Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 80

March 1, 2023

This is the March 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 4/1/2023

Vitamin D Assay Testing (Company) **MP94**	**Policy Updates:** No recommended changes to criteria **Codes/PA:** Additional diagnosis codes have been added for pair to pay with CPT codes, based on Medicare LCA for Vitamin D Assay Testing **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Stem Cell Transplantation (Company) **MP282**	**Policy Updates:** • Moved CMS NCD reference to Policy Guideline • Added coverage of tandem transplantations for multiple myeloma, germ cell tumors, and neuroblastomas. • Expanded indications for bone marrow failure disorders and inherited autoimmune conditions. • Generalized lymphoma section for allograft if unsuitable for allograft transplantation • Updated from Durie-Salon staging to Revised International Staging System (R-ISS) for multiple myeloma. **Codes/PA:** No changes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 5/1/2023

Back: Artificial Intervertebral Discs (Company) **MP34**	**Policy Updates:** Changed denial for non-covered artificial disc replacement procedures from "investigational" to "not medically necessary." **Codes/PA:** Changed "investigational" denial to "not medically necessary" for the following codes: • 0165T • 22860 **OHP:** OHP will follow the Company Policy above
Back: Fusion and Decompression Procedures (Company) **MP10**	**Policy Updates:** Changed denial for percutaneous and endoscopic decompression and fusion procedures from "investigational" to "not medically necessary." (Criterion VII) **Codes/PA:** Changed the denial to "not medically necessary" for the following codes: • 0275T • 0719T • G0276 • 0274T • 62287 • 62380 • S2348 • C2614 • C1831 **OHP:** OHP will follow the Company Policy above
Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (Company) **MP28**	**Policy Updates:** Changed denials to not medically necessary for criterion III, IV, V. **Codes/PA:** No changes to codes/PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Prostate: Protein Biomarkers and Genetic Testing (Company) **MP96**	**Policy Updates:** Changed denial for non-covered services from "investigational" to "not medically necessary." **Codes/PA:** Changed denial for the following codes from "investigational" to "not medically necessary": • 0011M • 0005U • 0021U • 0047U • 0053U • 0113U • 0133U • 81313 • 81539 • 81541 • 81542 • 81551 **OHP:** OHP will follow the Company Policy above
Surgical Treatments for Lymphedema (Company) **MP222**	**Policy Updates:** Changed denial for non-covered services from "investigational" to "not medically necessary." **Codes/PA:** No changes to codes/PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Speech Generating Devices (Company) **MP86**	**Policy Updates:** • Added "Documentation Requirements" and removed LCA language from Billing Guideline regarding documentation. • Added criteria for more than one speech generating device. • Made criteria changes in the "Accessories" section. • Added replacement criteria. • Added language in the "Policy Guidelines" clarifying that while *Medicare* doesn't recognize tablets as SGDs, the company policy does recognize these devices as possible SGDs. • Removal/deletion of certain Policy Guideline information to avoid repetition. **Codes/PA:** No changes to codes/PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Back: Sacroiliac Joint Fusion or Stabilization (Company) **MP24**	**Policy Updates:** Added LinQ SI Joint Stabilization System as an example of a fusion that is "not medically necessary." **Codes/PA:** Changed the "investigational" denial to "not medically necessary" for 0775T (new code for 1/1/23). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Fecal Incontinence (Company) **MP103**	**Policy Updates:** • Added device removal criteria for sacral nerve stimulation. • Changed denial to not medically necessary when criteria are not met (criteria II. IV. VIII) **Codes/PA:** No changes to codes/PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Urinary Incontinence (Company) **MP180**	**Policy Updates:** • Added device removal criteria for sacral nerve stimulation and percutaneous tibial nerve stimulation. • Added implantable tibial nerve stimulators to criterion XVI to deny as not medically necessary. **Codes/PA:** No changes to codes/PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE

Effective 4/1/23

Joint Resurfacing (Medicare) **MP353**	**Policy Updates: Recommendation:** No changes to criteria source (still using Company criteria); however, the following updates are made to the policy (similar changes have already been performed for the Company version, this will align Medicare and Company versions):

