Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 92

March 1, 2024

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

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

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

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

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

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

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 4/1/2024

Vitamin D Assay Testing **MP94**	**Policy Updates:** No changes to criteria. Continue to use Noridian LCD as noted in the policy. **Codes/PA:** Codes do not require PA but are adjudicated using diagnosis code pair-to-pay configuration. Update configuration as needed to align with LCA configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 5/1/2024

Whole Exome, Whole Genome, and Proteogenomic Sequencing and Genetic Testing for Mitochondrial Disorders *Previously: Whole Exome, Whole Genome, and Proteogenomic Genetic Testing* **MP219**	**Policy Updates:** Expanded criteria to include genetic testing for Mitochondrial Disorders, criterion III. **Codes/PA:** Added 81401, 81403, 81404, 81405, 81406 to policy, continue to PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Genetic Testing for Cytochrome P450 and VKORC1 Polymorphisms *Previously: Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms* **MP313**	**Policy Updates:** In criterion II, added six examples of non-covered cP450 genotyping. **Codes/PA:** No changes to codes or PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Stem Cell Transplantation
 	
MP282
	Policy Updates:
	• Changed denial type for criterion II. (allogenic HCST) to "not medically necessary" when medical necessity criteria are not met.
	• **New criterion**: added criterion III. to address donor lymphocyte infusions
	• **Liberalization**: criterion VI. – broadened coverage for AuSCT for multiple myeloma, with no reference to staging criteria.
	  ○ NCCN recommends autologous HCT to anyone with MM who has undergone at least one previous therapy, without reference to staging criteria.
	  ○ Updated "Policy Guidelines" to remove R-ISS table.
	Codes/PA: No changes to codes or PA.
	
	OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 6/1/2024

Hospital Beds, Support Surfaces, and Related Accessories **MP403**	**Policy Updates:** • Criteria are based on Medicare guidance. OHP criteria generally match Medicare guidance, but there are OHP criteria available, which are noted in the draft. • Items or features which are not addressed by Medicare will not be addressed in the policy at this time (e.g., built-in weight scales, hospital grade cribs, rocker beds, etc.) due to a lack of receiving these requests to date. **Codes/PA:** Code and configuration changes are as follows: • Added PA: E0194, E0300, E0301, E0302, E0303, E0304, E0328, E0329 • Added NMN denial: E0190, E0265, E0266, E0270, E0273, E0274, E0296, E0297, E0315, E0370, E0700, E0710 • Added t07 (not separately payable) denial: E0271, E0272, E0305, E0310

	• All other codes in the policy will continue with no medical policy configuration, but are still subject to member benefits, eligibility, and provider contracts. • Additional codes may be related to this topic but are excluded intentionally when no specific Medicare criteria are provided **and** when there is little to no utilization. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE

Effective 4/1/24

New and Emerging Technologies and Other Non-covered Services **MP220**	**Policy Updates:** Updated policy to include sources of evidence used in medical policies to align with new CMS Final Rule regulations. **Codes/PA:** • Removed codes without Medicare utilization (exception are newly created codes, which won't have utilization yet). • Removed 0720T, continue NMN configuration (code is addressed in a separate Medicare medical policy for electrical stimulation).
Vitamin D Assay Testing **MP525**	**Policy Updates:** No changes to criteria. Continue to use Noridian LCD as noted in the policy. **Codes/PA:** Codes do not require PA but are adjudicated using diagnosis code pair-to-pay configuration. Update configuration as needed to align with LCA configuration.
Blood Counts **MP209**	**Policy Updates:** No change to criteria, continue to apply CMS NCD 190.15 for blood count testing. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to deny*** configuration **retroactively effective 10/1/2023**: M800B1D M800B1G M800B1S M800B2D M800B2G M800B2S M800B9D M800B9G

	M800B9S M808B1D M808B1G M808B1S M808B2D M808B2G M808B2S M808B9D M808B9G M808B9S T56821S T56822S T56823S T56824S Z0284 Z62823 Z62831 Z62832 Z62833 Z62892 Z9185 • Claim adjustments **will NOT be** requested for this pair-to-deny policy set-up. • There is no other change to configuration.
Glycated Hemoglobin and Glycated Protein Testing **MP236**	**Policy Updates:** No changes to criteria, continue to apply CMS NCD 190.21 for glycated hemoglobin and glycated protein testing. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to pay*** configuration **retroactively effective 10/1/2023**: I21B I2585 J4A0 J4A8 J4A9 • Claim adjustments **will be** requested since this configuration change may result in coverage of previously denied claims. • There are no other changes to configuration: All other payable dx codes on the pair-to-pay set-up will remain allowed and claims submitted without a payable dx code will continue to deny NMN.

