Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 85

August 1, 2023

This is the August 1, 2023 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.

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 8/1/2023

Deep Brain and Responsive Cortical Stimulation **MP100**	**Policy Updates:** Remove documentation requirement for quantifiable testing for essential tremor. **Codes/PA:** No change to codes or configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Organ Transplantation MP159	**Policy Updates:** Liberalize criterion VIII.B. to allow for any kind of insulin-dependent diabetes SPK transplant. **Codes/PA:** No change to codes or configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Fecal Incontinence Treatments **MP103**	**Policy Updates:** • Add L9900- as no PA. Added note to billing guideline as not separately reimbursable as considered a bundled item or service (even if billed alone). • Manual Pump Enema System/Transanal irrigation (i.e. Peristeen Plus) addressed specifically as not covered in criteria. (This was already denying as NMN) **Codes/PA:** • L9900 added as no PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 10/1/2023

Urinary Incontinence Treatments **MP180**	**Policy Updates:** Changing denial type from investigational to not medically necessary. **Codes/PA:** One code (L9900) added to policy per coding review. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms **MP313**	**Policy Updates:** Changing denial type from investigational to not medically necessary. **Codes/PA:** CRFs are being requested to change configuration to NMN: • **0029U** (*currently pays without review)* • **0030U** (*currently pays without review)* • **0031U** (*currently denies INV)* • **0345U** (*currently denies INV)* **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Low-Level and High-Power Laser Therapy **MP201**	**Policy Updates:** Changing denial type from investigational to not medically necessary. **Codes/PA:** Change denial from INV to NMN (0552T and S8948**).** **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Pelvic Congestion Syndrome Treatment **MP174**	**Policy Updates:** Change denial language from investigational to not medically necessary. Separating out Medicare lines of business. **Codes/PA:** Change denial type from INV to NMN if billed with one of the dx codes listed: I86.2, I87.2, N94.89, R10.2. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Platelet-Rich Plasma (PRP) for Orthopedic Indications, Wound Care and Other Miscellaneous Conditions **MP249**	**Policy Updates:** Change denial language from investigational to not medically necessary. **Codes/PA:** Change denial for the following codes from investigational to not medically necessary: G0460, 0232T, P9020, G0465 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Proton Beam Radiation Therapy	**Policy Updates:** Change denial language in criterion III to not medically necessary. **Codes/PA:** No changes to coding or PA.

MP167	**OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Diagnostic Evaluation of Interstitial Lung Disease **MP178**	**Policy Updates:** Changing denial type from investigational to not medically necessary. **Codes/PA:** Change denial from INV to NMN (81554). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Tumor Treatment Fields Therapy for Glioblastoma **MP173**	**Policy Updates:** • Change tumor treatment field therapy for recurrent glioblastoma from investigational to not medically necessary when medically necessity criteria are not met. • Formatting updates **Codes/PA:** None **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Maturity-Onset Diabetes of the Young **MP396**	**Policy Updates:** New policy with medical necessity criteria **Codes/PA:** Several codes added to policy, all of which already require PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies **MP237**	**Policy Updates:** Clarify in criterion that non-covered antibody serum levels performed as part of a panel include tests which measure serum biologic levels. **Codes/PA:** No coding changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Gastric Electrical Stimulation **MP107** *Formerly all lines of business*	**Policy Updates:** • Separate by line of business. • Update investigational denial to not medically necessary. • Inclusion of language for change out of dead battery/nonfunctional device. • Removal of E0765 (ReliefBand)- removal from policy and remove PA, allow to pay per member benefits. **Codes/PA:** E0765- remove relationship to policy and PA; allow to pay per member benefits. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Hyperbaric Oxygen Therapy **MP204**	**Policy Updates:** • Update investigational noncoverage to not medically necessary when medically necessity criteria are not met. • Added frostbite under NMN indications. **Codes/PA:** No changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed

MEDICARE

Effective 10/1/23

Low-Level and High-Power Laser Therapy **MP338**	**Policy Updates:** No change to criteria, continue to use Company criteria. The Company policy criteria changing from investigational to not medically necessary changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration.
Pelvic Congestion Syndrome Treatment **MP397**	**Policy Update:** New Medicare Advantage medical policy, separating by line of business. No change to criteria, continue to use Company criteria. **Codes/PA:** No changes to codes or configuration.
Proton Beam Radiation Therapy **MP340**	**Policy Update:** No change to criteria, but minor updates made to the "Billing Guidelines" section. The Company policy criteria changing from investigational to not medically necessary changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration.
Urinary Incontinence Treatments **MP231**	**Policy Update:** No change to criteria. The Company policy criteria changing from investigational to not medically necessary. changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration.