	• With Company criteria being changed from E/I to NMN, revised language in the Medicare policy since the "investigational" language no longer applies. • Updated "Billing Guidelines", removing old language and referencing new policies to address MAKOplasty. **Codes/PA:** No changes to codes or configuration.
Premature Rupture of Membranes (PROM) Testing (Medicare) **MP383**	**Policy Updates:** New Medicare Advantage medical policy, separating by line of business. With no Medicare criteria available by our Medicare contractor (MAC), continue to use Company criteria. **Codes/PA:** No code or configuration changes
Lipid Testing (Medicare) **MP235**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare NCD guidance for lipid testing (NCD 190.23). **Codes/PA:** Update diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes. • **CMS January 2023 Updates:** ICD-10 codes **added to pay effective 10/1/2022** should be: F1090 F1091 I202 I25112 I25702 I25712 I25722 I25732 I25752 I25762 I25792 K7682 Z7985 • **CMS April 2023 Updates:** ICD-10 codes **added to pay effective 4/1/2023** should be: N18.1 N18.2 N18.30 N18.31 N18.32

Serum Iron Studies (Medicare) **MP322**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare NCD guidance for serum iron studies (NCD 190.18). **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes. • For Medicare, ICD-10 codes **added to pay effective 10/1/2022** should be: K7682 T43652S T43653A T43653D T43653S T43654A T43654D T43654S T43655A T43655D T43655S U071 • **CMS April 2023 Updates:** ICD-10 codes **added to pay effective 4/1/2023** should be: N18.1 N18.2 N18.30 N18.31 N18.32
Thyroid Testing (Medicare) **MP207**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare NCD guidance for thyroid testing (NCD 190.22). **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes. • **CMS January 2023 Updates:** ICD-10 codes **added to pay effective 10/1/2022** should be: F0670 F0671 M625A0 M625A1 M625A2 M625A9 Z28310 Z28311 Z7985 • **CMS April 2023 Updates:** ICD-10 codes **added to pay effective 10/1/2022** should be:

	Z79.620
Vitamin D Assay Testing (Medicare) **MP525**	**Policy Updates:** No change to criteria, continue to use Noridian LCD as published. **Codes/PA:** Updated diagnosis code configuration for 82306 and 0038U to align with updates made to the Noridian LCA.
Eye: Blepharoplasty, Blepharoptosis Repair, and Brow Lift (Medicare) **MP225**	**Policy Updates:** No change to criteria. Added note to state this policy isn't used for eye procedures performed for gender identity conditions. **Codes/PA:** For codes 15820/15821, keep NMN denial but add exceptions for gender affirming dx codes. No configuration changes to any other codes in the policy.

Effective 5/1/23

Back: Sacroiliac Joint Fusion or Stabilization (Medicare) **MP379**	**Policy Updates:** New Medicare Advantage medical policy, separating by line of business. With no Medicare guidance available for our service area by our Medicare contractor (MAC), continue to use Company criteria. **Codes/PA:** For code 0775T (new code as of 1/1/2023), remove E/I denial and replace with NMN denial. No changes to the other codes in the policy.
Electrical Stimulation and Electromagnetic Therapies (Medicare) **MP333**	**Policy Updates:** Updated language, removing reference to "investigational" criteria, for dorsal root ganglion (DRG) stimulation since this is being changed to not medically necessary on the Company policy. **Codes/PA:** No changes to codes or configuration related to the above recommendation; however new Q1 2023 codes (C1826 and C1827) will have the NMN denial replaced with a PA.
Fecal Incontinence Treatments (Medicare) **MP228**	**Policy Updates:** Consistent with the Company policy update, added device removal criteria for implanted nerve stimulation devices (e.g., sacral nerve stimulation and percutaneous tibial nerve stimulation). **Codes/PA:** No changes to codes/PA

Urinary Incontinence Treatments (Medicare) **MP231**	**Policy Updates:** Consistent with the Company policy update, added device removal criteria for implanted nerve stimulation devices (e.g., sacral nerve stimulation and percutaneous tibial nerve stimulation) and implantable tibial nerve stimulators as services which use Company criteria. **Codes/PA:** No changes to codes/PA

