PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 274

September 1, 2022

This is the September 1, 2022 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

ALL LINES OF BUSINESS

Effective 10/1/2022

COVID-19 In Vitro Testing **MP350**	**New Policy** • Creation of a medical policy on COVID-19 testing, which is based on the federal coverage mandates: FFCRA and CARES Act. • The policy considers antigen, molecular, and serologic testing for the primary *diagnosis* of COVID-19 to be medically necessary, including the 8 OTC tests allowed per month* (per FFCRA). • Antigen, molecular and serologic testing that is <u>not</u> primarily intended to diagnose COVID-19 will be considered not medically necessary. • The policy indicates high frequency COVID-19 testing is subject to a medical necessity review to ensure the testing is in-line with the federal mandates. • The policy indicates testing/billing for COVID-19 testing of friends and family members is not medically appropriate (in accordance with regulations). *Not applicable to the Medicare line of business • **OHP:** Continue to follow the Prioritized List for coverage of COVID-19 In Vitro Testing

ALL LINES OF BUSINESS EXCEPT MEDICARE

Effective 11/1/2022

Next Generation Sequencing for Cancer (All Lines of Business Except Medicare)
 	
MP352
	Policy Updates: New policy for next generation sequencing (NGS) testing for somatic cancers.
	
	Codes/PA: Added proprietary codes for NGS tests as well as general CPT codes and unlisted molecular pathology codes. Set up all codes to require PA.
	
	• NGS policy will affect criteria and/or code configuration for the following commercial policies
	  ○ NSCLC: Tumor Testing for Targeted Therapy
	  ○ GT: Non-Covered Genetic Panel Tests
	  ○ Genetic and Molecular Testing
	  ○ Circulating Tumor Cell and DNA Assays for Cancer Management
	  ○ GT: Gene Expression Profile Testing for Breast Cancer
	  ○ Cardiac: Disease Risk Screening
	  ○ Genetic Testing: Hereditary Breast and Ovarian Cancer
	  ○ Genetic Testing: Whole Exome, Whole Genome, and Proteogenomic Testing
	  ○ Genetic Testing: Inherited Susceptibility to Colorectal Cancer
	  ○ GT: GEP Testing for Melanoma
	  ○ Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms
	  ○ Genetic Testing: Inherited Thrombophilias
	
	OHP: Will follow the Company Policy above

Genetic and Molecular Testing (All Lines of Business Except Medicare) **MP215**	**Policy Updates:** • From criterion I.D, "each gene and/or component" was removed from clinical utility requirements. • Criterion IV was added, stating that repeat testing of the same germline content for the same genetic information is not medically necessary. **Codes/PA:** • Codes 81504 and 81540 were removed from the coding table **OHP:** No impact - no changes to existing PA requirements.

Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business Except Medicare) MP213	**Policy Updates:**
	• From criterion I: removed "ALL of the genes and/or components" when describing genetic panel testing that is investigational
	• Removed multiple panels from policy, which will be addressed in the new NGS policy.
	  ○ Caris MI Tumor Seek and MI Cancer Seek
	  ○ FoundationOne CDx
	  ○ GeneTrails NSCLC Genotyping Panel
	  ○ GeneTrails Solid Tumor Panel
	  ○ MSK-IMPACT
	  ○ Oncotype MAP Pan Cancer Tissue Test
	  ○ PGDx Elio Tissue Complete
	  ○ Arrhythmia Panel
	  ○ Ataxia Comprehensive Evaluation Panel
	  ○ Autosomal Dominant Polycystic Kidney Disease (ADPKD) Panel
	  ○ Bone Marrow Failure Syndrome Panel
	  ○ Breast/Gyn Cancer Panel
	  ○ BROCA Cancer Risk Panel
	  ○ CancerNext®
	  ○ Caris Molecular Intelligence (MI) MI Profile™
	  ○ CNGnome™
	  ○ ColoNext
	  ○ Colorectal Cancer Panel
	  ○ Comprehensive Platelet Disorder Panel
	  ○ FoundationOne Heme
	  ○ GeneKey
	  ○ GeneTrails Hematologic Malignancies 220 Gene Panel
	  ○ Invitae Common Hereditary Cancer Panel
	  ○ myRisk® Hereditary Cancer
	  ○ Nervous System/Brain Cancer
	  ○ NGS_Myeloid 37 Genes Panel
	  ○ OvaNext
	  ○ PanNext
	  ○ PancreasSeq Genomic Classifier
	  ○ Platelet Disorders Panel
	  ○ UW-OncoPlex - Cancer Gene Panel
	  ○ Versiti aHUS Genetic Evaluation
	  ○ Versiti Autosomal Dominant Thrombocytopenia Panel
	  ○ Versiti Coagulation Disorder Panel
	  ○ Versiti Comprehensive Bleeding Disorder Panel

	○ Versiti Comprehensive Platelet Disorder Panel ○ Versiti Fibrinolytic Disorder Panel ○ Versiti Inherited Thrombocytopenia Panel ○ Versiti Platelet Function Disorder Panel ○ Versiti Thrombosis Panel ○ VistaSeq Hereditary Cancer Panel • Added DetermaRx to list of non-covered panels **Codes/PA:** • Removed the following codes from this policy: ○ Currently PAs and will continue to PA on NGS: 81445, 81455 ○ Currently denies as investigational, will PA on NGS: 0037U, 0048U, 0211U, 0244U, 0250U • Added 81540 to coding table. Already configured to deny as investigational in system and already denying in criteria. • Added code 0288U to policy and code review worksheet, continue to deny as investigational, previously on NSCLC **OHP:** Will follow the Company Policy above
Non-Small Cell Lung Cancer: Tumor Testing for Targeted Therapy **(All Lines of Business Except Medicare)** **MP194**	**Policy Updates:** • This policy is no longer addressing multi-gene panels for the treatment of NSCLC; where relevant these panels will be addressed by the new "Next Generation Sequencing" policy. ▪ Updated criterion III.A. to clarify that genes other than those addressed in criterion I. may be covered when billed as part of a multi-gene panel that meets criteria per the "Next Generation Sequencing" policy. ○ Notes were edited to clarify that this policy no longer addresses cell-free DNA tests; where relevant these panels will now be addressed by the "Circulating Tumor Cells" policy. ▪ Removed criteria (formerly III.-IV.) addressing circulating tumor DNA testing. • Deleted criteria (Formerly VI.-VII.) addressing multi-gene panels that will now be addressed by NGS policy. • "Investigational" denial language changed to "not medically necessary." **Codes/PA:** • Removed 0009U. This code will now be addressed by the GT: GEP for Breast Cancer policy. • Removed 0179U. This code will now be addressed by the Circulating Tumor Cells policy. • Removed 0239U, 0242U, 0326U – already addressed by the Circulating Tumor Cells policy. • Removed 81445, 81455 (and 6 codes in "non-covered" section) – will now be addressed with PA in NGS policy.