Electrical Stimulation and Electromagnetic Therapies **MP333**	**Policy Update:** No change to criteria already in the policy criteria table; however, for any service that uses the Company *Electrical Stimulation: Non-Covered Therapies* policy, with this policy's criteria changing from investigational to not medically necessary, it changes some of the generic language found in the Medicare version. • Add row to criteria table for gastric electrical stimulation (GES) to the criteria table. The Company policy criteria is changing from investigational to not medically necessary for GES. • Add row to criteria table for transcutaneous electrical acupoint stimulation (TEAS) devices used for treatment of nausea and vomiting (aka, electrical acustimulation; formerly in the GES policy). • Add row to criteria table for transcutaneous electrical nerve stimulator, distal wrist nerves (e.g., Nerivio™ device) (The code used to represent this product is K1023, which is already in the policy with correct configuration). **Codes/PA:** • Add the codes related to gastric electrical stimulation (43647, 43648, 43659, 43881, 43882, 43999, 95980, 95981, and 95982) to this overarching electrical stimulation policy, but no change to the configuration for any of these codes. • Add HCPCS E0765 to this policy (this code was also in the GES policy, but it represents a different type of therapy). Remove PA and add NMN denial edit • No change to the codes currently in the policy.

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REIMBURSEMENT POLICIES

Effective 8/1/2023

Observation Status **RP69**	**Interim Update** **Recommendation:** Claims for observation services (OBS) are reviewed when they exceed a set number of hours. This policy is being updated to support appropriate denials when needed. Recommend the following updates to the policy: • Updated policy number from **UM**69 to **RP**69 • Clarify that while we use InterQual® as the primary base for criteria, we also apply individual clinician discretion as well, which requires taking into account the unique clinical situation for the individual member. This means on rare occasion, even if a member doesn't meet InterQual® criteria for an OBS stay or an inpatient admission, we have discretion to allow. • Add language that hospital claims ≥2 midnights do not automatically guarantee payment at an inpatient level of care; medical necessity requirements must still be met in order to be eligible for reimbursement at an inpatient level of care. • Add scenarios to list of non-eligible observation situations (not meant to change intent, only meant as examples). • Expand on the "Centers for Medicare and Medicaid Services (CMS)" section of the policy, including Oregon Health Plan (OHP) guidelines. • Add language about social or convenience considerations. • Update "Billing and Coding Guidelines" section to further detail CMS billing rules for changing the bill type after a patient has been discharged. However, no change to intent of this section. • Update and expand references. **Reimbursement Methodology:** No changes to reimbursement methodology. Currently OBS services are reviewed for medical necessity after 48 (Commercial) or 96 hours (Medicare). For OHP, observation care over 48 hours is generally billed as inpatient claim per the OAR. *NOTE: There is no change to reimbursement methodology with this interim update. However, potential changes to workflow are being considered, including when and how to continue to review Observation Care services.* **Plan Survey:** Review of other plans with a reimbursement or payment policy regarding observation services were consistent with their use of CMS guidelines, as well as including a 48-hour limit of observation service coverage. **Relevant References/CMS Guidance:** • Medicare Benefit Policy Manual, Chapter 6 - Hospital Services Covered Under Part B, §20.6 - Outpatient Observation Services, "A. Outpatient Observation Services Defined https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf • Medicare Claims Processing Manual, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS), §290.1 - Observation Services Overview https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf

	• Medicare Program Integrity Manual, Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services, §6.5.2 - Conducting Patient Status Reviews of Claims for Medicare Part A Payment for Inpatient Hospital Admissions, A. Determining the Appropriateness of Part A Payment https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf • Noridian web page for *Inpatient to Outpatient Status Change*; Available at: https://med.noridianmedicare.com/web/jfa/topics/observation/inpatient-to-outpatient-status. • Centers for Medicare & Medicaid Services. CMS Medicare Benefit Policy 100-02; Transmittal 42; Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r42bp.pdf. • Oregon Health Authority (OHA). Health Systems Division: Medical Assistance Programs - Chapter 410. Division 125 HOSPITAL SERVICES. 410-125-0360. Definitions and Billing Requirements; Available at: https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=84940
Preventable Adverse Events **RP73**	**Annual Update** **Recommendation:** • Updated policy number from **UM**73 to **RP**73 • Updated language to include name of serious reportable event (SRE)- usually referred to as "never event". "Never event" language also remains. • Updated list of Never Events/SREs as defined by National Quality Forum (NQF) & CMS- several added, please see policy. **Codes/PA:** None

Medicare Echo Scans and Nuclear Medicine

Effective 8/1/2023, for <u>Medicare only</u>, the below services no longer require prior authorization through Carelon:

Nuclear Cardiology	CPT
Myocardial Perfusion Imaging	78451 78452 78453 78454
Infarct Imaging	78466 78468 78469
Cardiac Blood Pool Imaging	78472 78473 78481 78483 78494

Cardiac Services	CPT
Stress Echo (SE)	93350 93351
Resting Trans Echo (TTE)	93303 93304 93306 93307 93308
Transesophageal Echo (TEE)	93312 93313 93314 93315 93316 93317

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Providence Health Assurance

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting June 2, 2023
Go-Live Date: Wednesday, August 02, 2023, unless otherwise noted

Table of Contents:

New Drugs or Combinations:

1. **Tremelimumab-actl (Imjudo) Vial**
    a. **Indication**:
        1. In combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC)
        2. In combination with durvalumab and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small-cell lung cancer (NSCLC) with no sensitizing EGFR mutations or ALK genomic tumor aberrations
    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: HCC: atezolizumab (Tecentriq®) + bevacizumab (Zirabev®, Mvasi®) NSCLC: First line- pembrolizumab (Keytruda®), alternative therapies: nivolumab (Opdivo®)/ipilimumab (Yervoy®), cemiplimab-rwlc (Libtayo®)			

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

2. **Elacestrant hydrochloride (Orserdu) Tablet**
   a. **Indication**: For the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.
   b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
* 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**: Added to Oral Anti-Cancer Medications Policy
d. **Prior Authorization Criteria for Medicare Part D**: Added to Anti-Cancer Agents Program

3. **Velmanase alfa-tycv (Lamzede) Vial**
   a. **Indication**: For the treatment of non-CNS manifestations of alpha-mannosidosis in adults and pediatric patients.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	Choose an item.
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: None			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to Enzyme Replacement Therapy Policy

PA PROGRAM NAME	Enzyme Replacement Therapy
MEDICATION NAME	Velmanase alfa-tycv vial (Lamzede®)
REQUIRED MEDICAL INFORMATION	For initial authorization all the following must be met:

	1. Documentation of FDA-labeled indication for the requested product **AND** 2. Dosing is within FDA-labeled guidelines 3. For velmanase alpha only, the following additional criteria apply: a. Confirmed diagnosis of alpha-mannosidosis as defined by alpha-mannosidase activity less than 10% of normal activity in blood leukocytes b. Documented baseline serum oligosaccharide level c. Documented baseline value of either 6-minute walk test, 3-minute stair climb or forced vital capacity. Note: This may be waved for children under the age of three. Improvement or stabilization is required for reauthorization. d. Therapy is being used to treat non-central nervous system manifestations of alpha mannosidosis such as skeletal abnormalities, myopathy, motor function disturbances, immune deficiency e. No prior history of bone marrow transplant Note: If request is for a non-FDA approved dose, medical rationale must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis. **REAUTHORIZATION:** Both of the following must be met: 1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms). 2. Dosing is within FDA-labeled guidelines 3. For velmanase alpha only, a. For initial reauthorization: a decrease of serum oligosaccharides of 3 micromoles per liter or at least 30% b. For subsequent reauthorizations: stabilization or improvement in either the 6-minute walk test, 3-minute stair climb or forced vital capacity Note: If request is for a non-FDA approved dose, medical rationale must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis.
COVERAGE DURATION	Initial and reauthorization will be approved for one year.

4. **Omaveloxolone (Skyclarys) Capsule**
    a. **Indication**: For treatment of Friedreich's ataxia.
    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			
* 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**: Add to Medications For Rare Indications Policy

5. **Trofinetide (Daybue) Solution**
    a. **Indication**: For the treatment of Rett syndrome (RTT) in adults and pediatric patients 2 years of age and older.
    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	No	N/A	N/A

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

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	trofinetide oral solution (Daybue®)
COVERAGE DURATION	For Nulibry®: Initial authorization will be approved for three months. Reauthorization will be approved for 12 months. For Daybue®: Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months. For all other medications: Initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

New Drug Strengths or Formulations:

1. **Pegcetacoplan-PF (Syfovre) Vial**
   a. **Indication:** For the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
   b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization

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

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

PA PROGRAM NAME	Syfovre
MEDICATION NAME	Pegcetacoplan-pf vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• History of or active choroidal neovascularization (CNV), associated with AMD or any other cause • History of ocular or periocular infections • History of endophthalmitis, retinal detachments, or increased intraocular pressure
REQUIRED MEDICAL INFORMATION	For initial authorization, all of the following criteria must be met: 1. Documentation of diagnosis of geographic atrophy (GA) confirmed by clinical exam or diagnostic imaging (such as Color Fundus Photography, Fundus Autofluorescence, Near Infrared Reflectance Imaging, Optical Coherence Tomography) 2. Documentation that GA is secondary to age-related macular degeneration (AMD) For reauthorization: Documentation of response to therapy defined as one of the following: 1. Reduction in GA growth lesion 2. Documentation of improvement in visual function through visual function assessment test (such as normal luminance best-correct visual acuity [BCVA], maximum reading speed, Functional Reading Independence Index, microperimetry)
AGE RESTRICTIONS	Age equal to or greater than 60 years of age.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an ophthalmologist.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

New Indications Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 2/1/2023– 3/31/2023

Therapies with Prior Authorization Policies (Non-oncology)

1. **Synjardy (**empagliflozin and metformin hydrochloride)
    a. Previous Indication(s):
        a. Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
        b. Reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
    b. New indication approved 02/06/2023:
        a. In adults with type 2 diabetes mellitus to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Medicaid policy with indication.