VENDOR UPDATES

Name Change for AIM and Beacon	AIM and Beacon are undergoing a name change to Carelon, effective 3/1/2023

Providence Health Plan

Providence Health Assurance

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting February 3, 2023

Go-Live Date: Saturday, April 01, 2023, unless otherwise noted

Table of Contents:

- New Drugs and Combinations
- New Strengths and Formulations
- New Indications Monitoring
- Drug Safety Monitoring
- Other Formulary Changes
- New Generic Medications
- Clinical Policy Changes

New Drugs and Combinations:

1. **Lecanemab-irmb (Leqembi) Vial**
   a. **Indication**: For treatment of Alzheimer's disease.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

PA PROGRAM NAME	Anti-Amyloid Monoclonal Antibodies
MEDICATION NAME	Lecanemab (Leqembi)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**Commercial/Medicaid:** Monoclonal antibodies directed against amyloid is not considered medically necessary and will not be covered due to insufficient evidence of a clinical benefit and safety concerns. **Medicare Part B:** Coverage of the requested drug will be provided in accordance with CMS's National Coverage Analysis: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N).
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	N/A

2. **Teplizumab-mzwv (Tzield) Vial**
   a. **Indication**: To delay the onset of stage 3 type 1 diabetes mellitus in adults and pediatric patients aged 8 years and older with stage 2 type 1 diabetes
   b. **Decision**: Approved with changes outlined below (removal of requirement for family history of T1DM)

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

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

Formulary Alternatives: N/A

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

PA PROGRAM NAME	Tzield
MEDICATION NAME	Teplizumab-mzwz vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Stage 3 (symptomatic) type 1 diabetes
REQUIRED MEDICAL INFORMATION	Initial authorization requires all the following be met: ~~1. Family history of type 1 diabetes~~ 2. Diagnosis of stage 2 type 1 diabetes (meaning that the patient is at risk of developing symptomatic type 1 diabetes) as evidenced by both the following (a and b): a. Documentation of the presence of two or more of the following autoantibodies: • Glutamic acid decarboxylase 65 (GAD) autoantibody • Insulin autoantibody (IAA) • Insulinoma-associated antigen 2 autoantibody (IA-2A) • Zinc transporter 8 autoantibody (ZnT8A) • Islet cell autoantibody (ICA) b. Evidence of dysglycemia without overt hyperglycemia confirmed by an oral glucose tolerance test (meaning a 2-hour post prandial blood glucose of 140-199 mg/dL) Note: If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be considered such as fasting plasma glucose 100–125 mg/dL 3. Dosing is within FDA-labeled guidelines
AGE RESTRICTIONS	May be approved for patients aged eight (8) years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an endocrinologist
COVERAGE DURATION	Authorization will be approved for one 14-day treatment course per lifetime

3. **Etranacogene dezaparvovec-drlb (Hemgenix) Kit**
   a. **Indication**: For the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: currently use Factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
   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: Factor IX concentrate: Alphanine SD®, Alprolix®, Benefix®, Idelvion®, Ixinity®, Mononine®, Profilnine®, Rebinyn®, Rixubis®			

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

PA PROGRAM NAME	Hemgenix®
MEDICATION NAME	etranacogene dezaparvovec-drlb suspension (Hemgenix®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Current or prior presence of factor IX inhibitors • HIV not controlled with antiviral therapy (CD4+ counts equal to 200/µL or by a viral load of greater than 200 copies/mL) • Active hepatitis B or C infection • Evidence of advanced liver fibrosis (Fibroscan score 9 kPA or greater) • ALT, AST, total bilirubin, alkaline phosphataste, or creatinine greater than two times the upper limit of normal • Previous treatment with gene therapy for the same indication
REQUIRED MEDICAL INFORMATION	Hemgenix® may be approved when all the following criteria are met: 1. Diagnosis of severe or moderately severe hemophilia B, defined by Factor IX level less than 2 IU/dL or less than or equal to 2% of normal 2. Patient is male 3. One of the following:

	a. Patient is currently on a stable dose of factor IX prophylaxis (has been receiving prophylaxis for 2 months of more) with more than 150 exposure days of factor IX prophylaxis b. Current or historical life-threatening hemorrhage c. Documentation of repeated, serious spontaneous bleeding episodes 4. Hemgenix® will be administered by or in consultation with a Hemophilia Treatment Center (HTC)
AGE RESTRICTIONS	Must be 18 years of age or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist
COVERAGE DURATION	Authorization will be limited to one treatment course per lifetime