	• Removed 0288U – will now be addressed on "Non-Covered Panels" policy • Removed all codes in "No PA required" section – more specific codes already exist for criteria. • Added two codes specific to proteomic and proteogenomic testing (0080U, 0092U) currently on IMT; changed denial to "not medically necessary" • Changed 81538 denial from "investigational" to "not medically necessary" **OHP:** Will follow the Company Policy above
Circulating Tumor Cell and DNA Assays for Cancer Management **(All Lines of Business Except Medicare)** **MP122**	**Policy Updates:** • Added non-small cell lung cancer as eligible indication for circulating tumor cell panel testing. • Clarified investigational statement (criterion III.). **Codes/PA:** • Changed investigational denials for 6 codes to "not medically necessary" • Moved 0179U to this policy from NSCLC policy, where the code will continue to PA. **OHP:** Will follow the Company Policy above
Apheresis (Therapeutic Pheresis) **(All Lines of Business Except Medicare)** **MP305**	**Policy Updates:** • Added denial language for selective high-density lipoprotein delipidation. This service and code currently deny per the IMT (Commercial) policy. **Codes/PA:** • Apheresis codes will now require PA except when billed at inpatient settings. • Added additional codes that may be used for therapeutic apheresis (36511-13,36522). These codes will also be configured to require PA when billed outside of location code 21 (inpatient hospital.) **OHP:** Will follow the Company Policy above
Investigational and Non-Covered Medical Technologies	**Policy Updates:** No changes to criteria. **Codes/PA:** • Moved 0342T from this policy to Apheresis policy, where the code will continue to deny E/I.

(All Lines of Business Except Medicare) **MP23**	• Removed 0080U and 0092U. These codes will now be addressed by NSCLC policy. • Removed 30468. This code will now be addressed by the Sleep Disorder: Surgical Treatments policy, effective 11/1 **OHP:** No impact - no changes to existing PA requirements.
Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing (All Lines of Business Except Medicare) **MP219**	**Policy Updates:** • Added "neurologic conditions" to list of indications for which whole genome sequencing is considered investigational. **Codes/PA:** • 0209U, code will now be addressed on NGS policy. **OHP:** No impact - no changes to existing PA requirements.
Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies (All Lines of Business except Medicare) *Formerly All LOB* **MP237**	**Policy Updates:** • Separating Medicare Only policy. **Codes/PA:** • Removed language & CPT code for serum testing (80299) as policy was only meant to address antibody testing. **OHP:** No impact - no changes to existing PA requirements.
Magnetic Resonance-guided Focused Ultrasound Surgery (MRgFUS) **(All Lines of Business Except Medicare)** **MP347**	**Policy Updates:** • New policy with medical necessity criteria for treating essential tremor and bone metastases with MRgFUS **Codes/PA:** • Four codes added with two codes that will require PA **OHP:** This new policy will not impact OHP

MEDICARE

Effective 11/1/22

Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring (Medicare Only) **MP344**	**Policy Updates:** • New Policy separating Medicare from Commercial. **Codes/PA:** • CPT code 81401: Removed E/I denial if reported with select CPT codes and added a NMN denial instead.
Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies (Medicare Only) **MP345**	**Policy Updates:** • New Policy separating Medicare from Commercial. **Codes/PA:** • For CPT codes 80145, 80230, and 80280 the E/I denial was removed and a NMN denial was added.
Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (Medicare Only) **MP348**	**Policy Updates:** • New Medicare policy, using Medicare LCD available for the service, which only considers MRgFUS to be potentially medically necessary when used for essential tremor. Other indications would not meet the LCD criteria. **Codes/PA:** • Codes added to the policy include 0398T, C9734, 0071T, and 0072T
New and Emerging Technologies and Other Non-Covered Services (Medicare Only) *Formerly: Investigational and Non-Covered Medical Technologies (Medicare Only)*	**Policy Updates:** • Updated title to remove reference to "investigational" coverage positions. This is to avoid confusion with respect to what denial is applied to the services in this policy. Updated criteria to reflect "investigational" services or devices are "not medically necessary" for Medicare and that all items in this policy will deny as not medically necessary. **Codes/PA:** • The following codes currently deny E/I under this policy and will be converted to a NMN denial: 30468, 57465, 64628, 64629, 64910, 77423, 93590, 93591, 93592, 0002U, 0054U, 0058U, 0059U, 0061U, 0109U, 0110U, 0112U, 0114U, 0166U, 0206U, 0207U, 0243U, 0247U, 0251U, 0329T, 0338T, 0339T, 0342T, 0351T, 0352T, 0353T, 0354T, 0378T, 0379T, 0397T, 0408T, 0409T, 0410T, 0411T, 0414T, 0415T, 0416T, 0417T, 0418T, 0422T, 0424T, 0425T, 0426T, 0427T, 0431T, 0432T, 0433T, 0434T, 0435T,