Hepatitis Panel and Acute Hepatitis Panel Testing **MP324**	**Policy Updates:** No changes to criteria, continue to apply CMS NCD 190.33 for hepatitis panel testing. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to pay*** configuration **retroactively effective 10/1/2023**: R402A • Claim adjustments **will be** requested since this configuration change may result in coverage of previously denied claims. • There are no other changes to configuration: All other payable dx codes on the pair-to-pay set-up will remain allowed and claims submitted without a payable dx code will continue to deny NMN.
Lipid Testing **MP235**	**Policy Updates:** No changes to criteria, continue to apply CMS NCD 190.23 for lipid testing. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to pay*** configuration **retroactively effective 10/1/2023**: E7527 E7528 E88811 E88818 E88819 E88A I1A0 I21B I2585 K90821 K90822 K90829 K9083 N02B1 N02B2 N02B3 N02B4 N02B5 N02B6 N02B9 O26641 O26642 O26643 O26649 • Claim adjustments **will be** requested since this configuration change may result in coverage of previously denied claims.

	• There are no other changes to configuration: All other payable dx codes on the pair-to-pay set-up will remain allowed and claims submitted without a payable dx code will continue to deny NMN.
Partial Thromboplastin Time (PTT) **MP326**	**Policy Updates:** No changes to criteria, continue to apply CMS NCD 190.16 for PTT testing. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to pay*** configuration **retroactively effective 10/1/2023**: I21B K90821 K90822 K90829 K9083 M800B1A M800B2A M800B9A M808B1A M808B2A M808B9A N02B1 N02B2 N02B3 N02B4 N02B5 N02B6 N02B9 O26641 O26642 O26643 O26649 • Claim adjustments **will be** requested since this configuration change may result in coverage of previously denied claims. • There are no other changes to configuration: All other payable dx codes on the pair-to-pay set-up will remain allowed and claims submitted without a payable dx code will continue to deny NMN.

Serum Iron Studies **MP322**	**Policy Updates:** No changes to criteria, continue to apply CMS NCD 190.18 for serum iron tests. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to pay*** configuration **retroactively effective 10/1/2023**: D5704 D57214 D57414 D57434 D57454 D57814 N02B1 N02B2 N02B3 N02B4 N02B5 N02B6 N02B9 T56821A T56821D T56821S T56822A T56822D T56822S T56823A T56823D T56823S T56824A T56824D T56824S • Claim adjustments **will be** requested since this configuration change may result in coverage of previously denied claims. • There are no other changes to configuration: All other payable dx codes on the pair-to-pay set-up will remain allowed and claims submitted without a payable dx code will continue to deny NMN.
Thyroid Testing **MP207**	**Policy Updates:** No changes to criteria, continue to apply CMS NCD 190.22 for thyroid testing. **Codes/PA:** Updated diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes (source link). • ICD-10 codes **added to *pair to pay*** configuration **retroactively effective 10/1/2023**: D8984

	I1A0 R402A • Claim adjustments **will be** requested since this configuration change may result in coverage of previously denied claims. • There are no other changes to configuration: All other payable dx codes on the pair-to-pay set-up will remain allowed and claims submitted without a payable dx code will continue to deny NMN.

Effective 5/1/2024

Stem Cell Transplantation **MP283**	**Policy Updates:** • No change to criteria. Continue to apply Medicare NCD or LCD, or Company coverage criteria as directed by the policy. • Since the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Criteria table of the Medicare version. • Updated "Policy Guidelines" **Codes/PA:** No change to codes or configuration.

Effective 6/1/2024

Hospital Beds, Support Surfaces, and Related Accessories **MP404**	**Policy Updates:** • Applied NCDs, LCDs, LCAs and other Medicare references as directed. This is for both the initial provision of the bed, supplies or accessories, as well as their replacement or upgrade. **Codes/PA:** Code and configuration changes are as follows: • Added PA: E0194, E0300, E0301, E0302, E0303, E0304, E0328, E0329 • Added NMN denial: E0190, E0265, E0266, E0270, E0273, E0274, E0296, E0297, E0315, E0370, E0700, E0710 • Added t07 (not separately payable) denial: E0271, E0272, E0305, E0310 • All other codes in the policy will continue with no medical policy configuration, but are still subject to member benefits, eligibility, and provider contracts. • Additional codes may be related to this topic but are excluded intentionally when no specific Medicare criteria are provided **and** when there is little to no utilization.