4. **Medicaid Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Program**
   a. **Topic**: Effective 3/1/2023
      - 2023 Medicaid updates: services for children (less than 21 years of age) can no longer be denied solely for being used to treat a condition that is considered unfunded on the Prioritized List of Healthcare Services
        - A medical necessity/medical appropriateness review must be conducted for these patients; medications and services may be covered for these conditions if there is documentation from the provider that the condition is of sufficient severity that it impacts the patient's health.
      - Reviewed definitions of medical necessity and medical appropriateness, which were based on Oregon Administration Rules (OARs).
   b. **Decision**: Approved Medical Necessity Policy and changes to a subset of policies for unfunded conditions to include EPSDT criteria (**Acne Medications, Constipation Agents, 2nd & 3rd Generation Antihistamines, Intranasal Allergy Medications**)

PA PROGRAM NAME	Medical Necessity - Medicaid
PA INDICATION INDICATOR	All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. For **children less than 21 years of age**: Medications and products may be covered if one of the following criteria are met: a. There is a P&T approved clinical policy for the requested service, and the patient meets the clinical criteria in the policy b. The request is for non-preferred/non-formulary medications, medications for unfunded conditions, or products traditionally not covered by Medicaid, and all the following criteria are met: i. Treatment is recommended by a licensed health provider practicing within the scope of their license

	ii. Patient is using the medication for a Food and Drug Administration (FDA) approved indication or compendia-supported indication, iii. The medication is not used solely for the convenience or preference of the patient or provider iv. One of the following: 1. The condition is designated a covered line-item by the Oregon Health Services Commission Prioritized List of Health Care Services 2. Documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.) c. For non-formulary/non-preferred products: Documentation of trial and failure, contraindication, or intolerance to at least <u>two preferred/formulary</u> products within the same class if available 2. For **adults 21 years of age and older**: Medications and products may be covered if one of the following criteria are met: a. There is a P&T approved clinical policy, and the patient meets the clinical criteria in the policy b. The request is for non-preferred/non-formulary medications and all the following criteria are met: i. Treatment is recommended by a licensed health provider practicing within the scope of their license ii. Patient is using the medication for a FDA approved indication or compendia-supported indication iii. The medication is not used solely for the convenience or preference of the patient or provider iv. The condition is designated a covered line-item by the Oregon Health Services Commission Prioritized List of Health Care Services, or there must be a co-morbid condition for which coverage would be allowed. v. Documentation that <u>all formulary drugs</u> in the same therapeutic class have been ineffective in the treatment of the patient's disease. Trial of formulary alternatives must be adequate in duration and dose to assess clinical benefit (based on the medication's properties, clinical guideline information, and/or consideration of other medical and scientific evidence). 1. If formulary drugs in the same therapeutic class of medication are not available, documentation that at least four formulary drugs indicated to treat the patient's condition (if available) have been ineffective in the treatment of the patient's disease. 3. For **quantity limit exceptions**, refer to the appropriate clinical policy if applicable. For all other quantity exceptions, requests may be covered if all the following criteria (a-e) are met:

	a. The requested quantity is below the maximum dose according to the FDA-approved package labeling, if applicable b. The requested medication is being used for a medically accepted indication (FDA approved indication or compendia-supported use) c. Documentation of an inadequate response to a trial of the allowed quantity. Trial must be adequate in duration to assess clinical benefit (based on the medication's properties, clinical guideline information, and/or consideration of other medical and scientific evidence). d. One of the following: i. Medical rationale has been provided that demonstrates the requested quantity is likely both safe and effective for the patient and the patient's condition (e.g., high-quality medical literature) ii. The prescribed dose cannot be achieved using a lesser quantity of a higher strength (such as one 20 mg capsule instead of two 10 mg capsules)
AGE RESTRICTIONS	Patient's age must be appropriate according to the FDA label for the requested medication
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	For acute-use medications and/or those with safety considerations (e.g., opioids): Initial authorization and reauthorization will be approved for six months, up to one year. For maintenance medications: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

