Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 101

December 1, 2024

This is the December 1, 2024 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

The Provider Alert, Prior Authorization Requirements, and Medical policies are all available on ProvLink and through the link above.

NOTE: For Oregon Medicaid requests, services which do not require prior authorization will process against the Prioritized List. To determine which services require prior-authorization, please see the current PHP prior authorization list here.

****EXTERNAL PROVIDER REVIEW OPPORTUNITY****

PHP Medical Policy Committee is seeking feedback from providers to serve as clinical subject matter experts (SMEs) through the policy development and annual review processes. This review process allows providers to offer their expertise and discuss relevant research in their field that will be used to support how these policy decisions are made. This will allow providers an opportunity to offer valuable insight that will help shape policies that affect provider reimbursement and patient care.

If interested, please email us at PHPmedicalpolicyinquiry@providence.org with your name, specialty, and preferred email address.

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 1/1/2025

Inpatient Surgical Site of Service
 	
MP184
	Policy Updates: No changes to criteria.
	Codes/PA:
	• Remove PA from 3 revision arthroplasty codes: 23473, 23474, 27703
	• CODE SET UPDATE:
	  ○ New code: 25448- requires PA for inpatient location, otherwise no PA.
	  ○ Code revision: 25447
	
	OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Partial Thromboplastin Time (PTT) **MP325**	**Policy Updates:** No changes. **Codes/PA:** Update diagnosis code pairing per CMS update. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 2/1/2025

Transcranial Magnetic Stimulation **MP269**	**Policy Updates:** Add to criterion III.C, regarding retreatment or relapse: "Previous TMS treatment(s) reduced clinical symptom severity, as evidenced by a 50% reduction on an evidence-based depression rating scale), *and this improvement was maintained for at least 2 months after the prior TMS treatment course.* **Codes/PA:** No changes to codes or PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE POLICIES

Effective 1/1/2025

Bone Growth Stimulators **MP226**	**Policy Updates:** No change to policy criteria. **Codes/PA:** Remove PA from E0748 for Medicare LOB. No change to configuration for other codes in this policy.

Surgical Site of Service
 	
MP395
	Policy Updates: No change to criteria.
	Codes/PA: Coding/Config updates include the following:
	• Remove "revision" arthroplasty code from scope of policy (23473), due to being medically necessary based on Company criteria (by nature of being a "revision" procedure, it would always be considered medically necessary in the inpatient setting, so separate PA for inpatient setting is not required).
	• **Q1 2025 Code updates:**
	  ○ **Add:** 25448 (PA if IP only)
	  ○ **Revise:** 25447

Partial Thromboplastin Time **MP326**	**Policy Updates:** No change to criteria, continue to apply NCD for partial thromboplastin time (PTT) testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.

Alpha-Fetoprotein **MP407**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.25 for alpha-fetoprotein (AFP) testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.
Blood Counts **MP209**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.15 for blood count testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.
Glycated Hemoglobin and Glycated Protein Testing **MP236**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.21 for glycated hemoglobin and glycated protein testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.
Lipid Testing **MP235**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.23 for lipid testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.
Prothrombin Time (PT) **MP413**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.17 for prothrombin time (PT) testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.
Serum Iron Studies **MP322**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.18 for serum iron studies. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.
Thyroid Testing **MP207**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.22 for thyroid testing. **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785.

Tumor Antigen Assays **MP415**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.29 for tumor antigen assay (TAA) for CA 15-3 and CA 27.29. *(NCDs 190.28 and 190.30 do not have changes with this MLN.)* **Codes/PA:** Update code configuration to align with CMS diagnosis code changes, as directed in CMS MLN MM13785, for CPT 86300

Effective 2/1/2025

Hyperbaric Oxygen Therapy **MP198**	**Policy Updates:** No change to criteria. Continue to use Medicare NCD, which lists medically necessary indications for hyperbaric oxygen therapy (HBOT). The use of HBOT for any other indication is not medically necessary according to this NCD. Due to high approvals of conditions being approved which do not meet the NCD coverage criteria, and to assist with coverage decisions, added Appendices to policy with CMS-directed diagnosis code lists for the applicable NCD. **Codes/PA:** No change to codes or configuration, continue PA for G0277 and 99183.

ARCHIVE

Effective 12/1/24

Biofeedback and Neurofeedback **MP515**	**Policy Updates:** Archive policy for Medicare LOB only due to low utilization over the past three years. **Codes/PA:** Term medical policy configuration for codes.