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 2, 2024

Go-Live Date: Monday, April 01, 2024, unless otherwise noted

Table of Contents:

New Drugs or Combinations

1. **Zuranolone (Zurzuvae) Capsule**
    a. **Indication**: f=For the treatment of postpartum depression in adults.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	N/A	N/A	Non-preferred Drug
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Managed by Fee-for-service	Prior Authorization
Quantity Limit	20mg and 25mg capsules: 28 capsules/180 days 30mg capsules: 14 capsules/180 days	Managed by Fee-for-service	20mg and 25mg capsules: 28 capsules/180 days 30mg capsules: 14 capsules/180 days

* 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: sertraline, escitalopram

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

PA PROGRAM NAME	Zurzuvae®
MEDICATION NAME	Zuranolone capsules (Zurzuvae®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• Past medical history of seizures • Past medical history of bipolar disorder, schizophrenia, or schizoaffective disorder • Current pregnancy
REQUIRED MEDICAL INFORMATION	Initial Authorization: 1. Diagnosis of moderate to severe major depressive disorder with documentation or provider attestation that depressive symptoms began between the third trimester of pregnancy to the first four weeks following delivery 2. Patient is within the first twelve months postpartum 3. Submission of validated screening tool results (for example, HAM-D, PHQ-9, MADRS) confirming diagnosis 4. Member has not received prior treatment with Zurzuvae® for the current pregnancy 5. Patient has tried and failed a formulary generic selective serotonin reuptake inhibitor (SSRI) or serotonin and norepinephrine reuptake inhibitor (SNRI) for the current episode of postpartum depression (after 4-6 weeks at an adequate dose), or has an intolerance/contraindication to all SSRIs/SNRIs. This may be waived in cases of severe post-partum depression. For Commercial only: Reauthorization: None; only one course allowed per pregnancy
AGE RESTRICTIONS	Ages 18 years and older
PRESCRIBER RESTRICTIONS	
COVERAGE DURATION	One month (one 14-day fill) per pregnancy

2. **Ritlecitinib tosylate (Litfulo) Capsule**
    a. **Indication**: For the treatment of severe alopecia areata in adults and adolescents 12 years and older.
    b. **Decision**: Decision deferred to April P&T

3. **Delandistrogene moxeparovec-rokl (Elevidys) Kit**
    a. **Indication**: Approved for ambulatory patients ages 4-5 years old with a confirmed mutation in the DMD gene.
    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: prednisone, deflazacort (Emflaza®)			

    c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Delandistrogene moxeparvovec-rokl, for Duchene muscular dystrophy, is not considered medically necessary and will not be covered due to the lack of clinical evidence of improved outcomes and safety.

4. **Fruquintinib (Fruzaqla) Capsule**
    a. **Indication**: For the treatment of adult patients with metastatic colorectal cancer (mCRC) as the third-line 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	5 mg: #21/28 days 1 mg: #105/28 days	5 mg: #21/28 days 1 mg: #105/28 days	5 mg: #21/28 days 1 mg: #105/28 days
* 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: Lonsurf, Stivarga			

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

5. **Repotrectinib (Augtyro) Capsule**
   a. **Indication**: For the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).
   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	8/day	8/day	8/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: Rozlytrek, Xalkori and Zykadia			

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

6. **Capivasertib (Truqap) Tablet**
   a. **Indication**: For the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant 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	64/28 days	64/28 days	64/28 days
* 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: Piqray in PIK3CA activating mutation			

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

7. **Toripalimab-tpzi (Loqtorzi) Vial**

a. **Indication**: For first-line treatment of adults of metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC) with cisplatin and gemcitabine and as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

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: cisplatin/gemcitabine, cisplatin/gemcitabine + other PD-1 inhibitor (such as pembrolizumab or nivolumab), cisplatin/5-FU, cisplatin or carboplatin/docetaxel or paclitaxel, carboplatin/cetuximab, gemcitabine/carboplatin, see NCCN guidelines for other recommended regimens			