MP220	0436T, 0443T, 0444T, 0445T, 0470T, 0471T, 0481T, 0485T, 0486T, 0487T, 0489T, 0490T, 0491T, 0492T, 0493T, 0506T, 0507T, 0508T, 0512T, 0513T, 0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T, 0525T, 0526T, 0527T, 0528T, 0529T, 0546T, 0547T, 0553T, 0567T, 0568T, 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0581T, 0582T, 0583T, 0594T, 0598T, 0599T, 0602T, 0603T, 0604T, 0605T, 0606T, 0607T, 0608T, 0609T, 0610T, 0611T, 0612T, 0613T, 0614T, 0615T, 0616T, 0617T, 0618T, 0621T, 0622T, 0632T, 0639T, 0643T, 0644T, 0645T, 0647T, 0655T, 0658T, 0659T, 0660T, 0661T, 0673T, 0674T, 0675T, 0676T, 0677T, 0678T, 0680T, 0681T, 0683T, 0684T, 0685T, 0686T, 0687T, 0688T, 0695T, 0696T, 0700T, 0701T, 0704T, 0705T, 0706T, 0707T, C1761, C1824, C9352, C9353, C9355, C9361, C9759, C9764, C9765, C9766, C9767, C9768, C9771, C9772, C9773, C9774, C9775, C9781, K1009, K1030 • 0342T will be moved from this policy to the apheresis policy.
Apheresis (Therapeutic Pheresis) (Medicare Only) **MP310**	**Policy Updates:** • Expanded scope of policy based on language in the Commercial policy regarding different types of apheresis procedures by adding additional criteria references. **Codes/PA:** Changes to codes/configuration are as follows: • Require current apheresis codes in the policy to PA ***except*** when billed at inpatient settings. • 36511, 36512, 36513, 36522: Added PA to these codes. These codes will also be configured to require PA when billed outside of location code 21 (inpatient hospital) • 0342T: Removed code from IMT policy and moved to this policy. Removed E/I denial and added NMN denial instead for Medicare.

Archive

Effective 9/1/2022

Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms (Medicare Only) **MP314**	**Policy Updates:** This Medicare Only policy will be archived. **Codes/PA:** Tests will be addressed by the *Genetic and Molecular Diagnostics (Medicare Only)* policy, but no change to configuration. Added any codes not already in the *Genetic and Molecular Diagnostics (Medicare Only)* policy (Exception: 0028U was deleted 10/1/2018 so it was **not** added to the GMT policy).

Genetic Testing: Diagnostic Evaluation of Interstitial Lung Disease (Medicare Only) **MP177**	**Policy Updates:** This Medicare Only policy will be archived. This policy addresses only one single test, the Envisia® test. This test is not currently addressed in the *Genetic and Molecular Diagnostics (Medicare Only)* policy, so added to the policy **Codes/PA:** Test will be addressed by the *Genetic and Molecular Diagnostics (Medicare Only)* policy, but no change to configuration (continue PA on CPT 81554 and unlisted review for CPT 81479).
Genetic Testing: Inherited Susceptibility to Colorectal Cancer (Medicare Only) **MP117**	**Policy Updates:** This Medicare Only policy will be archived. **Codes/PA:** Codes and tests in this policy will be addressed by the *Genetic and Molecular Diagnostics (Medicare Only)* policy. Changes to code configuration include the following: • Codes 81163, 81164, 81165, 81166, 81167, 81201, 81203, 81212, 81216, 81292, 81294, 81295, 81297, 81298, 81300, 81307, 81317, 81319, 81321, 81323, and 81351: Remove PA and add NMN denial per future LCA. This is also part of the Medicare *Genetic and Molecular Diagnostics (Medicare Only)* policy CRW. • No changes to configuration for any other code.
Genetic Testing: Pharmacogenetic Testing (Medicare Only) **MP217**	**Policy Updates:** This Medicare Only policy will be archived. **Codes/PA:** Codes and tests in this policy will be addressed by either the *Genetic and Molecular Diagnostics (Medicare Only)* policy or any other current Medicare GT policy they may be found in today, with changes to configuration for one code (81382; removing PA to be consistent with other HLA class testing codes) **Exceptions:** • Codes 88271-88275 were **not** added to the GMT policy (continue No PA for these codes). • Code 0177U is also found in the circulating tumor cell policy and is specific to plasma-based testing, so will not add it to the GMT policy at this time.

VENDOR UPDATES

InterQual

The ASAM Criteria® Powered by InterQual has Undergone a Name Change

Revision Summary	Product has been renamed to The ASAM Criteria® Navigator and required the notes at the subset level to reflect this name change. No changes have been made to the criteria.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting August 5, 2022
Go-Live Date: Saturday, October 01, 2022, unless otherwise noted

Special Announcement
Effective October 17th 2022, the following drugs will be added to the Self-Administered Drug Exclusion policy. These drugs will require a prior authorization for continued administration by a healthcare professional after an initial transition period of 60 days

- Xolair® (omalizumab) – this medication has a 90-day transition period
- Adbry®(tralokinumab-ldrm)
- Besremi® (ropeginterferon alfa-2b-njft)

Table of Contents:

New Drugs and Combinations:

1. **Mavacamten (Camzyos) Capsule**
   a. **Indication**: For the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 5 - 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 capsule per day	1 capsule per day	1 capsule 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: propranolol, metoprolol, verapamil, diltiazem, disopyramide			

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

PA PROGRAM NAME	Camzyos
MEDICATION NAME	Mavacamten (Camzyos®)

PA INDICATION INDICATOR	4 - All FDA-Approved Indications, Some Medically Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization requires documentation of all the following: 1. Clinical diagnosis of HCM, defined as left ventricular hypertrophy (LVH) in the absence of another cardiac, systemic, or metabolic disease capable of producing the magnitude of hypertrophy evident, and evidence of one of the following as measured by any imaging technique: a. Left ventricle wall thickness of 15 mm or greater **OR** b. Left ventricle wall thickness of 13 mm or greater with family history of HCM or in conjunction with a positive genetic test 2. New York Heart Association (NYHA) class II, III, or IV 3. Left ventricular ejection fraction (LVEF) 55% or greater 4. Left ventricular outflow tract (LVOT) peak gradient 50 mmHg or greater at rest or with provocation 5. Documented trial and failure, intolerance, or contraindication to all the following: a. A formulary generic non vasodilating beta blocker (such as propranolol, metoprolol, atenolol, bisoprolol) **AND** b. A formulary generic calcium channel blocker (verapamil or diltiazem) **AND** c. disopyramide Reauthorization requires documentation of a positive clinical response, as evidenced by at least one of the following: 1. Improvement in symptoms (such as dyspnea, fatigue, chest pain, palpitations, dizziness, fainting) **OR** 2. NYHA class reduction
AGE RESTRICTIONS	18 years of age or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