2. **Kevzara** (sarilumab)
    a. Previous Indication(s):
        a. Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
    b. New indication approved 02/28/2023:
        a. Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.
        Prior Authorization for Commercial/Medicaid:
        (Note: PMR is on line 106 on the current OHP Prioritized List and is a coverable diagnosis without disease severity requirements)

PA PROGRAM NAME	THERAPEUTIC IMMUNOMODULATORS (TIMs)
MEDICATION NAME	Kevzara (sarilumab)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Combination therapy with another therapeutic immunomodulator (TIM) agent
REQUIRED MEDICAL INFORMATION	For polymyalgia rheumatica (PMR), sarilumab (Kevzara®) may be covered if the following criteria are met: 1. Diagnosis of PMR and documentation of the following:

	• Age 50 years or older at disease onset AND
	• One of the following:
	  ○ Bilateral shoulder or pelvic aching or stiffness lasting longer than 45 minutes and persisting for at least two weeks OR
	  ○ If younger than 50 years of age and having asymmetric shoulder or pelvic pain, documentation of PMR with atypical features
	2. Documentation that similar disorders have been ruled out (such as giant cell arteritis rheumatoid arthritis, drug-induced maylgias, fibromyalgia, other muscoloskeletal disease, or other bone disease).
	3. One of the following:
	• Indadequate response to full dose systemic systemic corticosteroid
	• Documented PMR flare while attempting to taper systemic corticosteroid
	• Intolerance or contraindication to systemic corticosteroids

AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, juvenile idiopathic arthritis, polymyalgia rheumatica: must be prescribed by, or in consultation with, a rheumatologist
COVERAGE DURATION	• Prior Authorization: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes • Quantity Limitation: Initial authorization will be approved for six months, and reauthorization will be approved for one year. FDA-labeled dosing will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

3. **Eylea** (Aflibercept)
    a. Previous Indication(s):
        a. treatment of patients with:
            1. Neovascular (Wet) Age-Related Macular Degeneration (AMD)
            2. Macular Edema Following Retinal Vein Occlusion (RVO)
            3. Diabetic Macular Edema (DME)
            4. Diabetic Retinopathy (DR)
    b. New indication approved 02/08/2023:
        a. Retinopathy of Prematurity (ROP)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. This drug is ophthalmic vascular endothelial growth factor (VEGF) inhibitors policy was updated as part of annual review and is included in the policy review section of the consent agenda vote.

4. **Evkeeza** (evinacumab-dgnb)
    a. Previous Indication(s):
        i. Adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH) (DR)
    b. New indication approved 03/21/2023:
        a. Adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

Therapies with Prior Authorization Policies (Oncology)

5. **Verzenio (**abemaciclib)
    a. New indication(s) approved 03/03/2023:
        a. In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence. (Requirement of a Ki-67 score ≥20% as determined by an FDA approved test is no longer a part of the indication)
        b. in combination with an aromatase inhibitor as initial endocrine based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. (Indication previously was limited to men and postmenopausal women)
    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.
6. **Tafinlar (**dabrafenib)
    a. New indication(s) approved 03/16/2023:
        a. Treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic 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.
7. **Mekinist (**tramitinib)
    a. New indication(s) approved 03/16/2023:

    a. Treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic 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.
8. **Lutrate Depot** (leuprolide acetate)
  a. Previous Indication(s):
    a. Palliative treatment of advanced prostate cancer
  b. New indication approved 02/06/2023:
    a. Treatment of advanced prostate cancer.
  c. **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. Update policy with indication.
9. **Keytruda** (pembrolizumab)
  a. Full indication approved 03/28/2023:
    a. For the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options
  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. **Jemperli** (pembrolizumab)
  a. Full indication approved 02/09/2023:
    a. Treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or PD-1/PD-L1–blocking antibody radiation
  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. **Obdivo** (nivolumab)
  a. Full indication approved 02/15/2023:
    a. adult and pediatric (12 years and older) patients with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab.

   b. adult and pediatric (12 years and older) patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting
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. **Yervoy** (ipilimumab)
    a. Full indication approved 02/15/2023:
       a. Adult and pediatric (12 years and older) patients with unresectable or metastatic melanoma, as a single agent or 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.

Therapies Without Prior Authorization Policies

13. **Illuccix** (kit for the preparation of gallium Ga 68 gozetotide injection)
    a. Previous Indication(s):
       a. LLUCCIX, after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:
       b. with suspected metastasis who are candidates for initial definitive therapy.
       c. with suspected recurrence based on elevated serum prostate specific antigen (PSA) level indication
    b. New indication(s) approved 03/15/2023:
       a. For selection of patients with metastatic prostate cancer, for whom
       b. lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database from 2/1/2023– 3/31/2023

FDA Drug Safety Communications

There were no drug safety communications reported during this period.