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

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Idacio** (Adalimumab-AACF)
    a. Previous Indication(s):
        a. Rheumatoid Arthritis
        b. Juvenile Idiopathic Arthritis
        c. Psoriatic Arthritis
        d. Ankylosing Spondylitis
        e. Crohn's Disease
        f. Ulcerative Colitis

   g. Plaque Psoriasis
b. New indication approved 10/11/2023, 11/16/2023:
   a. Hidradenitis Suppurativa
   b. Uveitis
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

2. **Zoryve** (roflumilast)
   a. Previous Indication(s):
      a. Treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older
   b. New indication approved 10/11/2023:
      a. Treatment of plaque psoriasis, including intertriginous areas, in patients **6 years of age and older**
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy criteria with age.

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

PA PROGRAM NAME	Vtama, Zoryve
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
AGE RESTRICTIONS	Zoryve® - Approved for patients 6 years and older

3. **Enbrel** (etanercept)
   a. Previous Indication(s):
      i. Rheumatoid Arthritis (RA)
      ii. Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older
      iii. Psoriatic Arthritis (PsA)
      iv. Ankylosing Spondylitis (AS)
      v. Plaque Psoriasis (PsO) in patients 4 years or older
   b. New indication approved 10/18/2023:
      a. Adult patient with:
         1. Rheumatoid Arthritis (RA)
         2. Psoriatic Arthritis (PsA)
         3. Ankylosing Spondylitis (AS)
         4. Plaque Psoriasis (PsO)

   b. Pediatric patients with:
      1. Polyarticular Juvenile Idiopathic Arthritis (pJIA), 2 years of age or older
      2. Juvenile Psoriatic Arthritis, 2 years of age or older (JPsA)
      3. Plaque Psoriasis, 4 years of age or older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

4. **Voxzogo** (vosoritide)
   a. Previous indications:
      a. Increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)
   b. New indication(s) approved 10/20/2023:
      a. Increase linear growth in **pediatric patients** with achondroplasia with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy to remove age restrictions.

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

PA PROGRAM NAME	Voxzogo
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
AGE RESTRICTIONS	N/A

5. **Orencia** (abatacept)
   a. Previous Indication(s):
      a. The treatment of adult patients with moderately to severely active rheumatoid arthritis (RA)
      b. The treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
      c. The treatment of adult patients with active psoriatic arthritis (PsA)
      d. The prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

b. New indication approved 10/30/2023:
    a. The treatment of patients **2 years of age and older** with active psoriatic arthritis (PsA)
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

6. **Cosentyx** (secukinumab)
    a. Previous Indication(s):
        a. Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
        b. Active psoriatic arthritis (PsA) in patients 2 years of age and older
        c. Adults with active ankylosing spondylitis (AS)
        d. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
        e. Active enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older
    b. New indication approved 10/31/2023:
        a. Adults with moderate to severe hidradenitis suppurativa (HS)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

Therapies with Prior Authorization Policies (Oncology)

1. **Opdivo** (nivolumab)
    a. New indication(s) approved 10/11/2023:
        i. For the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
    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.

2. **Keytruda** (dabrafenib)
    a. New indication(s) approved 10/16/2023, 10/30/2023, 11/16/2023:
        i. Non-Small Cell Lung Cancer (NSCLC):
            - For the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery
        ii. Biliary Tract Cancer (BTC):

- In combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer

iii. Gastric Cancer:

- In combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. 1
- In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.

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.

3. **Braftovi** (encorafenib)
   a. New indication(s) approved 10/11/2023:
      i. In combination with binimetinib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test
   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.

4. **Mektovi** (binimetinib)
   a. New indication(s) approved 10/11/2023:
      i. In combination with encorafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test
   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.

5. **Rozlytrek** (entrectinib)
   a. New indication(s) approved 10/20/2023:
      i. Adult and pediatric patients 12 years of age and older with solid tumors that:
         - have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion as detected by an FDA-approved test without a known acquired resistance mutation

- are metastatic or where surgical resection is likely to result in severe morbidity
- have progressed following treatment or have no satisfactory alternative 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.