Providence Health Plan

Providence Health Assurance

REIMBURSEMENT POLICIES

Effective 3/1/25

Appropriate Use of Modifier -90 and Pass-Through Billing Practices **RP13**	**New Reimbursement Policy** **Recommendation:** • New reimbursement policy for all lines of business to address (1) a practice known as "pass-through billing" and (2) appropriate use of modifier 90. • **<u>Pass-through billing:</u>** This practice occurs when a provider, such as a physician, pays a laboratory to perform their tests and then files the claims as though they had performed the tests themselves. Concerns around this practice include: ○ It is often done to work around the lack of contractual relationships between a laboratory and payer, to avoid scrutiny of the laboratory in question, or to allow the provider to recoup some of the financial benefits of in-office testing without requiring them to operate a laboratory directly. This can also be done to leverage the contracted payment rates a physician may have in place if those are higher than the performing laboratory's own reimbursement rates. ○ Risks to this practice include, but are not necessarily limited to, potential violation of the Federal Anti-Kickback Statute (AKS), could put members at medical and financial risk if the laboratory and the test results they provide are not up to standard (e.g., poor quality test results can delay diagnosis, which can then delay care, or the results could be inaccurate and require repeat testing), and it could violate PHP provider contract language. ○ This policy does not apply to legitimate reference-laboratory arrangements between independent laboratories and hospital laboratories, or incident-to billing scenarios. It also doesn't apply to clinic-based labs and services they need to refer to outside laboratories. • **<u>Modifier -90 use:</u>** A pull of claim data revealed some incorrect use of modifier -90. This modifier is specific to services that are referred from one laboratory to another laboratory. This modifier should **not** be used on ***non-laboratory*** services, such as E&M codes, DME or supply items, psychotherapy services, etc. **Reimbursement Methodology:** At this time, we will not have automated configuration in place. Opportunities for claim automation are still under consideration, but this initial policy version provides internal teams (e.g., post-service, pre-pay review or the SIU teams) with a reference should they observe the practice during the course of one of their investigations, and it serves as an educational tool for providers. **Relevant References:** • 2018 Healthcare Fraud Prevention Partnership (HFPP) White Paper. • Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, 40.1 - Laboratories Billing for Referred Tests. • Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, 10.1.5.4.1 - Cases Involving Referral Laboratory Services.

	• Noridian webpage: Laboratories Billing for Referred Tests **OHP**: OHP will follow the Company Policy above

Vendor Updates

Effective 3/1/25

Carelon	**Annual Update**
	Changes to current criteria:
	- **Imaging of the abdomen and pelvis**
	  ○ **Tumor**: Added requirement for initial evaluation of testicular masses with ultrasound prior to advanced imaging.
	  ○ **Endometriosis**: Removed requirement for initial ultrasound in patients with established endometriosis.
	  ○ **Obstetric**: Specified that fetal MRI should be done in the second or third trimester.
	  ○ **Hepatobiliary**: Removed the criteria for LiverMultiScan as an alternative to MR elastography due to lack of data indicating a change in management.
	  ○ **Pancreatic**: Clarified that this indication is meant to apply only to indeterminate cystic lesions, including when IPMN is suspected. Known IPMN should be reviewed using the Tumor or Neoplasm NOS indication.
	  ○ **Nonspecific signs**: Removed general prerequisite for "prior imaging where available," as the intent is already addressed by the more specific requirements for US depending on pain location.
	- **Imaging of the chest**
	  ○ **Lymphadenopathy**: Moved the criterion for clinical/lab findings suggestive of malignancy as this does not apply only to mediastinal/hilar lymphadenopathy. No change in intent.
	  ○ **Signs and symptoms**: Added an indication for dyspnea to account for requests submitted without a differential diagnosis.
	- **Imaging of the Head and Neck -** Guidelines reaffirmed; FDG PET: NCCN alignment (treatment response, f/u of equivocal post-treatment PET)
	- **Oncologic Imaging:**
	  ○ **Colorectal:** NCCN alignment for definition of average risk and family history; MRI - NCCN alignments (surveillance interval, addition for nonoperative management) FDG-PET: Addition to account for lesions seen by MRI (eg post-liver directed therapy)
	  ○ **Hepatocellular:** NCCN alignment (interval of screening imaging)
	  ○ **Anal cancer:** CT: NCCN alignment (surveillance intervals)

