Medicaid: Formulary			
	Medicare Part D: Formulary, Tier 5,     Quantity Limit (1 tablet per day)			
Flutamide (Eulexin) Capsule	Return of generic. Line extend as generic;	Medicare Part D: Anti-Cancer Agents		
	Commercial: Formulary, Tier 4			
	Medicaid: Formulary			





NEW GENERICS			
Drug Name	Action Taken	Policy Name	
	<ul> <li>Medicare Part D: Formulary, Tier 5,</li> <li>Prior Authorization, Quantity Limit (1 tablet per day)</li> </ul>		
Gadoteridol Vial	First generic drug (Prohance). Line extend as generic;  • Medical Benefit for all lines of business	N/A	
Thyroid, Pork (Renthyroid) Tablet	New generic pork thyroid. Line extend with other generic pork thyroids;  Commercial: Formulary, Tier 2  Medicaid: Formulary  Medicare Part D: Formulary, Tier 4	N/A	
Sitagliptin-Metformin ER TBMP 24hr	First generic drug (Zituvimet XR). Line extend as generic;  Non-formulary for all lines of business	N/A	
Ticagrelor Tablet	First Generic Drug (Brilinta). Line extend as generic;  Commercial Standard: Formulary, Tier 2  Commercial Dynamic: Formulary, Tier 3  Medicaid: Formulary  Medicare Part D: Formulary, Tier 3	N/A	
Eslicarbazepine Acetate Tablet	First generic drug (Aptiom). Line extend as generic;  Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (2 tablets per day)  Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (2 tablets per day)  Medicaid: Step Therapy, Quantity Limit (2 tablets per day)  Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (2 tablets per day)	Antiepileptic Medications Step Therapy Policy	
Exenatide Pen Injctr	First generic drug (Byetta). Line extend as generic;	GIP and GLP-1 Receptor Agonists	





NEW GENERICS		
Drug Name	Action Taken	Policy Name
	<ul> <li>Commercial: Non-Formulary, Prior Authorization, Quantity Limit (2.4 mL/30)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (2.4 mL/30)</li> <li>Medicare Part D: Non-Formulary</li> </ul>	
Umeclidinium-Vilanterol Blst w/Dev	First generic drug (Anoro Ellipta). Line extend as Non-Formulary for Commercial/Medicare Part D  • Medicaid: Formulary	N/A
Pilocarpine hcl (Vuity) Drops	First generic drug (Vuity). Line extend as generic;  Commercial/Medicaid: Non-Formulary, Prior Authorization  Medicare Part D: Formulary, Tier 4	<ul> <li>Commercial/Medicaid: Qlosi, Vuity</li> <li>Medicare Part D: N/A</li> </ul>
<ul> <li>Ustekinumab 45 mg/0.5 mL Vial</li> <li>Ustekinumab 45 mg/0.5 mL Syringe</li> <li>Ustekinumab 90 mg/mL</li> </ul>	New generic (Stelara); Line extend as generic;  Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.5 mL per 84 days)  Medicare Part D: Non-Formulary, Quantity Limit (3 mL per 84 days)	Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)     Medicare Part D: N/A
Ustekinumab 130 mg/26 ml Vial	New generic (Stelara); Line extend as generic;  Commercial/Medicaid: Medical Benefit, Prior Authorization  Medicare Part D: Non-Formulary  Medicare Part B: Medical Benefit, Prior Authorization	<ul> <li>Commercial: Medically Infused         Therapeutic Immunomodulators (Tims)         - Comm</li> <li>Medicaid: Therapeutic         Immunomodulators (TIMS) - Medicaid</li> <li>Medicare Part D: Medically Infused         Therapeutic Immunomodulators (TIMs)         Prior Authorization and Step Therapy         Policy - Medicare Part B</li> </ul>
Eltrombopag Olamine 12.5mg & 25mg Tablets	First generic drug (Promacta). Line extend as generic;	Thrombocytopenia Medications





NEW GENERICS		
Drug Name	Action Taken	Policy Name
	<ul> <li>Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 tablet per day)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day)</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day)</li> </ul>	
Eltrombopag Olamine 50mg & 75mg Tablets	<ul> <li>First generic drug (Promacta). Line extend as generic;</li> <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)</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day)</li> </ul>	Thrombocytopenia Medications
Eltrombopag Olamine 12.5mg & 25mg Powd Pack	<ul> <li>First generic drug (Promacta). Line extend as generic;</li> <li>Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (12.5 mg 1 packet per day; 25 mg 6 packets per day)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (12.5 mg 1 packet per day; 25 mg 6 packets per day)</li> <li>Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (12.5 mg 1 packet per day; 25 mg 6 packets per day)</li> </ul>	Thrombocytopenia Medications
Tolvaptan Tablet SEQ	First generic drug (Jynarque). Line extend as generic;  Commercial: Formulary, Tier 6, Prior Authorization	<ul> <li>Commercial/Medicaid: Tolvaptan</li> <li>Medicare Part D: N/A</li> </ul>