6. **Tibsovo** (ivosidenib)
   a. New indication(s) approved 10/24/2023:
      i. Relapsed or refractory Myelodysplastic Syndromes (MDS):
         - For the treatment of adult patients with relapsed or refractory myelodysplastic syndromes
   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. **Xtandi** (enzalutamide)
   a. New indication(s) approved 11/16/2023:
      i. Treatment of patients with:
         - Castration-resistant prostate cancer
         - Metastatic castration-sensitive prostate cancer
         - Non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis
   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

1. **Veltassa** (patiromer)
   a. Previous Indication(s):
      i. Veltassa is a potassium binder indicated for the treatment of hyperkalemia
   b. New indication approved 10/02/23:
      i. Veltassa is a potassium binder indicated for the treatment of hyperkalemia in adults and pediatric patients ages 12 years and older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **Exparel** (bupivacaine liposome injectable suspension)

a. Previous Indication(s):
    i. In patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia
    ii. In adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia
b. New indication approved 11/09/2023:
    i. Local analgesia via infiltration in patients aged 6 years and older
    ii. Regional analgesia via:
        1. An interscalene brachial plexus nerve block in adults
        2. A sciatic nerve block in the popliteal fossa in adults
        3. An adductor canal block in adults
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name: Levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)**
    - **Date Posted: 11/28/2023**
    - **Safety Alert Title: FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)**
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-rare-serious-drug-reaction-antiseizure-medicines-levetiracetam-keppra-keppra-xr-elepsia-xr
    - **What safety concern is FDA announcing?**
        - The U.S. Food and Drug Administration (FDA) is warning that the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death. As a result, we are requiring warnings about this risk to be added to the prescribing information and patient Medication Guides for these medicines. This hypersensitivity reaction to these medicines is serious but rare. DRESS can include fever, rash, swollen lymph nodes, or injury to organs including the liver, kidneys, lungs, heart, or pancreas.
    - **What is FDA doing?**
        - We are requiring manufacturers of these medicines to add new warnings about DRESS to the prescribing information and the Medication Guide for patients and caregivers. For levetiracetam (Keppra, Keppra XR, Elepsia XR, and Spritam), this involves adding a new warning in the Warnings and Precautions section of the prescribing information, which describes the

most serious and significant potential safety issues. Currently the symptoms associated with this condition are described less prominently. For clobazam (Onfi and Sympazan), we are requiring a new warning specifically about DRESS to be added to the prescribing information. Symptoms related to this risk are already described more generally in other sections of the clobazam prescribing information. The warnings for both levetiracetam and clobazam medicines will include information that early symptoms of DRESS such as fever or swollen lymph nodes can be present even when a rash cannot be seen. This is different from other serious skin-related reactions that can happen with these medicines and where a rash is present early on, including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN). We are also requiring information on this risk to be added to the Medication Guides to help inform patients and caregivers about this risk.

- **What should health care professionals do?**
  - Health care professionals should be aware that prompt recognition and early treatment is important for improving DRESS outcomes and decreasing mortality. Diagnosis is often difficult because early signs and symptoms such as fever and swollen lymph nodes may be present without evidence of a rash. DRESS can develop 2 weeks to 8 weeks after starting the medicines, and symptoms and intensity can vary widely. DRESS can also be confused with other serious skin reactions such as SJS and TEN. Advise patients of the signs and symptoms of DRESS and to stop taking their medicine and seek immediate medical attention if DRESS is suspected during treatment with levetiracetam or clobazam.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Drug Recalls/Market Withdrawals

1. **Drug Name:** All Ion and Restore brands Nasal Products
   - **Date of Recall:** 10/02/2023
   - **Reason for recall:** Potential Contamination with Microbacterium spp., Fictibacillus spp., Bacillus spp., and Paenibacillus spp.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/biomic-sciences-issues-voluntary-nationwide-recall-ion-sinus-support-ion-sinus-and-restore-sinus
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** 4.2% Sodium Bicarbonate Injection, USP, 1% Lidocaine HCl Injection, USP, and 2% Lidocaine HCl Injection, USP
   - **Date of Recall:** 10/02/2023
   - **Reason for recall:** Potential Presence of Glass Particulates
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-42-sodium-bicarbonate-injection-usp-and-1-and-2
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Betaxolol Tablets, USPS
    - **Date of Recall:** 10/13/2023
    - **Reason for recall:** Potential Presence of Oxycodone HCl tablet
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kvk-tech-inc-issues-voluntary-nationwide-recall-one-lot-betaxolol-tablets-usp-10-mg-batch-number
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