5. **Futibatinib (Lytgobi) Tablet**
   a. **Indication**: For the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangement.
   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	5/day	5/day	5/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: Pemazyre, Truseltiq			

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

6. **Teclistamab-cqyv (Tecvayli) Vial**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.
   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: The CAR-T therapies idecabtagene vicleucel (Abecma®) and ciltacabtagene autoleucel (Carvykti®)			

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

PA PROGRAM NAME	CAR-T (to be renamed to “T Cell Therapy”)
MEDICATION NAME	Tecvayli
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Previous treatment with chimeric antigen receptor therapy (CAR-T) or other genetically modified T-cell therapy. Repeat administration of genetically modified T-cell therapy is considered experimental and investigational because the effectiveness of this approach has not been established

REQUIRED MEDICAL INFORMATION	1. Confirmed diagnosis of multiple myeloma 2. Refractory or relapsed disease to four or more prior lines of therapy. Prior therapy must have included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody 3. Asymptomatic or minimally symptomatic with Eastern Cooperative Oncology Group (ECOG) performance status 0-1 4. No evidence of active systemic infection
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	For Tecvayli: Initial authorization and reauthorization will be approved for 1 year and with up to four doses of tocilizumab (Actemra®) at up to 800 mg per dose

7. **Mirvetuximab soravtansine-gynx (Elahere) Vial**
   a. **Indication**: for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

8. **Terlipressin acetate (Terlivaz) Vial**
   a. **Indication**: Indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.
   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	N/A	N/A	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

9. **Testosterone undecanoate (Kyzatrex) Capsule**
   a. **Indication**: Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: testosterone 12.5/1.25g gel pump, testosterone 20.25/1.25g gel pump, testosterone 25mg (1% gel packet, testosterone 50mg (1%) gel, testosterone 50mg (1%) gel packet, testosterone cypionate, testosterone enanthate			

10. **Elivaldogene autotemcel (Skysona) Plast. Bag**
    a. **Indication**: To slow the progression of neurologic dysfunction in boys 4-17 years old with early, active cerebral adrenoleukodystrophy (CALD).
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	One treatment per lifetime	One treatment per lifetime	One treatment per lifetime
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	**Elivaldogene autotemcel (Skysona®)**
MEDICATION NAME	Skysona®
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	All of the following must be met: 1. Patient has early active cerebral adrenoleukodystrophy (CALD) defined by ALL of the following: 1) Elevated very-long-chain fatty acid (VLCFA) values 2) Confirmed Adenosine Triphosphate (ATP)-binding cassette, subfamily D, member 1 (ABCD1) mutation 3) Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating: a. Loes score between 0.5 and 9 (inclusive) on the 34-point scale b. Gadolinium enhancement on MRI of demyelinating lesions 4) Neurologic Function Score (NFS) of 1 or less 2. Documentation is provided indicating that patient has NONE of the following: 1) History of hematopoietic stem cell transplant (HSCT) 2) History of elivaldogene autotemcel treatment 3) HLA-matched willing sibling donor
AGE RESTRICTIONS	May be approved for patients aged 4-17

PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pediatric metabolic geneticist, neurologist, endocrinologist, hematologist, or oncologist
COVERAGE DURATION	Authorization is limited to one treatment course per lifetime. Approval duration will be for 12 weeks

11. **Eflapegrastim-xnst (Rolvedon) Syringe**
    a. **Indication**: Indicated to decrease the incidence of infection in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	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: filgrastim, pegfilgrastim			

12. **Deucravacitinib (Sotyktu) Tablet**
    a. **Indication**: For the treatment of moderate-to-severe plaque psoriasis in adults.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One tablet per day	One tablet per day	N/A

* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: apremilast (Otezla®), adalimumab (Humira®), secukinumab (Cosentyx®), risankizumab-rzaa (Skyrizi®), ustekinumab (Stelara®)

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Therapeutic Immunomodulators Policy as a non-preferred agent for psoriasis