	○ **Bladder and Urothelial:** CT - NCCN alignment (surveillance intervals, Chest imaging for NMIBC); FDG PET: NCCN 2B recommendation, aligned with standard imaging approach. ○ **Breast:** NCCN alignment (addition of risk subtypes for initial CT staging, MRI Breast surveillance, FDG PET staging). ○ **Cervical:** FDG PET: NCCN alignment (small cell NECC diagnostic workup/surveillance); clarification of management (no operational change) ○ **Esophageal and gastroesophageal junction:** CT - NCCN alignment (surveillance interval) FDG PET - NCCN alignment (to account for other perioperative treatment). ○ **Gastric cancer:** CT - NCCN alignment (surveillance interval) FDG PET - NCCN alignment (imaging interval, removal of imaging requirement) ○ **Hepatocellular and Biliary Tract:** CT/MRI - NCCN alignment (surveillance intervals). ○ **Histiocytic neoplasms:** FDG PET: NCCN alignment (PET threshold) ○ **Kidney:** CT/MRI – NCCN alignment (surveillance intervals) ○ **Lung cancer, small cell:** FDG-PET: Addition of standard imaging allowance when further characterization needed. ○ **Lymphoma – Non-Hodgkin and Leukemia:** CT - NCCN alignments (surveillance imaging) ○ **Multiple myeloma: FDG-PET:** NCCN alignment (indicated for patients suspected of having multiple myeloma or solitary plasmacytoma). ○ **Penile, Vaginal and Vulvar:** FDG-PET: NCCN alignment (added initial staging vaginal cancer, RT response scenarios). ○ **Thyroid cancer:** FDG and SSR PET - NCCN scenario alignments (initial staging/management).

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

Pharmacy & Therapeutics (P&T) Committee
Oregon Region P&T Committee August 2, 2024
Pharmacist & Technician Update
Go-Live Date: Tuesday, October 01, 2024, unless otherwise noted

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- Operational Policy Changes

New Drugs or Combinations

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

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: Medical
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	1 kit/21 days	1 kit/21 days	2 kits/21day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Flolan, Veletri, Remodulin, Tyvaso/DPI, Orenitram, Ventavis, Uptravi, bosentan (Tracleer), ambristentan (Letairis), Opsumit, Adempas, sildenafil, tadalafil			

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

PA PROGRAM NAME	Pulmonary Hypertension
MEDICATION NAME	Winrevair subcutaneous kit 45 mg Winrevair subcutaneous kit 60 mg
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	None
REQUIRED MEDICAL INFORMATION	For patients initiating therapy, the following criteria must be documented: 1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization as defined by: i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest AND

	ii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU) 2. Patient has one of the following: i. World Health Organization (WHO) Group 1 classification, pulmonary arterial hypertension (PAH; defined by a pulmonary capillary wedge pressure [PCWP] or left ventricular end diastolic pressure [LVEDP] less than or equal to 15 mmHg) with WHO/New York Heart Association (NYHA) functional class as outlined below: a. Flolan®, Veletri®, Tyvaso®, Tyvaso® DPI and Ventavis: Class III or IV b. Winrevair®: Class II or III c. All other therapies: Class II, III, or IV ii. For Adempas® only, WHO Group 4 classification CTEPH with WHO/New York Heart Association (NYHA) functional class II, III, or IV iii. For Tyvaso®/Tyvaso® DPI only, WHO Group 3 classification PH-ILD 3. For Winrevair®: i. Patient is currently established on (for at least 90 days) at least two of the following, unless all are not tolerated or contraindicated: a. Endothelin receptor antagonist (ERA; such as bosentan, ambrisentan, or macitentan) b. Phosphodiesterase-5 inhibitor (PDE5i; such as Revatio® [sildenafi] or Adcirca® [tadalafil]) OR a soluble guanylate cyclase stimulator (sGC; such as Adempas®) c. Prostacyclin analogue or receptor agonist (such as epoprostenol, Ventavis®, Uptravi®, treprostinil) ii. Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless all are not tolerated or contraindicated iii. Platelet count greater than or equal to 50,000/mm^3 For patients established on therapy: 1. Documentation of response to therapy such as lack of disease progression, improvement in WHO functional class must be provided. 2. Winrevair only: i. Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless not tolerated or contraindicated ii. Platelet count greater than or equal to 50,000/mm^3
AGE RESTRICTIONS	Winrevair: ages 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist
COVERAGE DURATION	Winrevair: Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.