4. **Drug Name:** Family Dollar Company Over-the-Counter Drug and Medical Device products
    - **Date of Recall:** 10/10/2023
    - **Reason for recall:** Products were stored outside of labeled temperature requirements
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/voluntary-recall-certain-over-counter-drugs-and-medical-devices
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

5. **Drug Name:** Kuka Flex Forte caplets, Reumo Flex caplets, and Artri King tablets
    - **Date of Recall:** 10/23/2023
    - **Reason for recall:** Undeclared drug, Diclofenac
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/botanical-be-issues-voluntary-nationwide-recall-kuka-flex-forte-reumo-flex-caplets-and-artri-king
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

6. **Drug Name:** Sodium Bicarbonate Injection, USP, Midazolam in 0.8% Sodium Chloride Injection ELCYS (cysteine hydrochloride Injection), USP
    - **Date of Recall:** 10/25/2023
    - **Reason for recall:** Potential presence of particulate matter
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-84-sodium-bicarbonate-injection-usp-50
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

7. **Drug Name:** Leader®: Eye Irritation Relief (Polyvinyl Alcohol, 0.5%, Povidone, 0.6%, and Tetrahydrozoline Hydrochloride, 0.05%), Dry Eye Relief (Carboxymethylcellulose Sodium, 1%), Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%), Dry Eye Relief (Polyethylene Glycol 400, 0.4% and Propylene Glycol, 0.3%), Lubricant Eye Drops (Propylene Glycol, 0.6%)
    - **Date of Recall:** 11/01/2023
    - **Reason for recall:** Insanitary manufacturing conditions
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cardinal-health-inc-issues-voluntary-nationwide-recall-certain-leadertm-brand-eye-drops-supplied
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

8. **Drug Name:** Rugby®: Polyvinyl Alcohol, 1.4% Lubricating Eye Drops, Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%)
    - **Date of Recall:** 11/01/2023
    - **Reason for recall:** Insanitary manufacturing conditions
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/harvard-drug-group-llc-issues-voluntary-nationwide-recall-certain-rugbyr-laboratories-brand-eye
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

9. **Drug Name: Target:** High Performance Lubricant Eye Drops 15 ml, Dry Eye Relief 15 mL; **Rite Aid:** Multi-Action Relief Drops 15 mL, Lubricating Gel Drops 10mL and 15mL; **Velocity:** Lubricant Eye Drop 10 mL; **CVS:** Lubricant Eye Drops 15 ML, Lubricant Gel Drops 15 ml, Multi Action Relief Drops, Mild Moderate Lubricating Eye Drops 15 mL, Lubricant Gel Drops 10 mL; **Walmart:** Equate Hydration PF Lubricant Eye Drops 10 mL
    - **Date of Recall:** 11/15/2023
    - **Reason for recall:** Device & Drug Safety Potential Safety Concerns
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kilitch-healthcare-india-limited-issues-voluntary-nationwide-recall-various-eye-drops-potential
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

10. **Drug Name:** SugarMD Advanced Glucose Support, Dietary Supplement
    - **Date of Recall:** 11/15/2023
    - **Reason for recall:** Undeclared Glyburide and Metformin
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sugarmds-llc-issues-voluntary-nationwide-recall-advanced-glucose-support-supplements-capsules-due

- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

11. **Drug Name:** KinderMed Infants' Pain & Fever (2 fluid ounces/59 mL) and (4 fluid ounces/118 mL), (Acetaminophen - 160 mg per 5 mL), Oral Suspension
    - **Date of Recall:** 11/17/2023
    - **Reason for recall:** Due to Acetaminophen Instability
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kinderfarms-llc-voluntarily-recalling-all-kindermed-pain-fever-products-due-acetaminophen
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

12. **Drug Name:** The Rock Supplement Lot#: 03032021,exp:12/2027,1200 mg/capsule
    - **Date of Recall:** 11/21/2023
    - **Reason for recall:** Undeclared drug, Sildenafil
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/noahs-wholesale-llc-issues-voluntary-nationwide-recall-rock-due-presence-undeclared-sildenafil
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

13. **Drug Name:** Vitrakvi® (larotrectinib) Oral Solution 20 mg/mL in 100mL glass bottles
    - **Date of Recall:** 11/21/2023
    - **Reason for recall:** Microbial contamination identified as Penicillium brevicompactum
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-nationwide-vitrakvir-larotrectinib-oral-solution-20-mgml-due-presence
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