NEW GENERICS		
Drug Name	Action Taken	Policy Name
	<ul> <li>Medicaid: Formulary, Prior Authorization, Specialty</li> <li>Medicare Part D: Non-Formulary</li> </ul>	
Phentermine-Topiramate ER CPMP 24hr	<ul> <li>First generic drug (Qsymia). Line extend as generic;</li> <li>Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (1 capsule per day)</li> <li>Commercial Dynamic: Non-Formulary, Prior Authorization, Quantity Limit (1 capsule per day)</li> <li>Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 capsule per day)</li> <li>Medicare Part D: Non-Formulary</li> </ul>	<ul> <li>Commercial/Medicaid: Weight Management Medications</li> <li>Medicare Part D: N/A</li> </ul>
Perampanel tablet	<ul> <li>First generic drug (Fycompa). Line extend as generic:</li> <li>Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (1 tablet per day)</li> <li>Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (1 tablet per day)</li> <li>Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day)</li> <li>Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (1 tablet per day)</li> </ul>	Antiepileptic Medications Step Therapy

# **Clinical Policy Changes:**

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	Summary of Change





Anti-Amyloid Monoclonal Antibodies - Medicaid	Updated criteria to align with Oregon Health Authority (OHA) policy, which excludes concurrent anti-coagulant or anti-platelet therapy (except aspirin 81 mg) and adds specific reauthorization requirements for Kisunla (donanemab).
Anti-Amyloid Monoclonal Antibodies Prior Authorization and Step Therapy Policy - Medicare Part B	Added Kisunla® (donanemab) and removed Aduhelm® (aducanumab) coverage per CMS National Coverage Determination (NCD).
Anti-Cancer Medications - Self-Administered	Scemblix® (asciminib) step criteria removed from policy.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Medicaid	For migraine prophylaxis: (1) updated trial and failure prerequisite drugs to align with OHA, (2) added wording to clarify appropriate dose required for prerequisite drugs, and (3) updated botulinum toxin language from two months to three months to capture all current users as botulinum toxinis dosed every 12 weeks. For cluster headaches: (1) updated trial and failure prerequisite drugs to align with OHA.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Commercial	Updated prerequisite drugs for migraine prophylaxis to align with current American Headache Society guidelines.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists Prior Authorization and Step Therapy Policy - Medicare Part B	Updated prerequisite drugs for migraine prophylaxis to align with current American Headache Society guidelines and removed Qulipta® (atogepant) as a preferred agent.
Elevidys	For Medicaid, added criteria for coverage to align with OHA. Continues to be considered not medically necessary for other lines of business.
Epidiolex	Added clobazam and felbamate as options to try for Lennox-Gastaut syndrome
Exon-Skipping Therapies for Duchenne Muscular Dystrophy	For Medicaid, added criteria for coverage to align with the OHA. Continues to be considered not medically necessary for other lines of business.
Fintepla	Added clobazam and felbamate as options to try for Lennox-Gastaut syndrome
Firdapse	Increase quantity limit to 10 tablets per day.
Gene Therapies for Hemoglobin Disorders	Requirement to use busulfan for pre-treatment conditioning added to support value-based agreement operationalization.
Hetlioz, Hetlioz LQ	Age updated to "must be appropriate based on FDA-approved indication"
Infusion Therapy Site of Care	Site of Care medication list expanded to include additional immunotherapy anti-cancer agents.
Insomnia Agents - Medicaid	Updated melatonin to not allow coverage for patients over 18 to align with OHA
Krystexxa	Allow radiographic damage to confirm diagnosis of symptomatic chronic gout and, require combination with methotrexate for reauthorization.
Long-Acting Opioids	Added nalmefene as another option for opioid reversal agent prescribing.
Maximum Allowable Opioid Dose	Removed quantity limit for morphine sulfate solution and hydromorphone tabs. Max morphine equivalent edit in claims processor will block excessive use.
Medications for Female Sexual Interest and Arousal Disorder	Removed exclusion criteria as duplicative with medical necessity criteria.





Narcolepsy Agents	Updated preferred agents and removed criteria for combination use of agents due to lack of evidence supporting combination therapy.	
Pediatric Analgesics	Updated to require trial and failure of all formulary drugs, unless not indicated.	
Qudexy XR	Removed requirements for coverage of brand-name formulation, as brand is no longer available.	
Radicava, Radicava ORS	Policy updated to include Awaji-Shima criteria to establish amyotrophic lateral sclerosis diagnosis.	
Spravato	Prescriber restrictions were updated to clarify that medication must be prescribed directly by a psychiatrist or psychiatric nurse practitioner.	
Therapies for Spinal Muscular Atrophy	Add quantity limit of one tablet per day to Evrysdi tablets; Added allowance for therapies with worsening of disease after gene therapy administration.	
Triptan Quantity Limit	Criteria combined for all headache types to require prophylactic therapy, rule-out medication overuse headache, and requiring medical rationale for all initial requests. Added requirement for prophylactic therapy for continuation of therapy.	
VMAT2 Inhibitors	Updated quantity limits	

DEFERRED POLICIES		
Policy Name		
Journavx	Non-Preferred Fumarate Products	
Lemtrada	Tysabri	
Lemtrada Prior Authorization and Step Therapy Policy -	Tysabri Prior Authorization and Step Therapy Policy -	
Medicare Part B	Medicare Part B	
Medically Administered Multiple Sclerosis Agents	Zeposia	
Medically Administered Multiple Sclerosis Agents Prior		
Authorization and Step Therapy Policy – Medicare Part	Zeposia - Medicaid	
В		
Multiple Sclerosis Agents		

RETIRED POLICIES	
Policy Name	Summary Of Change
Chenodal, Ctexli	Medications moved to Medications for Rare Indications policy
Fentanyl Citrate	Due to the drugs on the policy are obsolete