	All others: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

4. **Prior Authorization Criteria for Medicare Part D**:

PA PROGRAM NAME	Pulmonary Antihypertensives
MEDICATION NAME	Winrevair subcutaneous kit 45 mg Winrevair subcutaneous kit 60 mg
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization the following criteria must be documented: 1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization, as defined by all of the following: i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest, ii. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg, AND iii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU), 2. Patient has documentation of one of the following i. World Health Organization (WHO) Group 1 classification PAH (or WHO Group 4 classification CTEPH for Adempas® only) with WHO/New York Heart Association (NYHA) functional class II, III, or IV, ii. For Tyvaso® DPI only, pulmonary hypertension associated with interstitial lung disease (WHO Group 3 classification PH-ILD). iii. For Winrevair only: World Health Organization (WHO) Group 1 classification PAH with WHO/New York Heart Association (NYHA) functional class II or III, 3. For Opsumit, Uptravi, Tracleer tablets for suspension, patient has had a therapeutic failure to generic bosentan or ambrisentan. 4. For Winrevair®: i. Patient is currently established on two of the following, unless all are not tolerated or contraindicated: a. Endothelin receptor antagonist (ERA; such as bosentan, ambrisentan, or macitentan) b. Phosphodiesterase-5 inhibitor (PDE5i; such as Revatio® [sildenafi] or Adcirca® [tadalafil]) OR a soluble guanylate cyclase stimulator (sGC; such as Adempas®) c. Prostacyclin analogue or receptor agonist (such as epoprostenol, Ventavis®, Uptravi®, treprostinil)

	ii. Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless all are not tolerated or contraindicated iii. Platelet count greater than or equal to 50,000/mm^3 Reauthorization requires documentation of response to therapy including lack of disease progression or improvement in WHO functional class and the following drug-specific criteria, if applicable: 1. Winrevair only: i. Medication will be used as add-on therapy in combination with at least two other pulmonary arterial hypertension agents, unless not tolerated or contraindicated ii. Platelet count greater than or equal to 50,000/mm^3
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist
COVERAGE DURATION	Winrevair: Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months. All others: Authorization will be approved until no longer eligible with the plan.

2. **Danicopan (Voydeya) Tablet**
   a. **Indication**: For treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	Danicopan 150 mg dose pack: six tablets per day Danicopan 200 mg dose pack: six tablets per day	Danicopan 150 mg dose pack: six tablets per day Danicopan 200 mg dose pack: six tablets per day	
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: pegcetacoplan (Empaveli)			

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

PA PROGRAM NAME	Complement Inhibitors
MEDICATION NAME	Danicopan (Voydeya) tablet
REQUIRED MEDICAL INFORMATION	For initial authorization for Paroxysmal Nocturnal Hemoglobinuria (PNH): 1. Documented, confirmed diagnosis of PNH by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (such as red blood cells [RBCs] and white blood cells [WBCs]) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64) 2. Symptomatic hemolytic PNH defined as lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal and at least one of the following prior to initiating therapy with a complement inhibitor: a. Documented history of thrombosis b. Transfusion dependence (for example, hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL) c. Disabling fatigue d. End-organ complications e. Frequent pain paroxysms (for example, dysphagia or abdominal pain) 3. For Soliris and Fabhalta: Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®) 4. For danicopan (Voydeya): all the following criteria must be met: a. Documentation of extravascular hemolysis while on ravulizumab or eculizumab b. Trial and failure, intolerance, or contraindication to pegcetacoplan (Empaveli) OR documentation of medical rationale for not switching to Empaveli therapy c. Documentation that danicopan will be used concomitantly with ravulizumab or eculizumab d. For authorization of danicopan 200 mg dose, must meet one of the following: i. Documentation of a hemoglobin (Hgb) level that has not increased by greater than 2 g/dL after at least four weeks of initial therapy with 150 mg three times daily ii. Patient required a transfusion during the previous four weeks For reauthorization: Documentation of positive response to therapy
QUANTITY LIMITS	For danicopan (Voydeya): 6 tablets per day

3. **Immune globulin,gamma(igg)stwk (Alyglo) Vial**
   a. **Indication**: For the treatment of primary humoral immunodeficiency (PI) in adults.

b. **Decision**:

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

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

4. **Melphalan hcl (Hepzato) Vial**
   a. **Indication**: For adult patients with uveal melanoma with unresectable hepatic metastases.
   b. **Decision**:

	Commercial	Medicaid	Medicare
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	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

5. **Nogapendekin alfa inbakic-pmln (Anktiva) Vial**
   a. **Indication**: For the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
   b. **Decision**:

	Commercial	Medicaid	Medicare
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
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

6. **Pemivibart (Pemgarda (EUA)) Vial**
   a. **Indication**: A monoclonal antibody for pre-exposure prophylaxis of COVID-19 for immune compromised individuals.
   b. **Decision**: Informational