Drug Recalls/Market Withdrawals

1. **Drug Name:** TIROSINT®-SOL (levothyroxine sodium)
   - **Date of Recall**: 02/01/2023
   - **Reason for recall:** Possible sub potency in 27 lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ibsa-pharma-inc-issues-voluntary-nationwide-recall-select-lots-tirosintr-sol-levothyroxine-sodium
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Artificial Tears Lubricant Eye Drops from EzriCare & Delsam Pharma
   - **Date of Recall:** 02/02/2023
   - **Reason for recall:** Potential microbial contamination in all lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/global-pharma-healthcare-issues-voluntary-nationwide-recall-artificial-tears-lubricant-eye-drops-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert**.**

3. **Drug Name:** PrimeZEN Black 6000 male enhancement capsules
   - **Date of Recall:** 02/13/2023
   - **Reason for recall:** Product contains undeclared tadalafil and sildenafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/volt-candy-issues-voluntary-nationwide-recall-primezen-black-6000-capsules-due-presence-sildenafil
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Artificial Eye Ointment from Delsam Pharma
   - **Date of Recall:** 02/24/2023
   - **Reason for recall:** Potential microbial contamination of batch
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/global-pharma-healthcare-issues-voluntary-nationwide-recall-delsam-pharma-artificial-eye-ointment
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Brimonidine Tartrate Ophthalmic Solution, 0.15%
   - **Date of Recall:** 03/02/2023

- **Reason for recall:** Potential lack of sterility due to cracked lids in six lots
- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-brimonidine-tartrate-ophthalmic-solution-015-due
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert**.**

6. **Drug Name:** 15% MSM Drops
   - **Date of Recall:** 03/03/2023
   - **Reason for recall:** Non-sterility in two lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pharmedica-usa-llc-issues-voluntary-worldwide-recall-purely-soothing-15-msm-drops-due-non-sterility
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

7. **Drug Name:** Dabigatran Etexilate Capsules, USP
   - **Date of Recall:** 03/22/2023
   - **Reason for recall:** Detection of N-nitroso-dabigatran (NDAB) impurity in multiple lots
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

8. **Drug Name:** Atovaquone Oral Suspension
   - **Date of Recall:** 03/31/2023
   - **Reason for recall:** Potential Bacillus cereus contamination of one lot
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
• **Codeine phosphate/guaifenesin (Guaifenesin AC) 10-100mg/5 Liquid**	Remove from Commercial formulary Effective 11/01/2023	N/A

• **Codeine Phosphate/Guaifenesin (Guaifenesin-Codeine) 10-100mg/5; 20-200/10 Liquid**		
Naloxone hcl (Kloxxado) Spray	• Commercial: Move to Tier 4 • Medicaid: Remove from formulary Effective 09/01/2023	N/A
Omeprazole/sodium bicarbonate (Konvomep) Susp Recon	New dosage form (susp recon) and strength (2-84mg/ml); • 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
Mifepristone 200 mg Tablet	• Commercial/Medicaid: Non-formulary, Prior Authorization	Mifepristone
Naloxone hcl (Narcan) Spray	• Commercial: Move brand to Tier 4 • Medicare Part D: Down tier generic to Tier 2	N/A
Dabigatran etexilate mesylate (Pradaxa) Pellet Pack	New Dosage Form (Pellet Pack) and Strength; • Commercial/Medicaid: Non-Formulary, Quantity Limit (2 packs per day) • Medicare Part D: Non-Formulary	N/A
Ropinirole ER 2 mg Tab ER 24H	• Commercial: Add Quantity Limit (1 tab per day) Effective 09/01/2023	N/A
Ropinirole ER Tab ER 24H (4 mg, 6 mg)	• Commercial Standard: Add to Formulary, Tier 2, Quantity Limit (1 tab per day) • Commercial Dynamic: Add to Formulary, Tier 3, Quantity Limit (1 tab per day) • Medicaid: Add to Formulary, Quantity Limit (1 tab per day) Effective 09/01/2023	N/A
Ropinirole ER Tab ER 24H (8 mg, 12 mg)	• Commercial Standard: Add to Formulary, Tier 2, Quantity Limit (2 tabs per day) • Commercial Dynamic: Add to Formulary, Tier 3, Quantity Limit (2 tabs per day)	N/A

	• Medicaid: Add to Formulary, Quantity Limit (2 tabs per day) Effective 09/01/2023	
Pseudoephed/codeine/guaifen (Virtussin Dac) Syrup	Remove from Commercial formulary	N/A
Naloxone hcl (Zimh) Syringe	• Commercial: Move brand to Tier 4 • Medicaid: Remove from Formulary Effective 09/01/2023	N/A
Dapsone (Aczone) Gel (Gram)/Gel w/Pump	Commercial: Add to Formulary, Tier 4	N/A
Ipratropium bromide (Atrovent) Spray	Remove from Medicaid formulary	Intranasal Allergy Medications – Medicaid
Epinephrine (Auvi-Q) Auto Injct	Remove from Commercial and Medicaid formularies Effective 09/01/2023	N/A
Roflumilast (Daliresp) Tablet	• Commercial Dynamic formulary: Down tier generic to Tier 3, add Quantity Limit (1 tablet per day) • Medicaid: Add Quantity Limit (1 tablet per day) Effective 09/01/2023	N/A
Erythromycin/benzoyl peroxide 3%/5% Gel	Add to Medicaid formulary	Acne Medications – Medicaid
Somatropin (Genotropin) Cartridge/Disp Syrin	Add to Commercial Formulary, Tier 5	Human Growth Hormones for Adults
• **Ambrisentan (Letairis) Tablet** • **Bosentan (Tracleer) Tablet**	Down-tier generic for Commercial: ○ Standard formulary: Tier 2 ○ Dynamic formulary: Tier 3	Pulmonary Hypertension
Somatropin (Nutropin AQ Nuspin) Cartridge	Remove from Medicaid Formulary	Human Growth Hormones for Adults
Macitentan (Opsumit) Tablet	• Commercial: Move to Tier 6 from Tier 5 • Medicaid: Remove from formulary Effective 09/01/2023	Pulmonary Hypertension
Becaplermin (Regranex) Gel (Gram)	• Commercial/Medicaid: Add Quantity Limit (15 grams per 6 months) Effective 09/01/2023	Regranex