14. **Drug Name:** 2% Miconazole Nitrate Athlete's Foot Spray Antifungal SprayPowder
    - **Date of Recall:** 11/24/2023
    - **Reason for recall:** Presence of benzene
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/insight-pharmaceuticals-issues-voluntary-nationwide-recall-tingr-2-miconazole-nitrate-athletes-foot
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

15. **Drug Name:** Sandimmune (cyclosporine oral solution, USP) Oral Solution 100 mg/mL
    - **Date of Recall:** 11/27/2023
    - **Reason for recall:** Due to crystallization formation
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-us-nationwide-recall-two-lots-sandimmuner-oral-solution-cyclosporine-oral
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

16. **Drug Name:** Magnum Male Sexual Enhancement XXL 9800 capsule
    - **Date of Recall:** 11/29/2023
    - **Reason for recall:** Undeclared Sildenafil
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/meta-herbal-issues-voluntary-nationwide-recall-magnum-xxl-9800-capsules-due-presence-undeclared
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
• **Dalfampridine (Ampyra) Tab ER** • **Glatiramer acetate (Copaxone) Syringe** • **Fingolimod hcl (Gilenya) 0.5 mg Capsule**	Remove brand-name formulations from Commercial formulary Effective: 5/1/2024	Brand Over Generic
Metronidazole (Likmez) Oral Susp	New strength (500mg/5ml) and dosage form (oral susp); Non-formulary for all lines of business	N/A
Miglustat (Opfolda) Capsule	New strength; Assign along with Pombiliti; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Medications For Rare Indications • Medicare Part D: N/A

Nalmefene hcl (Opvee) Spray	New strength (2.7mg), route (nasal), dosage form (spray); • Commercial/Medicare Part D: Formulary, Tier 3 • Medicaid: Formulary	N/A
Trientine hcl Capsule	New strength (500mg); • 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
Cantharidin (Ycanth) Sol w/Appl	New dosage form (solution w/applicator); • Covered Medical benefit for all lines of business	N/A
• **Avapritinib (Ayvakit) Tablet** • **Lenvatinib mesylate (Lenvima) 4 mg Capsule**	Add to Medicaid formulary with Prior Authorization	Oral Anti-Cancer Medications
Glipizide 2.5 mg tablet	New strength. Add to formulary: • Commercial: Formulary, Tier 1 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 1	N/A
Buprenorphine 8 mg sublingual tablets	Increase quantity limit for all lines of business from 3 per day to 4 per day	N/A

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

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Sotagliflozin (Inpefa) Tablet	New strength. Line extend with Oct 23 P&T Decision;	Medicaid: SGLT-2 Inhibitors

	• Commercial: Non-Formulary, Quantity Limit (60 tablets per 30 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (60 tablets per 30 days) • Medicare Part D: Non-Formulary	
Methotrexate (Jylamvo) Solution	New strength (2mg/ml). Line extend with Xatmep; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Alpha-1-proteinase inhibitor (Zemaira) Vial	New strengths (4,000mg, 5,000mg). Line extend with Zemaira 1,000mg vial; • Medical Benefit, Prior Authorization for all lines of business	Alpha-1 Proteinase Inhibitors
Entrectinib (Rozlytrek) Pelet Pack	New strength (50mg) and dosage form (pellet pack). Line extend with Rozlytrek capsule; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Crizotinib (Xalkori) Pel DSP CP	New strengths (20mg, 50mg, 150mg) and dosage form (pellet). Line extend with Xalkori capsules; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization	Oral Anti-Cancer Medications

	• Medicare Part D: Formulary, Tier 5, Prior Authorization	
Adalimumab-atto (Amjevita(CF)) Auto Injct / Syringe	New strengths (20mg/0.2ml, 40 mg/0.4mL, 80mg/0.8mL). Line extend as non-preferred biosimilar; • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (2 syringes per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 syringes per 28 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) / Self-Administered Drugs (SAD) Policy • Medicare Part D: N/A
adalimumab-aaty (Yuflyma(CF) / Yuflyma(CF) Al Crohn's-UC-HS) Autoinjkit	New kit. Line extend as non-preferred biosimilar; • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (2 syringes per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 syringes per 28 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) / Self-Administered Drugs (SAD) Policy • Medicare Part D: N/A
Meningococ a,c,y,w-135,tt comp/n. Mening b,fhbp rec comp/pf (Penbraya) Kit	New entity. Line extend with meningococcal vaccines; • Commercial: Preventive, Quantity Limit (1 dose (0.5ml) per day) • Medicaid: Medical benefit • Medicare Part D: Formulary, Tier 3	Operational Policy - Vaccine Program - (excluding influenza and pneumococcal conjugate vaccine)
Estradiol/progesterone (Bijuva) Capsule	New strength (0.5mg/100mg). Line extend with Bijuva 1mg/100mg strength; • Commercial: Formulary, Tier 4	N/A