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

	Commercial	Medicaid	Medicare
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	One tablet per day	One tablet per day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Rezdiffra
MEDICATION NAME	Rezdiffra
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Presence of cirrhosis
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Diagnosis of nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH), confirmed by liver biopsy or vibration-controlled transient elastography (such as FirbroScan) within the previous six months 2. Baseline nonalcoholic fatty liver disease activity score (NAS) taken within previous three months that is at least four (4), with a score of 1 or more for each component 3. Fibrosis stage 2 or 3 (F2/F3) by liver biopsy within the previous six months 4. Attestation that patient is abstaining from alcohol consumption 5. Documentation of all the following: a. For patients with body mass index (BMI) 27 and above: engaged in weight management lifestyle modifications b. For patients with hypertension or hyperlipidemia: patients are currently using guideline directed medication therapy (such as statins and antihypertensives) c. For patients with type 2 diabetes, one of the following: i. Currently A1c less than 7% (taken within previous six months) ii. A1c 7% or higher and are currently stable on (for at least six months), or have a contraindication to, additional guideline directed medication therapy with all the following:

	1) Metformin 2) Glucagon-like peptide 1 (GLP-1) receptor agonist 3) Sodium-glucose cotransporter-2 (SGLT2) inhibitor. For reauthorization: Documentation of response to therapy, defined as no worsening of fibrosis score and no worsening of NAS
AGE RESTRICTIONS	May be covered for patients aged 18 year and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist
COVERAGE DURATION	Authorization and reauthorization will be approved for one year

8. **Tovorafenib (Ojemda) Susp Recon and Tablet** reviewed by Jenna Newman, PharmD.
   a. **Indication**: For treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.
   b. **Decision**:

Health Plan Recommendations			
	Commercial	**Medicaid**	**Medicare**
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	Suspension: 96 mL/28 days, Tablets: 24/28 days	Suspension: 96 mL/28 days Tablets: 24/28 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: dabrafenib (Tafinlar) + trametinib (Mekinist)			

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

Other Formulary Changes:

DRUG NAME	RECOMMENDATION	POLICY NAME
Eltrombopag choline (Alvaiz) Tablet	New entity; • Non-formulary for all lines of business Effective: 08/01/2024	N/A
Bromfenac Sodium Drops	First generic drug; • Non-formulary for all lines of business Effective: 08/01/2024	N/A
Adalimumab-RYVK (Simlandi) Autoinjkit	Moving to preferred biosimilar for Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (Two injections per 28 days)	Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)
Adalimumab-atto (Amjevita) Auto Injct / Syringe	Change in preferred biosimilar products. Remove Amjevita from Commercial formulary: Non-Formulary, Prior Authorization, Quantity Limit (Two injections per 28 days) Effective: 11/01/2024	Therapeutic Immunomodulators (TIMS)
Clomiphene citrate Tablet	• Commercial: Remove from Formulary, add Prior Authorization • Medicaid: Remove from Formulary Effective: 11/01/2024	• Commercial: Fertility and Related Medications • Medicaid: N/A
Baclofen Tablet	New strength; • Non-formulary for all lines of business	N/A
Valbenazine tosylate (Ingrezza Sprinkle) sprinkle cap	New Formulation • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (One per day) • Medicare: Non-Formulary	• Commercial/Medicaid: VMAT2 Inhibitors • Medicare: N/A
Diazepam (Libervant) Film	New formulation; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Commercial/Medicaid: N/A • Medicare Part D: Rescue Medications for Epilepsy

Macitentan/tadalafil (Opsynvi) Tablet	New combination; • 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
Spesolimab-sbzo (Spevigo) Syringe	New strength and formulation (150 mg/ml syringe); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 mL per 28 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Medications for Rare Indications • Medicare Part D: N/A
Levomilnacipran hcl (Fetzima) Cap SA 24H	Remove from Commercial formulary	N/A
Frovatriptan succinate (Frova) Tablet	Remove from Commercial formulary	N/A
Istradefylline (Nourianz) Tablet	Commercial: Up tier to Tier 6 Effective: 09/01/2024	N/A
Ramelteon (Rozerem) Tablet	Commercial Dynamic: Down tier generic to Tier 2	N/A
Vigabatrin (Sabril) Tablet	Commercial: Down tier generic to Tier 5	N/A
Vortioxetine hydrobromide (Trintellix) Tablet	Remove from Commercial formulary Effective: 11/01/2024	Antidepressants Step Therapy Policy
Ubrogepant (Ubrelvy) Tablet	Add to Medicaid formulary: Formulary, Prior Authorization, Quantity Limit (16 per 30 days)	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists
Ganaxolone (Ztalmy) Oral Susp	Remove from Commercial and Medicaid formularies: Non-Formulary, Prior Authorization, Quantity Limit (37 mL/day)	Medications for Rare Indications
Mirabegron (Mirabegron ER) Tab ER 24H	First generic drug (Myrbetriq). • Commercial/Medicare Part D: Non/Formulary • Medicaid: Formulary, Step Therapy Effective Date: 5/1/2024	• Commercial/Medicare Part D: N/A • Medicaid: Overactive Bladder Medications Step Therapy Policy
Topiramate ER capsules (Trokendi XR)	Commercial/Medicaid: Add Quantity Limit (one capsule per day)	New Medications and Formulations without Established Benefit