13. **Dextroamphetamine (Xelstrym) Patch TD24**
    a. **Indication**: For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years 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	N/A	Prior Authorization	N/A
Quantity Limit	One patch per day	One patch 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: dextroamphetamine ER capsules, dextroamphetamine IR tablets, dextroamphetamine/amphetamine ER capsules			

c. **Prior Authorization Criteria for Medicaid**: Added to Long-Acting Stimulant policy, as non-preferred agent

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Oxlumo® (**lumasiran)
    a. Previous Indication(s):
        a. For the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients
    b. New indication approved 10/06/2022:
        a. For the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary **and plasma** oxalate levels in pediatric and adult patients

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The policy was updated as part of annual review and is included in the policy review section of the consent agenda vote.

2. **Rinvoq® (**Upadacitinib)
   a. Previous Indication(s):
      a. Multiple (see package labeling)
   b. New indication approved 10/21/2022:
      a. Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Commercial policy was updated and is included in the policy review section of the consent agenda vote.

3. **Trulicity® (**dulaglutide)
   a. Previous Indication(s):
      a. As an adjunct to diet and exercise to improve glycemic control in **adults** with type 2 diabetes mellitus
      b. To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors
   b. New indication approved 11/17/2022:
      a. As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients **10 years of age and older** with type 2 diabetes mellitus.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication

<u>Therapies with Prior Authorization Policies (Oncology)</u>

a. **Cotellic® (**Cobimetinib)
   i. New indication(s) approved 10/28/2022:
      - As a single agent for the treatment of adult patients with histiocytic neoplasms
   ii. **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.

b. **Imfinzi® (**durvalumab)
   i. New indication(s) approved 11/10/2022 and 10/21/2022:
      - In combination with tremelimumab-actl, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC)
      - In combination with tremelimumab-actl, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC)

ii. **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.

c. **Enhertu® (**fam-trastuzumab deruxtecan-nxki)
   i. New indication(s) approved 11/04/2022:
      - adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, **as determined by an FDA-approved test**, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy
   ii. **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.

d. **Adcentris® (**brentuximab vedotin)
   i. New indication(s) approved 11/10/2022:
      - Pediatric patients 2 years and older with previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
   ii. **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.

e. **Libtayo® (**cemiplimab-rwlc)
   i. New indication(s) approved 11/08/2022:
      - In combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no EGFR, ALK or ROS1 aberrations and is:
        - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
        - metastatic.
   ii. **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.

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

a. **Liletta® (**Levonorgestrel)
   i. Previous Indication(s):
      - Prevention of pregnancy for up to 6 years
   ii. New indication(s) approved 11/10/2022:
      - Prevention of pregnancy for up to 8 years
   iii. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

b. **Brexafemme® (**Ibrexafungerp)
   i. Previous Indication(s):

- In adult and post-menarchal pediatric females for: Treatment of vulvovaginal candidiasis (VVC)

ii. New indication(s) approved 11/10/2022:
- In adult and post-menarchal pediatric females for: Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC)

iii. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

c. **Vemlidy® (**tenofovir alafenamide)
i. Previous Indication(s):
- For the treatment of chronic hepatitis B virus infection in **adults** with compensated liver disease

ii. New indication(s) approved 10/17/2022:
- For the treatment of chronic hepatitis B virus infection in adults **and pediatric patients 12 years of age and older** with compensated liver disease

iii. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

d. **Lyumjev® (**insulin lispro-aabc)
i. Previous Indication(s):
- To improve glycemic control in adults with diabetes mellitus

ii. New indication(s) approved 11/10/2022:
- To improve glycemic control in adults and **pediatric patients** with diabetes mellitus

iii. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

e. **Udenyca® (**pegfilgrastim-cbqv)
i. Previous Indication(s):
- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

ii. New indication(s) approved 1/6/2022:
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

iii. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name:** Prolia® (denosumab)
   - **Date Posted:** 11/22/2022
   - **Safety Alert Title:** FDA investigating risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia (denosumab)
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-investigating-risk-severe-hypocalcemia-patients-dialysis-receiving-osteoporosis-medicine-prolia