2. **Lutetium lu-177 vipivotide tetraxetan (Pluvicto) Vial**
   a. **Indication**: For adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. PSMA expression tumors can be diagnosed using Gallium Ga 68 PSMA-11 (Locametz®) or an approved PSMA-11 imaging agent.
   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: Jevtana® (Medical benefit)			

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

3. **Tenapanor hcl (Ibsrela) Tablet**
   a. **Indication**: For the treatment of IBS-C in adults.
   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	2 tablets per day	2 tablets per day	N/A

* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: soluble fiber, polyethylene glycol, lubiprostone and linaclotide (Linzess®)

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

PA PROGRAM NAME	Constipation Agents
MEDICATION NAME	Tenapanor (Ibsrela®)
REQUIRED MEDICAL INFORMATION	For Medicaid: Constipation is considered "below the line." Therefore, coverage is dependent on whether the constipation adversely affects, or is secondary to, a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services. The following conditions are not covered: • Chronic idiopathic constipation • Constipation secondary to irritable bowel syndrome • Opioid-induced constipation in patients with non-cancer pain 1. **For all requests**, the patient must have an FDA labeled indication for the requested agent. 2. **For all requests**, medication will not be used concomitantly with other intestinal secretagogues, selective 5-HT agonists or peripherally acting mu-opioid receptor antagonists covered by this policy 3. For patients *already established* on the requested product (starting on samples will not be considered as established on therapy): a. Documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools) 4. For patients *not established* on the requested product must meet ALL of the following indication-specific criteria: a. For **irritable bowel syndrome with constipation (IBS-C):** 1) Documentation of recurrent abdominal pain occurring, on average, at least one day per week during the previous three months with two or more of the following criteria: 1) Related to defecation (either increased or improved pain) 2) Associated with a change in stool frequency 3) Associated with a change in stool form (appearance)

	2) Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) to ALL of the following: 1) Regular use of dietary fiber supplementation (e.g., cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids) 2) Routine laxative therapy with polyethylene glycol (Miralax®) 3) For Ibsrela®: Failure, contraindication, or intolerance to one of the following medications: i. Lubiprostone (Amitiza®) ii. Linaclotide (Linzess®)
AGE RESTRICTIONS	Ibsrela®: May be approved for patients aged 18 years and older

4. **Difelikefalin acetate (Korsuva) Vial**
   a. **Indication**: For treatment of moderate-to-severe pruritis associated with chronic kidney disease, in adults undergoing hemodialysis.
   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: gabapentin, pregabalin, oral antihistamines			

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

PA PROGRAM NAME	Korsuva
MEDICATION NAME	Difelikefalin acetate vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Use with peritoneal dialysis

REQUIRED MEDICAL INFORMATION	For Medicaid: Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services For initial authorization, all the following must be met: 1. Diagnosis of moderate to severe pruritis associated with chronic kidney disease. Moderate to severe pruritis is defined as a score of 4 or higher on the Worst Itching Intensity numerical scale (WI-NRS) or pruritis that is severe enough to impair quality of life 1. Undergoing hemodialysis for at least three months 2. Prescriber attestation that the following have been optimized: a. Dialysis b. Laboratory abnormalities such as parathyroid, phosphate, magnesium c. Use of topical emollients 3. Documented inadequate response to at least two weeks trial of an oral antihistamine, or intolerance/ contraindication to antihistamine therapy 4. Documented inadequate response to at least two weeks trial of pregabalin or gabapentin, or intolerance/ contraindication to both pregabalin and gabapentin 5. Dose and frequency are in accordance with FDA-approved labeling For reauthorization, all the following must be met: 1. Undergoing hemodialysis 2. Documentation of positive response to therapy, defined as an improvement of at least three points on the WI-NRS from baseline or improvement in quality of life 3. Dose and frequency are in accordance with FDA-approved labeling
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. XIGDUO XR® (DAPAGLIFLOZIN AND METFORMIN HCL EXTENDED-RELEASE)
   a. Previous Indication(s):
      a. (Xigduo) As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
      b. (Dapagliflozin) For adults with type 2 diabetes mellitus to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors
      c. (Dapagliflozin) To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction

b. New indication approved 04/11/2022:
    a. (Dapagliflozin) To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression

- RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted. Add the new indication to the SGLT2 Inhibitors policy in FDA Approved Indications, Table 1 as a "Farxiga® only" indication

2. BEOVU® (BROLUCIZUMAB-DBLL)
    a. Previous Indication(s):
        a. Treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD)
    b. New indication approved 05/27/2022:
        a. Treatment of Diabetic Macular Edema (DME)
    c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Update policy by adding this drug to the existing criteria for DME as outlined below

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	BIOLOGICAL OPHTHALMIC VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF) INHIBITORS
MEDICATION NAME	Beovu
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**Diabetic macular edema or Diabetic retinopathy:** 3. For faricimab (Vabysmo®) and brolucizumab (Beovu®): Documentation that bevacizumab and aflibercept (Eylea®) have been ineffective, not tolerated/contraindicated, or medical rationale is provided why therapy is not appropriate for member

4. OLUMIANT® (BARICITINIB)
    a. Previous Indication(s):
        a. Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers
    b. New indication approved 05/10/2022:
        a. Treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO

- RECOMMENDATION: Inform prescribers via Medical Policy Alert. Update policy with new indication

5. ULTOMIRIS® (RAVULIZUMAB-CWVZ)
    a. Previous Indication(s):
        a. Treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)

b. The treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)

b. New indication approved 04/27/2022:
   a. The treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive

- RECOMMENDATION: Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria. Update Soliris policy to require trial and failure of Ultomiris for gMG

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	ULTOMIRIS
MEDICATION NAME	Ultomiris
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent therapy with Soliris® or Empaveli®
REQUIRED MEDICAL INFORMATION	For Generalized **Myasthenia Gravis (gMG)**, all of the following must be met: 1. Anti-acetylcholine receptor (anti-AChR) antibody positive **AND** 2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV **AND** 3. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five **AND** 4. Failed treatment for at least one year with the following: A. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids) **OR** B. ONE immunosuppressive therapy and required at least four infusions/ year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE) **AND** 5. Dose and frequency is in accordance with FDA-approved labeling