	Effective: 11/01/2024	
• **Votrient capsule and gel** • **Truvada** • **Afinitor** • **Targretin** • **Kuvan** • **Provigil** • **Tobi neb solution** • **Zoloft** • **Lexapro** • **Sutent** • **Adcirca**	Brand Name Formulations to be removed from the Commercial formulary (generics to remain on formulary) Effective: 11/01/2024	
Abiraterone submicronized (Yonsa)	Remove from Commercial Formulary. Preferred product is generic abiraterone, which will be required prior to coverage of Yonsa Effective: 11/01/2024	Anti-Cancer Medications - Self-Administered
Estrogen Class Review • **Angeliq® (estradiol/drospirenone tablet)** • **Estradiol 0.06% gel** • **Estradiol 0.1% gel** • **EvaMist® (estradiol transdermal spray)** • **Femring® (estradiol vaginal ring)**	Add to formulary: • Commecial: Tier 4 • Medicaid: Formulary • Medicare: Formulary, Tier 4 ○ Angeliq® and Femring® are already on formulary	N/A
Estradiol/norethindrone (Activella, Mimvey, Fyavolv, Jinteli)	Medicare: Move to Tier 2	N/A

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

Drugs released from 04/26/2024 – 06/28/2024

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Pneumoc 21-val conj-dip crm/pf (Capvaxive) Syringe	New entity. Line extend with other pneumonia vaccines; • Commercial: Formulary, Preventive, Quantity Limit (0.5 mL per day) • Medicaid: Medical Benefit, Quantity Limit (0.5 mL per day) • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
Fosaprepitant dimeglumine (Focinvez) Vial	New strength. Line extend with Emend (fosaprepitant dimeglumine); • Medical Benefit for all lines of business	N/A
Rsv vaccine, pref, mrna/pf (Mresvia) Syringe	New entity. Line extend with Abrysvo; • Commercial: Formulary, Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Tralokinumab-ldrm (Adbry Autoinjector) Auto Injct	New formulation. Line extend with Adbry 150 mg/ml; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Adbry • Medicare Part D: N/A
Futibatinib (Lytgobi) 12 mg/day Tablet	New MedID. Line extend with Lytgobi 4mg tablets; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (3 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (3 tablets per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 tablets per day)	Anti-Cancer Medications - Self-Administered
Futibatinib (Lytgobi) 16 mg/day Tablet	New MedID. Line extend with Lytgobi 4mg tablets;	Anti-Cancer Medications - Self-Administered

	• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (4 tablets per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 tablets per day)	
Futibatinib (Lytgobi) 20 mg/day Tablet	New MedID. Line extend with Lytgobi 4mg tablets; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (5 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (5 tablets per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 tablets per day)	Anti-Cancer Medications - Self-Administered
Asciminib hydrochloride (Scemblix) Tablet	New strength. Line extend with Scemblix 20mg and 40mg; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (4 tablets per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 tablets per day)	Anti-Cancer Medications - Self-Administered
Cenobamate (Xcopri) Tablet	New strength. Line extend with other Xcopri strengths; • Commercial: Formulary, Tier 4, Step Therapy, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Step Therapy, Quantity Limit (1 tablet per day) • Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (1 tablet per day)	Antiepileptic Medications Step Therapy Policy

Corticotropin (Acthar Selfject) Pen Injctr	New formulation. Line extend with Acthar Gel; • Commercial: Formulary, Tier 6, Prior Authorization, Specialty • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: HP Acthar Gel • Medicare Part D: N/A
Benralizumab (Fasenra) Syringe	New strength. Line extend with other Fasenra subcutaneous syringe: Medical Benefit, with Prior Authorization for all lines of business	• Commercial/Medicaid: Il-5 Inhibitors • Medicare Part B: Il-5 Inhibitors Prior Authorization and Step Therapy – Medicare Part B
Mirikizumab-mrkz (Omvoh) Syringe	New formulation. Line extend with other Omvoh strengths; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) / Self-Administered Drugs (SADs) • Medicare: N/A
Upadacitinib (Rinvoq LQ) Solution	New formulation. Line extend with Rinvoq tablets; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (12 mL per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (12 mL per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators (TIMS)
Adalimumab-adbm (Adalimumab-ADBM(CF) Syringekit	New formulation. Line extend with non-preferred Humira biosimilars; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.8 mL per 28 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare: N/A
Alpelisib (Vijoice) Gran Pack	New formulation. Line extend with Vijoice 50mg tablets; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 packet per day)	Vijoice

	• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 packet per day)	
Deutetrabenazine (Austedo XR) Tab ER 24H	New strength. Line extend with Austedo XR 12mg & 24mg; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day)	VMAT2 Inhibitors

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Carbinoxamine maleate (Carbinoxamine Maleate ER) sus ER 12H	First generic drug (Karbinal ER). Line extend as generic; Non-Formulary for all lines of business	N/A
Estradiol Gel MD PMP	First generic drug (Estrogel). Line extend as generic; • Non-Formulary for all lines of business	N/A
Deflazacort Oral Susp	First generic (Emflaza). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Agamree, Emflaza • Medicare Part D: N/A
Eribulin Mesylate Vial	First generic drug (Halaven). Line extend as generic; • Medical Benefit, with Prior Authorization for all lines of business	Anti-Cancer Medications - Medical Benefit
Liraglutide Pen Injctr	First generic drug (Victoza). Line extend as generic; • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (9 mL per 30 days)	GIP and GLP-1 Receptor Agonists

	• Medicaid: Formulary, Prior Authorization, Quantity Limit (9 mL per 30 days) • Medicare Part D: Non-Formulary	

Clinical Policy Changes:

1. **Major Changes:**

POLICY NAME	SUMMARY OF CHANGE
Addyi	Combined Addyi and Vyleesi into one policy, "Medications for Female Sexual Interest/Arousal Dysfunction." • Addyi: Added requirement for 6 months of diagnosis, quantity limit of one per day i • Vylessi: change quantity limit to 1.2 per 28 days, • Decreased initial authorization to two months
Antiepileptic Medications Step Therapy Policy	Updated quantity limit for Briviact to align with maximum dosing per FDA labeling
Antipsychotics	Added quantity limits
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists	Added criteria to acute migraine indication to require evaluation of medication overuse headache and exclude concomitant use of CGRPs indicated for acute migraine. Added reauthorization criteria for cluster headache.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Medicaid	Updated prophylactic therapy trial and failure prerequisite drugs to allow a trial of three drugs from any class as outlined to align with the Oregon Health Authority (OHA). For acute migraines, added criteria to evaluate for medication overuse headache and require use of preferred acute CGRP (Ubrelvy) to align with OHA. Added criteria to exclude use of dual prophylactic CGRP therapy or dual acute migraine CGRP therapy due to lack of safety and efficacy data. Prescriber restrictions were updated to clarify intent of requiring a specialist consultation on initial review.

Dupixent	Atopic Dermatitis: • Updated to allow as first line for patients with body surface area greater than 40%, • Require trial and failure of a topical corticosteroid and topical calcineurin inhibitor for body surface area of 10-40% with allowance to waive calcineurin if an oral immunosuppresant was tried, Asthma: • Updated diagnostic criteria • Decrease requirement for stable oral corticosteroid for steroid-dependence to four weeks, Reauthorization for Asthma and Nasal Polyps requires combination with standard maintenance therapy, Coverage Duration for Atopic Dermatitis reauthorization extended to long-term
Dupixent - Medicaid	Split policy from Commercial policy Asthma: • Updated diagnostic criteria to align with OHA • Decrease requirement for stable oral corticosteroid for steroid-dependence to four weeks, • Align tried and failed therapy to adherence for 12 months • Reauthorization for asthma requires combination with maintenance therapy Atopic Dermatitis: • Added allowance for EPSDT (under 21 only needs to show the condition significantly impacts life and does not need to meet severity criteria) • Reauthorization increased to long-term Nasal polyps: aligned criteria with OHA for trial and failure of two courses of intranasal steroids for at least 12 to 26 weeks each Esophagitis: remove requirement for symptoms and weight; Prurigo Nodularis: • Remove requirement for itching for six weeks • Add EPSDT allowance
Epidiolex	Decreased trial criteria to one instead of two for Medicaid, for Lennox-Gastaut syndrome to align with OHA criteria