- **What safety concern is FDA announcing?**
  - The U.S. Food and Drug Administration (FDA) is investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with the osteoporosis medicine Prolia (denosumab). Our review of interim results from an ongoing safety study of Prolia suggests an increased risk of hypocalcemia, or low calcium levels in the blood, in patients with advanced kidney disease. Preliminary results from a separate internal FDA study further investigating hypocalcemia in dialysis patients treated with Prolia show a substantial risk with serious outcomes, including hospitalization and death.
- **What is FDA doing?**
  - Because of the frequency and seriousness of these risks, we are alerting health care professionals and patients about them and that we are continuing to evaluate this potential safety issue with Prolia use in patients with advanced kidney disease, particularly those on dialysis. We will communicate our final conclusions and recommendations when we have completed our review or have more information to share.
- **What should health care professionals do?**
  - Health care professionals should consider the risks of hypocalcemia with the use of Prolia in patients on dialysis. When Prolia is used in these patients, adequate calcium and vitamin D supplementation and frequent blood calcium monitoring, possibly more often than is already being conducted, may help decrease the likelihood or severity of these risks. Advise patients on dialysis to immediately seek help if they experience symptoms of hypocalcemia. Report side effects involving Prolia or other medicines to the FDA MedWatch program.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL vial
   i. **Date of Recall:** Expanded 11/29/2022 (originally announced 10/13/2022)
   ii. **Reason for recall:** Vial breakage of 63 total lots
   iii. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-expands-voluntary-nationwide-recall-sodium-bicarbonate-injection-usp-84-50
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Quinapril and Hydrochlorothiazide Tablets USP, 20mg / 12.5mg, 90's HDPE bottle
   i. **Date of Recall:** 10/25/2022
   ii. **Reason for recall:** Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril in two lots
   iii. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-recall-two-2-lots-quinapril-and
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Octreotide Acetate Injection, 500 mcg/mL
   i. **Date of Recall:** 10/25/2022
   ii. **Reason for recall:** Glass particulates present in one lot
   iii. **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Amphetamine sulfate (Evekeo ODT) Tab Rapdis	Correction from October 2022 P&T: • Medicaid: Retire Prior Authorization (medication will remain non-formulary)	N/A
Levocarnitine (Carnitor) Solution	Remove from Commercial and Medicaid formularies due to availability as over-the-counter Effective: 05/01/2023	N/A
Bexarotene capsule	Commercial: Move generic from Tier 6 to Tier 5	Oral Anti-Cancer Medications
Furosemide (Furoscix) Kit	New dosage form (kit); • Commercial / Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary	N/A
Lomustine (Gleostine) Capsule	Medicare Part D: Add to Formulary, Tier 4, Prior Authorization	Anti-Cancer Agents
Posaconazole (Noxafil) Powdermix Susp	New dosage form; • Commercial / Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	Antifungal Agents
Rosuvastatin Calcium Tablet	• Commercial / Medicaid: Remove quantity limit Effective: 03/01/2023	N/A
Torsemide (Soaanz) Tablet	• Commercial / Medicaid: Non-Formulary, Add Prior Authorization to Brand • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A

Fingolimod Lauryl Sulfate (Tascenso ODT) UL - Tab Rapdis	New strength (0.5mg), dosage form (tab rapdis) and salt form (lauryl sulfate); • Commercial / Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Tascenso • Medicare Part D: N/A
Pegfilgrastim-bmez (Ziextenzo) Syringe	• Commercial: Formulary, Tier 5, Specialty; Medical (straddle) • Medicaid: Formulary, Specialty; Medical (straddle) • Medicare Part D: Formulary, Tier 5 • Medicare Part B: Covered	N/A
Somatropin (Genotropin)	• Add to Commercial formulary as co-preferred with Norditropin: Tier 5, Prior Authorization **Effective 2/3/2023**	Human Growth Hormones for Adults and Pediatrics

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

Drugs released November 2022

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Angiotensin II acetate, human (Giapreza) Vial	New dosage strength (0.5mg/ml). Line extend with Giapreza 2.5mg/ml; • Medical benefit for Commercial, Medicaid, and Medicare Part B	N/A
Bortezomib Vial	New formulation. Line extend with other bortezomib; • Medical benefit for Commercial, Medicaid, and Medicare Part B	• Commercial/Medicaid: Injectable Anti-Cancer Medications • Medicare Part B: Injectable Anti-Cancer Medications - Medicare Part B