Netarsudil mesylate (Rhopressa) Drops	• Commercial/Medicaid: Add Quantity Limit (2.5 ml per 25 days) Effective 09/01/2023	Anti-Glaucoma Agents Step Therapy Policy
Tretinoin 0.025 % Cream	Add to Medicaid formulary	Acne Medications – Medicaid
Oxymetazoline hcl/pf (Upneeq) Droperette	• Commercial/Medicaid: Add Quantity Limit (2 dropperettes per day) Effective 09/01/2023	Upneeq
Sinecatechins (Veregen) Ointment	Remove from Commercial and Medicaid formularies	N/A
Tirzepatide (Mounjaro®)	Add to Commercial formulary, Tier 3, Step Therapy, Quantity Limit (2 mL per 28 days)	GLP-1/GIP Receptor Agonists
Desvenlafaxine ER tablets	Add Priori Authorization for Commercial	New Medications and Formulations without Established Benefit
Vibegron (Gemtesa)	Add to Medicare Part D formulary, Tier 3 Effective 07/01/2023	N/A

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

Drugs released between March 4, 2023 and April 1, 2023

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Sodium picosulfate/magnesium oxide/citric acid (Clenpiq) Solution	New strength (10-3.5/175). Line extend with Clenpiq 10-3.5/160; • Commercial: Formulary, Tier 4 • Medicaid: Non- Formulary • Medicare Part D: Non- Formulary	N/A
Pegfilgrastim-pbbk (Fylnetra) Syringe	Biosimilar to Neulasta. Line extend to Neulasta; • Commercial: Formulary, Tier 5 (Covered Medical Benefit) • Medicaid: Formulary, Specialty (Covered Medical Benefit) • Medicare Part D: Formulary, Tier 5	N/A

	• Medicare Part B: Covered Medical Benefit	
Sotorasib (Lumakras) Tablet	New Strength (320mg). Line extend with Lumakras 120mg; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Onasemnogene abeparvovec-xioi (Zolgensma) Kit	New dose kit. Line extend with other Zolgensma; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non- Formulary	Zolgensma
Methoxy polyethylene glycol-epoetin beta (Mircera) Syringe	New strength (120mcg/0.3ml). Line extend with existing Mircera strengths; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid: Erythropoiesis Stimulating Agents • Medicare Part B: Erythropoiesis Stimulating Agents (ESAs) - Medicare Part B
Gabapentin (Gralise) Tab ER 24H	New strength (450mg, 750mg, 900mg). Line extend with Gralise (300mg, 600mg); • 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
Leuprolide acetate (Lupron Depot-Ped) SyingeKit	New kit (45mg). Line extend with Lupron Depot-PED (7.5mg, 11.25mg, 15mg); • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid: Gonadotropin Releasing Hormone Agonists • Medicare Part D: Lupron Depot Program • Medicare Part B: Gonadotropin Releasing Hormone Agonists – Medicare Part B
Elexacaftor/tezacaftor/ivacaftor (Trikafta) Gran PK SQ	New dosage form (GRAN PK SQ). Line extend with Trikafta tablets; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 packets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 packets per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 packets per day)	CFTR Modulators

New Generics:

Drug Name	Action Taken	Policy Name
Bismuth-Metronidazole Tetracyc Capsule	First generic (Pylera). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Quantity Limit (120 capsules per 28 days) • Commercial Dynamic: Formulary, Tier 4, Quantity Limit (120 capsules per 28 days) • Medicaid: Non-Formulary, Quantity Limit (120 capsules per 28 days) • Medicare Part D: Formulary, Tier 4	N/A
Diltiazem hcl (Diltiazem 24HR ER (LA)) Tab ER 24H	First generic (Cardizem LA). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Teriflunomide Tablet	First generic (Aubagio). Line extend as generic; • Commercial: Formulary, Tier 5, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Specialty, Quantity Limit (1 tablet per day) • Medicare Part D: Formulary, Tier 3	N/A
Vancomycin HCL Soln Recon	NDA authorized generic (Firvanq). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Non-Formulary • Formulary, Tier 4	N/A
Baclofen Oral Susp	First generic drug (Fleqsuvy). Line extend as generic; • Non-formulary for all lines of business	N/A
Budesonide Foam/Appl	First generic drug (Uceris). Line extend as generic; • Commercial/Medicaid: Non-formulary, Prior Authorization; • Medicare Part D: Non-formulary	• Commercial/Medicaid: Uceris • Medicare Part D: N/A
Naftifine hcl Gel (Gram)	First generic drug (Naftin). Line extend as generic; • Non-formulary for all lines of business	N/A