Fintepla	Added criteria requiring therapy to be adjunct based on guideline recommendations and OHA policy. Added criteria required echocardiogram screening for initial and reauthorization per package insert black box warning and to align with OHA. For Medicaid only: reduced prerequisite therapy criteria to one drug to align with OHA
Firdapse	Added criteria requiring baseline assessment of function to align with other insurers and OHA, updated reauthorization criteria to require improvement from baseline validated assessment scale
Formulary and Quantity Limit Exceptions	Criteria for brand name medications with formulary, generic alternatives were added to this policy.
Infusion Therapy Site of Care	Several drugs were added to this policy that can be self-administered.
Insomnia Agents - Medicaid	Prior authorization removed from flurazepam as no utilization of this drug. It will be reviewed as a non-formulary medication.
Krystexxa	Add requirement for combination with methotrexate, increase duration of authorization from six months to 12 months for both initial and reauthorization
Long-Acting Opioids	Allowed for waiver of prerequisite therapy with long-acting morphine sulfate therapy for patients with metastatic cancer. Clarified requirement regarding prior short-acting opioid use. Added requirement for naloxone prescription.
Long-Acting Stimulant Medications Quantity Limit	Add allowance for patients aging into a maximum dose
Maximum Allowable Opioid Dose	Updated coverage duration for chronic pain for initial authorization and reauthorization to both be one year.
Narcolepsy Agents	Updated indication for Wakix for excessive daytime sleepiness (EDS) in pediatric patients six years and older. Added Wakix as a prerequisite for coverage of oxybate salts for children with EDS in narcolepsy. Added prerequisite therapy requirements for patients with cataplexy
Nuedexta	Added exclusion of complete atrioventricular block without implanted pacemaker/high risk of atrioventricular block to align with package insert
Pediatric Analgesics	Removing all non-formulary medications as no utilization. Review will default to non-formulary review process.
Qudexy XR, Trokendi XR	Move Trokendi to New Medications and Formulations Without Established Benefit policy; Add Quantity Limit of one per day to Qudexy and Trokendi
Reyvow	Combined Cambia and Reyvow into “Acute migraine Medications policy”, added reauthorization criteria;

Spinraza	Combined Spinraza, Evrysdi and Zolgensma into one policy, "Therapies for spinal muscular atrophy". Updated reauthorization for Spinraza/Evrysdi to "established on therapy".
Spravato	Remove some exclusion criteria
Strensiq	Removed criteria for patients 18 years and older at time of request and age specific criteria on reauthorization to align with package label. Expanded prescriber restrictions to include any specialist in the area of perinatal or juvenile onset hypophosphatasia.
• **Tepezza** • **Tepezza Prior Authorization and Step Therapy Policy - Medicare Part B**	Removed requirement for clinical activity score for active disease
Therapeutic Immunomodulators (TIMS) – Commercial	Preferred adalimumab biosimilar products were updated, as Simlandi® will replace Amjevita® as one of the preferred products. Tocilizumab-aazg (Tyenne®), a new biosimilar product, will be covered in parity with the innovator product Actemra®.
Topical Agents for Skin Conditions - Medicaid	Change to align with OHA criteria
Triptan Quantity Limit	Changed some quantity limits. Added combination with other acute migraine medications as exclusion criteria, reauthorization requires documentation that increased quantity is still necessary
VMAT2 Inhibitors	Update to quantity limits to reflect newly available dosage strengths, removed exclusion criteria that was a boxed warning only when used in Huntington's disease, updated re-authorization duration to reflect long-term use of these medications.

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

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

3. **Minor Change**:

POLICY NAME		
Diacomit	Medically Administered Multiple Sclerosis Agents	Savella

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

4. **Retired Policies**:

POLICY NAME	SUMMARY OF CHANGE
Antidepressants Step Therapy Policy	Drugs will be removed from the formulary. Criteria from "Formulary and Quantity Limit Exception" policy will apply
Brand Over Generic	Criteria will be combined with the "Formulary and Quantity Limit Exception" policy.
Cambia	Policy combined with Reyvow on new “Acute Migraine Medications” policy
Evrysdi	Combined Spinraza, Evrysdi and Zolgensma into one policy, "Therapies for spinal muscular atrophy".
Ketorolac Intramuscular Injection	Utilization and safety concerns will be assessed with quantity limits.
Non-Preferred Triptan Therapy	Drugs will be removed from the formulary. Criteria from "Formulary and Quantity Limit Exception" policy will apply
Nourianz	Low risk of inappropriate utilization
Qalsody	Moved to “Medications for Rare Indications” policy
Relyvrio	Drug no longer available on the market to new patients
Rescue Medications for Epilepsy	Low risk of inappropriate utilization
Sabril	Low risk of inappropriate utilization
Skysona	Moved to “Medications for Rare Indications” policy
Spevigo	Moved to “Medications for Rare Indications” policy
Vyleesi	Combining with Addyi in the “Medications for Female Sexual Interest/Arousal Disorder” policy
Zolgensma	Combined Spinraza, Evrysdi and Zolgensma into one policy, "Therapies for spinal muscular atrophy".

Ztalmy	Moved to “Medications for Rare Indications” policy

PHP Operational Policies: Go-live September 1, 2024

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