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Penciclovir Cream (G)	First generic (Denavir). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (10 ml per 365 days) • Commercial Dynamic: Formulary, Tier 4, Prior Authorization, Quantity Limit (10 ml per 365 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (10 ml per 365 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Denavir/Sitavig/Xerese/Zovirax • Medicare Part D: N/A
Leuprolide Depot (Leuprolide Acetate) Vial	New generic. Line extend with Lupron Depot; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Formulary, Tier 4, Prior Authorization	Gonadotropin Releasing Hormone Agonists
Pralatrexate Vial	First generic (Folotyn). Line extend as generic; • Medical benefit with Prior Authorization for Commercial, Medicaid, and Medicare Part B	Injectable Anti-Cancer Medications
Tafluprost/PF (Tafluprost) Droperette	Authorized generic (Zioptan). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (1 droperette per day) • Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (1 droperette per day)	• Commercial/Medicaid: Anti-Glaucoma Agents Step Therapy Policy • Medicare Part D: N/A

	• Medicaid: Non-Formulary, Step Therapy, Quantity Limit (1 droperette per day) • Medicare Part D: Non-Formulary	

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Antifungal Agents	Removed prescriber restrictions for oropharyngeal or esophageal candidiasis if prescribing itraconazole solution. Simplified criteria for evaluating high-risk patients with onychomycosis and required fungal test to confirm diagnosis. Removed requirement for treatment area size for dermatomycosis and added options for step therapy requirement. Removed criteria for recurrent vulvovaginal candidiasis that requires diagnosis by slide or culture and included criteria that patient must have had three or more episodes.
CAR-T	Simplified criteria to require that requested indication aligns with National Comprehensive Cancer Network guidelines. Replaced requirement of a specific Eastern Cooperative Oncology Group (ECOG) score with provider attestation that a patient's functional status is adequate to undergo treatment.
Dupixent	Updated policy criteria from what was approved at the last Meeting for prurigo nodularis to require trial of two conventional treatments, instead of three.
Gonadotropin Releasing Hormone Agonists	Updated policy with the following changes: clarified which drugs are covered for each indication, changed duration of approval for oncological indications to be approved until no longer eligible with the plan, aligned criteria for Medicaid with recommendations from Oregon Health Authority, updated basal luteinizing hormone level criteria for central precocious puberty after consultation with endocrinologist specialist and review of literature, removed duration of approval for fertility as this condition is addressed in the "Fertility and Related Medications" clinical policy.
Gonadotropin Releasing Hormone Agonists - Medicare Part B	Updated policy with the following changes: clarified which drugs are covered for each indication, changed duration of approval for oncological indications to be approved until no longer eligible with the plan, updated basal luteinizing hormone level criteria for central precocious puberty after consultation with endocrinologist specialist and review of literature, removed duration of approval for fertility as this condition is addressed in the "Fertility and Related Medications" clinical policy.
Oxlumo	Added criteria requiring patient weight and requested dose to be within FDA-recommended dosing.

Oxlumo – Medicare Part B	
Self-Administered Drug (SAD) Exclusion Policy	Three drugs were added to this policy: galcanezumab (Emgality®), ofatumumab (Kesimpta®), and methylnaltrexone (Relistor®)
Therapeutic Immunomodulators (TIMS) - Comm	Upadacitinib (Rinvoq®) received new indication for non-radiographic axial spondyloarthritis and it is considered a preferred agent after trial of Tumor Necrosis Factor (anti-TNF) agent. Criteria were updated to required objective signs of inflammation aligned with FDA indication.
Therapeutic Immunomodulators (TIMS) - Medicaid	Policy was updated to reflect all FDA approved indication for products. Additionally, criteria were added for coverage of infliximab for immune checkpoint inhibitor related diarrhea/colitis

RETIRED POLICIES	
Policy Name	**Summary of Change**
Thiola, Thiola EC	Due to low utilization and low risk of inappropriate use