Providence Health Plan

Providence Health Assurance

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Acne Medications – Medicaid	Removed prior authorization on preferred products for children under age of 21 years.
Adbry	• Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions. • Removed Commercial requirement for chronic condition of at least one year, clarified quantity limit for initial authorization, and aligned exclusion criteria with primary therapeutic immunomodulator (TIM) policy to exclude combination use with other TIM agents.
Anti-Glaucoma Agents Step Therapy Policy	Addition of Rhopressa® to policy with quantity limit.
Benlysta	Age restriction updated to allow coverage in patients five and older for both Systemic lupus erythematosus (SLE) and active lupus nephritis due to FDA label change.
Bepreve, Zerviate	Updated policy criteria language regarding trial and failure of brand azelastine 0.05% ophthalmic solution to require trial and failure of generic azelastine as brand has been discontinued.
Camzyos	Updated prerequisite therapy to require trial and failure of two preferred therapies, instead of three.
CFTR Modulators	Updates age restrictions and added quantity limit for new Trikafta® packet formulation.
Cibinqo	• Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions. • Updated age restriction to align with FDA label. • Removed Commercial requirement for chronic condition of at least one year, aligned exclusion criteria with primary therapeutic immunomodulator (TIM) policy to exclude combination use with other TIM agents
Compounded Drugs	Updated to require trial of all formulary options to mirror formulary exception policy
Corlanor	Rearranged guideline-directed therapy criteria.
Dupixent	• Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions. • Updated age restriction to align with FDA label. • For Atopic Dermatitis in Commercial: Removed requirement for severe symptoms. • For nasal polyps: Removed requirement for previous nasal surgery, lack of candidacy for nasal surgery, or trial of oral systemic corticosteroids. • For eosinophilic esophagitis: Added weight requirement of 40 kg per FDA-approved indication.

	• For prurigo nodularis: removed requirement for trial and failure of standard anti-itch therapy, removed quantity of lesions required, changed requirement for prurigo nodularis for at least three months to itching for at least six weeks. • Aligned exclusion criteria with primary therapeutic immunomodulator (TIM) policy to exclude combination use with other TIM agents
Elidel, Protopic – Medicaid	Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions. Medications will not require prior authorization for children less than 21 years of age.
Enstilar, Taclonex, Taclonex Scalp, Wynzora	Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions.
Eucrisa	• Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions. • Updated Commercial criteria to only require tacrolimus in patients at least two years of age as allowed by FDA-approved indication
Fertility and Related Medications Prior Authorization and Step Therapy Policy - Medicare Part B	New Policy- Policy was split from Commercial policy due to differences in authorized uses of these medications by the Centers of Medicare and Medicaid Services (CMS).
GIP/GLP-1 Receptor Agonists Step Therapy Policy	Tirzepatide (Mounjaro®) added as preferred therapy. Policy criteria was updated to clarify medications will only be covered with step through metformin and/or diagnosis of type 2 diabetes.
GIP/GLP-1 Receptor Agonists Step Therapy Policy – Medicaid	Policy criteria was updated to clarify medications will only be covered with step through metformin and/or diagnosis of type 2 diabetes.
• **Homozygous Familial Hypercholesterolemia (FH) Agents** • **Homozygous FH Agents - Medicare Part B**	Added additional genetic mutation for diagnosis [LDL receptor adapter protein 1 (LDLRAP1)] and updated definition of clinical diagnosis of homozygous familial hypercholesterolemia to align with American Heart Association and European Atherosclerosis Society definitions.
Human Growth Hormones for Adults	• Combined Pediatric and Adult policy for ease of review • Provider restrictions updated to align with respective disease states
Human Growth Hormones - Medicaid	New Policy - Separated from Commercial policy due to significant differences in coverage criteria. Updated to align with Oregon Health Authority criteria
• **IL-5 Inhibitors**	For EGPA: Updated diagnostic criteria to align with the American College of Rheumatology and Lanham guidelines. For HES: Updated trial and failure criteria to only apply to commercial line of business to align with Oregon Health