	Reauthorization for Myasthenia Gravis (MG): 1. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from baseline. 2. Dose and frequency is in accordance with FDA-approved labeling
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
PRESCRIBER RESTRICTIONS	~~Must be prescribed by or in consultation with a nephrologist, hematologist, or an oncologist,~~ PNH or HUS: Prescribed by an hematologist/oncologist or nephrologist MG or NMOSD: Prescribed by a neurologist
COVERAGE DURATION	Initial authorization for up to three months and reauthorization will be approved for up to one year

6. EVRYSDI® (RISDIPLAM)
   a. Previous Indication(s):
      a. Treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older
   b. New indication approved 05/27/2022:
      a. The treatment of spinal muscular atrophy (SMA) in pediatric and adult patients
   c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. The policy will be updated through its annual review at August 2022 ORPTC.
7. DUPIXENT ® (DUPILUMAB)
   a. Previous Indication(s):
      a. Atopic Dermatitis: for the treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids
      b. Asthma: as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
      c. Chronic Rhinosinusitis with Nasal Polyposis: as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
   b. New indication approved 05/20/2022:
      a. Eosinophilic Esophagitis: for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)
   c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria

<u>Prior Authorization for Commercial/Medicaid:</u>

PA PROGRAM NAME	DUPIXENT
MEDICATION NAME	Dupixent

COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (such as omalizumab, mepolizumab, benralizmab, reslizumab, upadacitinib)
REQUIRED MEDICAL INFORMATION	Eosinophilic Esophagitis (EoE): 1. For initiation of therapy, all the following must be met a. Diagnosis of eosinophilic esophagitis, defined as all of the following: i. Eosinophil-predominant inflammation on esophageal biopsy with ≥15 eosinophils per high power field (HPF) ii. Symptoms of esophageal dysfunction such as dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting b. Patient had an inadequate response to, or has an intolerance or contraindication to all of the following therapies: i. At least 8 weeks of at least one proton pump inhibitor ii. At least one topical glucocorticoid (e.g. fluticasone inhaler, swallowed budesonide) For reauthorization for EoE: documentation of positive clinical response to therapy such as symptom improvement
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
PRESCRIBER RESTRICTIONS	Eosinophilic Esophagitis: Must be prescribed by, or in consultation with, an allergist and/or a gastroenterologist
COVERAGE DURATION	For atopic dermatitis, eosinophilic esophagitis, and chronic rhinosinusitis with nasal polyposis: Initial authorization will be approved for six months. Reauthorization will be approved for one year. For asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	DUPIXENT
MEDICATION NAME	Dupixent
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

PRESCRIBER RESTRICTIONS	For eosinophilic esophagitis: Must be prescribed by, or in consultation with, an allergist or a gastroenterologist.
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
OTHER CRITERIA	For eosinophilic esophagitis (EoE), all of the following: 1. Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF). 2. Symptoms of esophageal dysfunction including dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting. 3. Documented trial and failure, contraindication, or hypersensitivity to both of the following treatment modalities: a. Proton pump inhibitors (e.g. omeprazole, pantoprazole) AND b. Topical glucocorticoids (e.g. fluticasone, budesonide). Reauthorization for EoE: Documentation of response to therapy or disease stabilization.

Therapies with Prior Authorization Policies (Oncology)

8. ENHERTU® (FAM-TRASTUZUMAB DERUXTECAN-NXKI)
    a. New indication(s) approved 05/04/2022:
        a. For adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy
    b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted
9. YERVOY® (IPILIMUMAB)
    a. New indication(s) approved 05/27/2022:
        a. Treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma, as first line treatment in combination with nivolumab
    b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted
10. OBDIVO® (NIVOLUMAB)
    a. New indication(s) approved 05/27/2022:
        a. For patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with ipilimumab
        b. For patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy
    b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted
11. VIDAZA® (AZACITIDINE)

a. New indication(s) approved 05/20/2022:
    a. Pediatric patients aged 1 month and older with newly diagnosed Juvenile Myelomonocytic Leukemia (JMML)
b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted

12. TIBSOVO® (IVOSIDENIB)
    a. New indication(s) approved 05/25/2022:
        a. For the treatment of adult patients with relapsed or refractory AML
    b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted
13. LUPRON DEPOT® (LEUPROLIDE ACETATE)
    a. Previous Indication(s):
        a. Palliative treatment of advanced prostatic cancer
    b. New indication approved 04/18/2022:
        a. Treatment of advanced prostatic cancer
    c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria for this indication is based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted

<u>Therapies Without Prior Authorization Policies</u>

14. ZERBAXA® (CEFTOLOZANE AND TAZOBACTAM)
    a. Previous Indication(s):
        a. For patients 18 years or older for the treatment of the following infections caused by designated susceptible microorganisms:
            1. Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
            2. Complicated Urinary Tract Infections (cUTI), including Pyelonephritis
            3. Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
        b. To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA and other antibacterial drugs, ZERBAXA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria
    b. New indication approved 04/21/2022:
        a. For the treatment of the following infections caused by designated susceptible microorganisms:
            1. Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole, in adult and pediatric patients (birth to less than 18 years old)
            2. Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis, in adult and pediatric patients (birth to less than 18 years old)
            3. Hospital-acquired Bacterial Pneumonia and Ventilator-associated bacterial Pneumonia (HABP/VABP), in adult patients 18 years and older

c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.

15. VEKLURY® (REMDESIVIR)
    a. Previous Indication(s):
        a. For the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are:
            1. Hospitalized, or
            2. Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
    b. New indication(s) approved 04/25/2022:
        a. For the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are:
            1. Hospitalized, or
            2. Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
    c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.
16. QELBREE® (VILOXAZINE EXTENDED-RELEASE CAPSULES)
    a. Previous Indication(s):
        a. Qelbree is a selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age
    b. New indication(s) approved 04/29/2022:
        a. Qelbree is a selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older
    c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.
17. TPOXX® (TECOVIRIMAT)
    a. Previous Indication(s):
        a. For the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg
    b. New indication(s) approved 05/18/2022:
        a. For the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg

Drug Safety Monitoring:

FDA Drug Safety Communications

No drug safety communications to report for this period.