	• Medicaid/Medicare Part D: Non-Formulary	
Lipase/protease/amylase (Zenpep) Capsule DR	New strength. Line extend with other Zenpep; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Immune globulin, gamma (igg)/proline/iga (Hizentra) Syringe	New strength (10gm/50ml). Line extend with Hizentra; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Non- Formulary, Prior Authorization	Immune Gamma Globulin (IGG)
Roflumilast (Zoryve) Foam	New dosage form. Line extend with Zoryve cream; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (60 grams per 30 days) • Medicare Part D: Non-Formulary	Vtama, Zoryve

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Fluticasone propionate Blst w/Dev	First generic (Flovent Diskus). Line extend as generic; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Pitavastatin calcium Tablet	First generic drug (Livalo). Line extend as generic;	N/A

	• Commercial Standard: Formulary, Tier 2, Quantity Limit (1 tablet per day) • Commercial Dynamic: Formulary, Tier 4, Quantity Limit (1 tablet per day) • Medicaid/Medicare Part D: Non-Formulary	
Spironolactone Oral Susp	First generic drug (Carospir). Line extend as generic; • Non-formulary for all lines of business	N/A
Teriparatide Pen Injctr	First generic (Forteo). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	Osteoanabolic Agents
Cyanocobalamin Spray	First generic drug (Nascobol). Line extend as generic; Non-formulary for all lines of business	N/A
Dextroamphetamine Sulfate Tablet	First generic drug (Zenzedi). Line extend as generic; • Non-formulary for all lines of business	N/A
Podofilox Gel (Gram)	First generic drug (Condylox). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Non- Formulary	N/A

Risperidone microspheres (Risperidone ER) Vial;	First generic drug (Risperdal Consta). Line extend as generic; • Commercial: Medical Benefit • Medicaid: Covered by DMAP • Medicare Part D: Formulary, Tier 5 (12.5 mg strength is Tier 4) • Medicare Part B: Medical benefit	N/A

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Amyloid Monoclonal Antibodies - Medicaid	Created new policy to align with criteria created by Oregon Health Authority (OHA).
Anti-Amyloid Monoclonal Antibodies Prior Authorization and Step Therapy Policy - Medicare Part B	Split policy from Commercial due to differing coverage.
Cabenuva	Removed prior authorization for Medicare Part B due to protected class status
Fertility and Related Medications	For groups with fertility preservation benefits, adding coverage for patients with sickle cell disease.
Filspari	Updated EGFR cut-off criteria to align with package labeling
Gonadotropin Releasing Hormone Agonists	Removed Lupaneta and Vantas from the policy as drugs are now obsolete. For gender dysphoria, clarified that only diagnosis is required for coverage for Medicaid to align with OHA criteria. Added requirement of failure of oral contraceptives for endometriosis.
Gonadotropin Releasing Hormone Agonists - Medicare Part B	Removed Lupaneta and Vantas from the policy as drugs are now obsolete. Added requirement of failure of oral contraceptives for endometriosis.
• **Injectable Anti-Cancer Medications** • **Injectable Anti-Cancer Medications - Medicare Part B**	Policy renamed to "Anti-cancer medications (Medical Benefit)". The following drugs have been removed from the policy: 1. Besremi, Actimmune - billed through pharmacy benefit so moved to self-administered anti-cancer medications policy 2. Pepaxto, Synribo - obsolete drug
Oral Anti-Cancer Medications	Policy renamed to "Anti-cancer medications (Self-Administered)". Policy Changes: Added quantity limits to several medications.
• **Rituximab**	Clarified requirement for use of targeted immune modulators for rheumatoid arthritis

• **Rituximab Prior Authorization and Step Therapy Policy - Medicare Part B**	
Soolantra Step Therapy Policy	Added azelaic acid and duration for t/f to policy, update position statement.
T-Cell Therapy	Simplified criteria for initial approval to align for all agents. Clarified exclusion criteria for combination use to allow for initiation of secondary agent after disease progression.