• **Il-5 Inhibitors – Medicare Part B**	Authority guidance. For nasal polyps: Removed surgery criteria to align with the International Consensus Statement on Rhinology and Allergy. For all indications, updated exclusion criteria to specify which drug classes are not allowed to be used in combination with requested agent. Updated duration of approval.
Immune Gamma Globulin (IGG)	Adding criteria for Myelin Oligodendrocyte Glycoprotein Antibody Disease
Immune Gamma Globulin (IGG) Prior Authorization and Step Therapy Policy - Medicare Part B	New policy – separated from Commercial policy due to differences in authorized uses of these medications by the Centers of Medicare and Medicaid Services (CMS).
Intranasal Allergy Medications – Medicaid	Updated criteria to align with Oregon Health Authority criteria.
Lidocaine Patch	Added ICD-10 codes that are considered coverable and will set up to pay automatically at point-of-sale if diagnosis code submitted.
Luxturna	Updated policy coverage duration from 12 weeks to 6 months to align with coverage duration from Oregon Health Authority.
Mifepristone	New policy – clarify coverage for non-elective termination of pregnancy uses
• **Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors**	Retired prior authorization for Cimerli® (biosimilar for Lucentis) , as this is now considered a preferred product. Added criteria for non-preferred products to require
Opzelura	Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions.
Palforzia	Clarified wording of criteria to ensure use is reserved for patients with history of severe-type reaction to peanut containing products.
PCSK9 Inhibitors – Commercial	1. Updated statin intolerance criteria to include trial of at least two different statins instead of just either rosuvastatin or atorvastatin, 2. Removed "clinically significant multi vessel coronary hear disease" from clinical ASCVD option as it does not align with the American College of Cardiology/American Heart Association guideline definitions of clinical ASCVD, 3. added coverage for primary hypercholesterolemia (LDL-c greater than 190 g/dL) when secondary causes have been ruled out to align with American College of Cardiology/American Heart Association guidelines.
PCSK9 Inhibitors - Medicare Part B	1. Updated statin intolerance criteria to include trial of at least two different statins instead of just either rosuvastatin or atorvastatin, 2. Removed "clinically significant multi vessel coronary hear disease" from clinical ASCVD option as it does not align with the American College of Cardiology/American Heart Association guideline definitions of clinical ASCVD.

PCSK9 Inhibitors- Medicaid	1. simplified criteria for familial hypercholesterolemia to state a “possible” diagnosis of FH via Simon Broome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria, 2. Increased initial authorization to 12 months.
Pulmonary Arterial Hypertension	Change policy name to Pulmonary Hypertension, requiring trial and failure or medical rationale for use of brand Tracleer, Opsumit, or Letairis over generic ambrisentan or bosentan.
Regranex	Updated Medicaid criteria to align with Oregon Health Authority criteria. Commercial criteria updated to require only diagnosis and concurrent wound care.
• **Rituximab** • **Rituximab - Medicare Part B**	Updated coverage duration to allow long-term authorization for oncologic diagnoses (aligning with oncology policies).
Second and Third generation antihistamines – Medicaid	Updated duration of approval.
• **Soliris** • **Soliris - Medicare Part B**	Adding step through Ultomiris® for Atypical Hemolytic Uremic Syndrome and Paroxysmal Nocturnal Hemoglobinuria, removing Uplizna as a trial option for Neuromyelitis Optica Spectrum Disorder.
Tafamidis	Updated radionuclide imaging criteria to include additional acceptable radiotracers.
Testosterone Replacement Therapy (TRT)	Added language around coverage of pellet insertion procedural codes and for coverage of hormone replacement for females. Renamed policy to "Hormone Replacement Therapy"
Therapeutic Immunomodulators (TIMS)	Added medical necessity criteria for the use of baricitinib (Olumiant®) in the treatment of alopecia areata
TIMS – Medicaid	Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions. Added medical necessity criteria for the use of baricitinib (Olumiant®) in the treatment of alopecia areata
Upneeq	Update quantity limit in clinical policy criteria to align with package insert dosing.
Vascepa	Statin intolerance criteria updated to align with other policies for hypercholesterolemia. Modified age cutoff for ASCVD risk factors to match trial evidence.
Vtama, Zoryve	Updated Medicaid criteria to align with updated criteria from the Oregon Health Authority Prioritized List of Healthcare services for inflammatory skin conditions.
Xolair	• For urticaria: Updated Medicaid criteria to align with Oregon Health Authority • For nasal polyps: Removed surgery criteria to align with the International Consensus Statement on Rhinology and Allergy. • For all indications, updated exclusion criteria to specify which drug classes are not allowed to be used in combination with requested agent. • Updated duration of approval.
Xolair – Medicare Part B	• For urticaria: Added definition of chronic disease.

	• For nasal polyps: Removed surgery criteria to align with the International Consensus Statement on Rhinology and Allergy. • For all indications, updated exclusion criteria to specify which drug classes are not allowed to be used in combination with requested agent.
Zinplava	Removed exclusion criteria to align with label, added dosing criteria and updated risk factor criteria to only apply to Commercial and Medicare Part B to align with the Oregon Health Authority.
Zyflo CR	Due to low utilization, simplified policy to step therapy, requiring a trial of both formulary leukotriene modifiers (montelukast and zafirlukast).

RETIRED POLICIES	
Policy Name	**Summary of Change**
Aczone Step Therapy Policy	Due to low utilization.
Daliresp	Due to low utilization and to align with market due to generic availability.
Human Growth Hormones for Pediatrics	Combined with Human Growth Hormones for Adults policy.
Pneumococcal Vaccines / Pneumococcal Vaccines - Medicare Part B	Due to recommendations continuing to change and the Plan does not want to limit access to Pneumococcal vaccines.
Topical Androgen Receptor Inhibitors	Will manage utilization with criteria as outlined in the "Formulary and Quantity Exceptions" and "Medical Necessity" policies.
Veregen	Due to low utilization.