Risk Evaluation and Mitigation Strategy (REMS) Program Modifications

1. **Drug Name:** Bosentan products (including Tracleer)
    - **Date Posted:** 04/29/2022
    - **Link to more information:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/021290Orig1s043,%20209279Orig1s009ltr.pdf
        - https://bosentanremsprogram.com/#Main
    - **What changes to the REMS has the FDA approved?**
        - Addition of the Prescriber Designee role on the REMS website to allow prescribers to delegate certain administrative activities.
        - Changes to the REMS website to allow certified pharmacies to enter testing and counseling information through the REMS website and allow pharmacists requesting a PDA to confirm counseling information.
    - **What should health care professionals do?**
        - Review REMS program changes if prescribing this medication
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Subutex (buprenorphine) sublingual tablets, Suboxone (buprenorphine and naloxone) sublingual tablets and films
    - **Date Posted:** 05/03/2022
    - **Link to more information:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/020732Orig1s026,%20020733Orig1s030,%20022410Orig1s045ltr.pdf
        - https://www.btodrems.com/SitePages/Welcome.aspx
    - **What changes to the REMS has the FDA approved?**
        - These products have joined the Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) Shared System REMS.
        - Each product was previously on a product-specific REMS and is now consolidated into a single REMS.
        - The BTOD REMS uses a shared system for the Medication Guide, elements to assure safe use, an implementation system, and a timetable for assessments of the REMS.
        - The BTOD REMS currently includes the products listed on the FDA REMS website. Other products may be added to the BTOD REMS in the future if additional products are approved.
    - **What should health care professionals do?**
        - Review REMS program changes if prescribing this medication
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert. ‘
3. **Drug Name:** Prolia
    - **Date Posted:** 05/03/2022

- **Link to more information:** https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=43
- **What changes to the REMS has the FDA approved?**
  - Revised the Medication Guide to clarify that Prolia is not approved for use in pediatric patients.
  - **What should health care professionals do?**
  - Review REMS program changes if prescribing this medication
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Accupril (Quinapril HCl) tablets 10mg, 20mg, 40 mg
   - **Date of Recall:** 04/22/2022
   - **Reason for recall:** Presence of a nitrosamine, Nnitroso-quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level in 5 lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuprilr-quinapril-hcl-due-n-nitroso-quinapril-content
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
2. **Drug Name:** Artri Ajo King Joint Supplements
   - **Date of Recall:** 5/28/2022
   - **Reason for recall:** Presence of diclofenac not listed on the product label, all lots recalled
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/walmart-inc-issues-voluntary-nationwide-recall-various-artri-ajo-king-joint-supplements-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
3. **Drug Name:** SyrSpend SF Cherry
   - **Date of Recall:** 05/02/2022
   - **Reason for recall:** Potential contamination with Burkholderia gladioli in two lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fagron-inc-issues-voluntary-nationwide-recall-syrspend-sf-cherry-due-microbial-contamination
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
4. **Drug Name:** Pink Pussycat 3000 mg capsules (dietary supplement)
   - **Date of Recall:** 04/01/2022
   - **Reason for recall:** FDA analysis has found the product Pink Pussycat to be tainted with sildenafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fs-medical-supply-dba-pink-toyz-issues-voluntary-nationwide-recall-pink-pussycat-capsules-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Varenicline tartrate (Tyrvaya) Spray Metr	Correction from April 2022 P&T: • Commercial/Medicaid: Update quantity limit to 8.4 ml per 30 days Effective: 06/01/2022	N/A
Benzoyl Peroxide (Epsolay) Cream	New entity; • Non-formulary for all lines or business	N/A
Dexmedetomidine hcl (Igalmi) Film	New route (sublingual), dosage form (film), and strength (120 mcg, 180 mcg); • Medical Benefit for Commercial, Medicaid, and Medicare Part B. • Medicare Part D: Non-Formulary	N/A
Insulin glargine,human recombinant analog (Insulin Glargine / Insulin Glargine Solostar) Vial/Insuln Pen	New MedID (Lantus vial/Solostar) • Non-formulary for all lines or business	N/A
Baclofen (Lyvispah) Gran Pack	New dosage form (gran pack); • Commercial/Medicaid: Non-Formulary, Quantity Limit (5 mg, 10 mg: 90 for 30 days; 20 mg:120 for 30 days) • Medicare Part D: Non-Formulary	N/A
Metformin hcl Tablet	New strength (650 mg); • 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
Mirtazapine Tablet/Tab Rapdis	Increase tier for Commercial; • Commercial Standard: Change from Tier 1 to Tier 2 • Commercial Cost-Based: Change from Tier 2 to Tier 3 Effective 11/01/2022	N/A
Clonidine hcl (Nexiclon XR) Tab ER	• 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

Amlodipine besylate (Norliqva) Solution	New Dosage Form (solution) and strength (1mg/ml); • Non-formulary for all lines of business	N/A
Edaravone (Radicava Ors) Oral Susp	New route (oral), dosage form (oral susp), and strength (105mg/5ml); • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (50 ml per 28 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (50 ml per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (50 ml per 28 days)	Radicava
Torsemide (Soaanz) Tablet	New brand: Non-formulary for all lines of business	N/A
Trandolapril 2 mg, 4 mg Tablets	Add to Medicaid formulary	N/A
Valsartan Solution	New dosage form (solution) and strength (4mg/ml); • Non-formulary for all lines of business	
Cyclosporine (Verkazia) Droperette	New strength (0.1%); • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Verkazia • Medicare Part D: N/A
Morphine Sulfate (Avinza) CPMP 24HR	Remove from Commercial formulary	New Medications and Formulations without Established Benefit
Methylphenidate hcl (Concerta) Tab ER 24	Add generic to Medicaid formulary	Long-Acting Stimulant Medications - Medicaid
Diclofenac Epolamine (Flector) Adh. Patch	Remove from Commercial Formulary	N/A
Gabapentin Enacarbil (Horizant) Tablet SR	Remove from Commercial Formulary	N/A
Morphine Sulfate (Kadian) Cap ER Pel	Remove from Long Acting Opioids policy and add to New Medications and	New Medications and Formulations without Established Benefit

	Formulations without Established Benefit policy	
Dextromethorphan hbr/quinidine (Nuedexta) Capsule	Remove from Medicaid formulary	Nuedexta
Oxymorphone hcl (Opana) Tablet	Remove from Commercial and Medicaid formulary	N/A
Atogepant (Qulipta) Tablet	• Commercial: Add to Formulary, Tier 3	Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists
Lisdexamfetamine dimesylate (Vyvanse) Tab Chew	Add to Medicaid formulary	Long-Acting Stimulant Medications – Medicaid
Tetrabenazine Tablet	Down tier; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4	VMAT2 Inhibitors
Tramadol hcl 100 mg Tablet	Add Quantity Limit (4 tablets per day) to all lines of business	Pediatric Analgesics
Nucynta (tapentadol) tablets	Remove from Commercial and Medicaid formularies	N/A
Ruzurgi (amifampridine) 10 mg tablet	Obsolete drug without utilization: Remove from formulary for all lines of business	N/A
Fentanyl transdermal 37.5, 62.5, and 87.5 mcg patch	Add prior authorization for Commercial and Medicaid formularies	New Medications and Formulations without Established Benefit
Imbruvica (ibrutinib) 140 and 280 mf tablet	Remove from Commercial and Medicaid Formularies and require use of 140 mg capsules.	Oral Anti-Cancer Agents

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

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Bupivacaine (Posimir) Vial	New strength (660mg/5ml). Line extend with Zynrelef;	N/A

	• Medical Benefit for Commercial, Medicaid, and Medicare Part B. • Medicare Part D: Non-Formulary	
Measles, Mumps, and Rubella vaccine live/PF (Priorix) Vial	New formulation; Vaccine. Line extend with M-M-R II; • Commercial: Preventive • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Tick-Borne Encephalitis Vaccine (Ticovac) Syringe	New strength (1.2mcg/ml). Line extend with Ticovac 2.4mcg/ml; • Medical benefit for all lines of business	N/A
Mepolizumab (Nucala) Syringe	New strength (40mg/0.4ml); Line extend with Nucala; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.4 ml per 28 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (0.4 ml per 28 days)	Il-5 Inhibitors
Bevacizumab-maly (Alymsys) Vial	Biosimilar to Avastin. Line extend with Avastin; • Commercial/Medicaid: Specialty, Medical Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Prior Authorization, Step Therapy	• Commercial/Medicaid: Injectable Anti-Cancer Medications • Medicare Part B: Injectable Anti-Cancer Medications - Medicare Part B
Risankizumab-rzaa (Skyrizi) Vial	New dosage form (vial) and strength (600mg/10ml). Line extend with Stelara; • Medical Benefit, with Prior Authorization for Commercial, Medicaid, Medicare Part B • Medicare Part D: Non-Formulary	• Commercial: Medically Infused Therapeutic Immunomodulators (Tims) • Medicaid: Therapeutic Immunomodulators (TIMS) – Medicaid • Medicare Part B: Medically Infused Therapeutic Immunomodulators (TIMs) - Medicare Part B

New Generics:

Drug Name	Action Taken	Policy Name
Bortezomib Vial	First generic (Velcade). Line extend as generic; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization	Injectable Anti-Cancer Medications
Levamlodipine maleate Tablet	Marketed under NDA (Conjupri). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Varenicline tartrate (Varenicline) Tab DS PK	First generic (Chantix – Starting pack). Line extend as generic; • Commercial: Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Pirfenidone Tablet	First generic (Esbriet). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Esbriet, Ofev
Diclofenac sodium SOL MD PMP	First generic (Pennsaid). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Mesalamine (Mesalamine ER) Capsule ER	First generic (Pentasa). Line extend as generic; • Commercial Standard: Formulary, Tier 2	N/A

	• Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 5	
Fluticasone Propionate (Fluticasone Propionate HFA) AER W/ADAP	Authorized Generic (Flovent HFA); Remove generic coverage from Commercial and Medicare; • Commercial/Medicare Part D: Non-Formulary • Medicaid: Formulary	N/A
Pemetrexed disodium Vial	First generic (Alimta). Line extend as generic; • Medical Benefit for Commercial, Medicaid, and Medicare Part B. • Medicare Part D: Non-Formulary	N/A
Varenicline tartrate (Varenicline) Tab DS PK	First generic (Chantix – Starting pack). Line extend as generic; • Commercial: Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Vilazodone hcl Tablet	First generic (Viibryd). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost-Based: Formulary, Tier 4, Step Therapy • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Step Therapy	Commercial/Medicare Part D: Antidepressants Step Therapy Medicaid: N/A
Lacosamide Solution	First generic (Vimpat soln). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Formulary	• Commercial/Medicaid: N/A • Medicare Part D: Antiepileptic Agents

	• Medicare Part D: Formulary, Tier 4, Step Therapy	
Bexarotene Gram	First generic (Targretin). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Sorafenib Tosylat (Sorafenib) Tablet	First generic (Nexavar). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications

Clinical Policy Changes:

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Addyi	Policy reviewed without minor updates to the diagnosis criteria (added ICD-10 code for reference and removed language regarding distress and inter-personal difficulty to ease administration).
Amifampridine	• Ruzurgi is no longer available on the market due to litigation so it will be removed from the policy. • For Firdapse, remove requirements for trial of pyridostigmine (not first-line) and Ruzurgi®. Added exclusion criteria for patients with history of seizures (contraindication per package insert).
Antidepressants Step Therapy	Updated required information to include criteria for patients already established on therapy.
Antiepileptic Medications Step Therapy	Removed Vimpat from policy due to low-cost generic availability.
Antipsychotics Step Therapy	Updated required information to include criteria for patients already established on therapy.
Botulinum Toxin - Medicare Part B	Policy format was updated to reference the local coverage determination (LCD) for Medicare. This criteria is required to be used for all requests.

Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists	The newest agent in this class, Quilipta®, was added as a preferred agent for migraine prophylaxis. Additionally, quantity limits will be added to all prophylactic agents to ensure appropriate use.
Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists - Medicaid	Updated criteria to align with oregon health Auhtority criteria. Trial of two triptans (instead of three) will be required for acute CGRP agents.
Corlanor	Prior authorization policy criteria has been updated to include trial and failure of sodium-glucose cotransporter-2 inhibitors (SGLT-2 inhibitors) as SGLT-2 inhibitors are now recommended for heart failure for quadruple therapy by the newly updated heart failure guideline.
Diacomit	Added hematologic monitoring to required medical information.
Evrysdi	• Updated to allow for coverage of presymptomatic spinal muscular atrophy (SMA) and removed age restriction to align with new FDA labeling. This comes from preliminary efficacy and safety data from the RAINBOWFISH trial (presymptomatic SMA infants from birth to six weeks). Moved tracheostomy or invasive ventilator support to exclusion criteria.
Extavia	• Added criteria for patients already established on therapy. • Added Mavenclad and Kesimpta as preferred agents. • Clarified trial and failure requirements and added trial time frame of at least six months.
Fintepla	• Added age restriction of two years or older per FDA labelling.
Hetlioz, Hetlioz LQ	• Changed melatonin trial and failure requirement from am to pm.
IL-5 Inhibitors	• Updated eosinophilic asthma criteria to align with dupilumab (Dupixent)
Lemtrada **Lemtrada - Medicare Part B**	• Update coverage duration to allow for treatment courses beyond two years to reflect FDA labeling.
Long-Acting Opioids	• Criteria were updated to strengthen requirements and provide more clarification for reviewers. Criteria is more heavily focused on the initiation of new long-acting opioid therapy. • Avinza® and Kadian® were removed from this policy and added to the "New Medications and Formulations without Established Benefit" policy as there is no advantage of these formulations over generic morphine sulfate ER. • Nucynta ER®, methadone and fentanyl patch were added to this policy and will required prior authorization for new starts.
Mavenclad	• Added pathway to allow for coverage for highly active disease without meeting specific drug trial and failure requirements. This aligns with recommendations from National Institute for Health and Care Excellence guidance on cladribine.

	• Updated prerequisites to include previous use of any three MS treatment drugs or one of the preferred generics.
Maximum Allowable Opioid Dose – Comm	• Criteria were updated to strengthen requirements and provide more clarification for reviewers. Criteria is more heavily focused on the initiation of new opioid therapy above 90 MME.
Narcolepsy Agents	• Removed criteria for a cerebrospinal fluid (CSF) assay for Type 2 narcolepsy
Non-Preferred Fumarate Products	• Removed criteria allowing for coverage of non-preferred fumarates after therapeutic failure of generic dimethyl fumarate as all drugs have same active metabolite (only criterion is unmanageable side effects or allergy to excipients in all generic dimethyl fumarate products). • Specified that an attempt to manage common side effects of dimethyl fumarate needs to be done. • Added criteria to allow for coverage for patients already established on the medication
Nuedexta	• Retired from Medicaid prior authorization policy as diagnosis of pseudobulbar affect is not a funded condition by Oregon Health Authority. No other significant changes made to Commercial prior authorization policy.
Nuplazid	• Removed specific SLUMS and MMSE requirements
Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors **Ophthalmic VEGF Inhibitors - Medicare Part B**	• Clarified requirements for trial of preferred agents from previous review.
PCSK9 Inhibitors - Medicare Part B	• Exclusion criteria updated to exclude diagnosis not covered by FDA approval and provider restrictions removed.
Qudexy XR, Trokendi XR – Medicaid	• Criteria updated to align with Medicaid PA criteria - drugs are covered without prerequisites for epilepsy and migraine prevention, drugs are covered off-label in bipolar affective disorder or schizoaffective disorder after trying two formulary drugs.
Radicava	• A new oral formulation of edaravone was recently approved by the FDA and is being added to this policy.
Rescue Medications for Epilepsy	• Increased the quantity limit for Commercial and Medicaid to FDA max.
Savella	• Quantity limit was updated for Savella titration pack from one pack (55 tablets) per 28 days to one pack (55 tablets) per 365 days.

SGLT-2 Inhibitors - Medicaid	• Prior authorization policy criteria have been updated to include trial and failure of sodium-glucose cotransporter-2 inhibitors (SGLT-2 inhibitors) as SGLT-2 inhibitors are now recommended for heart failure for quadruple therapy by the newly updated heart failure guideline.
Tysabri **Tysabri – Medicare Part B**	• Updated preferred infliximab products under trial and failure requirements in Crohn's disease.
Verkazia	• New policy
Verquvo	• Prior authorization policy criteria has been updated to include trial and failure of sodium-glucose cotransporter-2 inhibitors (SGLT-2 inhibitors) as SGLT-2 inhibitors are now recommended for heart failure for quadruple therapy by the newly updated heart failure guideline.
VMAT2 Inhibitors	• Defined moderate to severe tardive dyskinesia
Vyepti - Medicare Part B	• Updated list of preferred CGRPs.
Weight Management Medications	• New policy. Policy will apply only to those members with a weight loss benefit. Preferred products subject to criteria will be: phentermine/topiramate (Qsymia®), liraglutide (Saxenda®), and semaglutide (Wegovy®).
Zeposia - Medicaid	• Updated preferred therapies outlined for ulcerative colitis to match Medicaid preferred products (adalimumab, infliximab biosimilars, and vedolizumab).

RETIRED POLICIES	
Buprenorphine	Due to low risk for overutilization and regulatory requirements
Flector Patch Step Therapy Policy	Drug will be non-formulary
Horizant	Drug will be non-formulary
Long-Acting Opioids – Medicaid	Combined with commercial Long-Acting Opioids policy
Nucynta ER	Combined with commercial Long-Acting Opioids policy
Maximum Allowable Opioid Dose – Medicaid	Combined with Commercial Maximum Allowable Opioid Dose policy
Nucynta	Due to low risk of inappropriate utilization as this drug will be non-formulary and has had very few requests for authorization
Oxaydo	Due to low risk of inappropriate utilization as this drug remains non-formulary with very few requests for authorization
Oxymorphone	Low risk of inappropriate utilization as this drug will be non-formulary and has had very few requests for authorization

Parenteral Antibiotic Use in the Treatment of Lyme Disease	N/A